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September 20, 2021

*Attention: LHLcomments@tdi.texas.gov*
Cassie Brown, Commissioner of Insurance
Texas Department of Insurance

**RE: AHIP Comments on HB 3459 Request for Information**

Dear Commissioner Brown,

On behalf of AHIP[1], I write today in response to the Texas Department of Insurance's (TDI) Request for Information on the implementation of HB 3459, legislation that mandates a waiver of prior authorization (PA) for certain health care providers.

Health insurance providers work diligently to ensure that enrollees are getting the right care, at the right time, from the right provider. Utilization management tools, like prior authorization, are critically important to ensure enrollees receive safe, evidence-based, timely, and high quality care. These tools rely upon provider-developed clinical guidelines, consultation with specialists, input from medical associations, and nationally recognized care criteria to ensure consideration of the latest medical evidence based on the highest standards of care.

Under the supervision of medical professionals, prior authorization reduces inappropriate, unsafe and low value patient care – all of which contributes to potential harm to patients and unnecessary costs. The Medicare and Medicaid programs recognize the importance of prior authorization to seniors and taxpayers alike.

It is vital that policy makers recognize the essential role of these tools and refrain from dismantling prior authorization programs because they are highly effective in addressing the long-standing challenges to safe and affordable evidence-based health care for Texans. As the Department considers implementing rules, we request your consideration of our responses to the questions posed in the RFI:

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Question 1. ***Texas administrative medical licenses - Insurance Code Section 4201.206(a) requires that before an adverse determination is issued, the ordering health care provider be given the opportunity to discuss the treatment plan with a licensed physician. Please provide input on TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a).***

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[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

AHIP believes current Texas law would allow an Administrative Medical License to satisfy the requirements in §4201.206 (a). The new provisions of HB 3459 in this section provide that for peer-to-peer discussion between health care providers about treatment plans, such providers must be of the same or similar specialty, and licensed in the state.

Under the definitions of "active practice of medicine" in Texas Administrative Code (TAC) §163.11, physicians employed by health insurance providers as medical directors are unable to obtain full clinical licensure, and instead obtain a limited license for administrative medicine (TAC §172.17). Additionally, TAC §19.1706 provides for such physicians conducting utilization review to hold an administrative license.

Health insurance providers employ physicians, nurses, pharmacists and other clinicians as utilization management reviewers with extensive knowledge and experience in evidence-based reviews, and who are well-positioned to have the necessary dialogue with prescribing/ordering providers. Chief medical officers within health plans oversee large teams of clinicians and experts to assure enrollees receive high quality and affordable health care. These clinical professionals understand industry trends and market dynamics and promote the practice of evidence-based medicine and population health. They provide senior medical leadership and direction for medical management, clinical quality improvement, and medical policy development. Therefore, as rulemaking moves forward, we request the Department confirm and clarify that an Administrative Medical License satisfies the requirements of this section.

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***Question 2. Preauthorization requests - Insurance Code Section 4201.653(a) exempts physicians and other health providers from preauthorization requirements for certain services if the HMO or health plan "has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service."***

- ***a. When determining a provider's approval rate for preauthorization requests, should requests for a certain quantity (such as five days of inpatient care) be counted as a single request or multiple requests? What is the approval rate if, using the inpatient care example, three days were approved and two days were denied?***
- ***b. How should approval rates be calculated for preauthorization requests for a treatment regimen (such as three-drug regimen) where some services within the request may be approved and others denied or approved with changes?***
  - ***i. Should each distinct service be counted as a separate request?***
  - ***ii. Should a preauthorization request for a drug be treated as the same particular health care service if the prescribed dosage or other dispensing details are different?***

Operationally, AHIP members have indicated that partial denials of PA requests are considered adverse determinations, and thus would affect approval percentages during an evaluation. Whether a partial or full denial of a PA request, the reasoning for a denial is

based on evidence-based guidelines. An industry-wide AHIP survey of commercial health insurance providers found that the most common reason for an initial PA denial is that the provider did not submit the clinical information necessary to support the initial health care service request, and the most common reason for a final denial is that the requested medical service or medication is not evidence-based. This underscores the importance of PA to ensure patients receive safe, evidence-based care. Like other adverse determinations, partial denials can be appealed. Given that it is standard industry practice for partial denials to be considered adverse determimations, we request that TDI confirm that partial denials are adverse determinations for purposes of calculating a provider's preauthorization request approval rate.

Additionally, the language in HB 3459 applies to health care services subject to PA, which does not include prescription drugs. Throughout the bill, there are no references to prescription drugs, and a plain language reading of the bill shows the exemption requirements apply only to health care services provided, and not for products (prescription drugs or devices).

AHIP's prior authorization survey also shows that specialty drug services are the most common treatments PA requirements. For these complex drugs, health plans use nationally recognized care criteria, the input of a pharmacy and therapeutics committee composed of specialty clinicians for specific medical protocols, and consideration of the latest medical evidence based on the highest standards of care. Medical evidence usually links efficacy of drugs and services to a specific population or subpopulation and condition, so it is important that a prescribed drug is safe and effective for the individual patient's specific condition.

With prescription drugs, PA is also vitally important in circumstances where risk of addiction looms large, such as opioids for chronic pain, where interaction with another drug can be dangerous, where unnecessary treatment can be harmful, and where a drug or service (which otherwise may have a high rate of PA approval) is being prescribed for non-standard use. Health insurance providers have the benefit of a 360-degree view of the health care system, evidence-based resources, and insight into patients' medical claims histories to prevent dangerous or inappropriate prescription drug utilization. AHIP requests that rules confirm and clarify that the exemption requirement does not apply to prior authorization of prescription drugs, and only to health care services.

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***Question 3. Preauthorization exemptions - Under Insurance Code Sections 4201.655(a)(2) and 4201.656(d), the issuer must make a determination by evaluating a random sample of at least five claims from the most recent six-month evaluation period. Please provide input on how an exemption should be considered when there are four or fewer claims for the particular health care service in the most recent six-month evaluation period.***

The provisions of HB 3459 do not specify a minimum number of PA requests or services performed to qualify for an exemption. Additionally, under Section 4201.653(2) a recission of the preauthorization exemption can only be done on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted by the physician during the most recent evaluation period. Therefore, under this criteria, an exemption based on a provider who submitted four or fewer claims can not be rescinded. This creates a scenario where a provider could qualify for or maintain a PA exemption indefinitely, without performing a statistically significant amount of procedures to maintain it, and without accountability that the provider is adhering to evidence-based standards of patient care. In order to avoid such a situation, a provider should, at a minimum, have at least five claims in the most recent six-month period to qualify for an exemption evaluation and determination.

When health insurance providers have initiated voluntary "gold carding" programs to increase provider efficiencies, PA requirements are relaxed or reduced for health care providers who demonstrate a consistent pattern of high performance and adherence to evidence-based medical guidelines. In practice it is not a blanket exemption from all prior authorization for an indefinite period and it is not a practice that is appropriate for all providers and all services. Such programs may be targeted to specific services and where used, provider performance can be regularly reviewed and revoked where the provider's standard of practice is inconsistent with the standard of safe, timely, evidence-based, affordable and efficient care. HB 3459 eliminates these important patient protections and distorts the gold carding concept by mandating broad provider exemptions from PA with no concomitant accountability from providers.

Health care providers submitting a low volume of PA requests incur minimal administrative burden associated with PA. Moreover, because the services in question constitute a small number of their delivered services, these low-volume providers are among those more likely to deliver inappropriate or unsafe care and, thus, most likely to benefit from the utilization management under the PA process.

Guardrails are necessary to ensure that providers who receive exemptions continue to deliver consistent patterns of high quality performance to the patients they serve. As a result, we request that TDI clarify in rules that either a minimum of 5 claims from the most recent six-month period is required for an initial exemption and clarify that a rescission may be based on a review of all claims if there are fewer than five.

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***Question 4. Under Insurance Code Section 4201.653(d), a physician or provider is not required to request an exemption to qualify. Under Section 4201.653(c), an issuer may grant an exemption without evaluating whether the physician or provider qualifies. Please provide input on TDI's consideration of rules that would require***

***physicians or providers to be automatically granted an exemption by an issuer at the end of the first six-month evaluation period, unless the insurer shows that the 90% threshold was not met during the evaluation period.***

HB 3459 applies only to health care services for which the health insurance provider requires a PA process, and does not apply broadly to all services. While the percentage of covered services, procedures, and treatments requiring PA is relatively small (typically less than 15%), plans report that up to 25% of PA requests they receive from clinicians are for care that is not supported by medical evidence. Prior authorization identifies potential overuse, misuse, and safety issues before patient care is delivered. Waiving this vital tool without evaluating health care providers would be jeopardize patient care. To that end, TDI should clarify the rule only applies to those services and health care providers with a 90% approval rate.

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***Question 5. Please provide input on TDI's consideration of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician or provider for a particular health care service rather than when the exemption is granted.***

HB 3459 dictates major changes to health plan programs designed to promote patient safety and best practices, and therefore, plans need flexibility to adjust. AHIP would request TDI allow for permissive language in the notices of denials and granting of exemptions. Health insurance providers need to see and understand the result of the health care provider evaluations and until then - health insurance providers need flexibility in choosing to send notices only when an exemption is denied, or notice when exemption is granted for a particular health care service. Some health care providers may be eligible for exemptions for multiple PA health care services, but may not qualify for all those services.

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***Question 6. Under Insurance Code Section 4201.655, an issuer may rescind an exemption from preauthorization requirements only during January or June of each year. Under Section 6 of HB 3459, Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care service made on or after January 1, 2022. Please provide input on TDI's consideration of rules that would require issuers to provide an initial notice of exemption or denial of exemption in June 2022, based on an evaluation of preauthorization requests that were submitted on or after January 1, 2022.***

As health insurance providers work to implement the requirements of HB 3459, AHIP requests flexibility on the 6-month evaluation period, and supports delayed applicability of exemptions to allow plans to perform the necessary evaluations and understand the results.

To determine whether a health care provider qualifies for an exemption, health insurance providers must perform evaluations to determine whether the 90% approval threshold has

been met by reviewing every PA request and claim for each health care provider. The volume of claims paid by Texas health insurance providers numbers over 100 million per year, and the required evaluations will involve significant time and resources. To comply with this bill, plans will have to reconfigure systems that were developed to ensure patient safety and affordability of care. The bill's provisions eliminate these protections in many cases and will require plans to retool systems."Additionally, IT infrastructure must be developed to remove PA restrictions for all health care providers qualifying for an exemption, and notices will need to be sent within 5 days for all qualifying providers. To avoid undue burden and make this new process work, it is important to avoid setting a specific timeframe too close to the date exemptions must be in place, and to avoid having to review every provider type at the same time.

The January to June timeframe outlined in this question sets an evaluation period of less than six months and does not provide any time to perform the necessary evaluations. Further guidance is required on the specific 6-month time period(s) to be used in initial exemption evaluations and evaluations for rescissions. HB 3459 specifies that rescissions of exemptions can only occur in January or June of each year, which only allows for an evaluation period of 5 months after January 1, 2022. The evaluation period should not be tied to the start date of the exemptions.

Additionally as health insurance providers regularly update their list of benefits for which a prior authorization is required, these reviews are conducted at different intervals. For example, some health insurance providers currently elect to conduct these reviews during the second quarter to ensure that all the data from the previous year is available. We request the additional flexibility to determine evaluation periods as health insurance providers review and update PA lists.

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***Question 7. Rescinding preauthorization exemptions - Starting from the date notification is received, how much time should a physician or provider have to request an appeal of the issuer's determination to rescind the exemption?***

HB 3459 establishes a new independent review process for health care providers who appeal adverse determinations of a PA exemption. At the very least, AHIP believes the timeframe for appealing a rescission determination should mirror the timeframe for providing notice to a health care provider that they qualify for a PA exemption (5 days). To ensure parallel timeframes, we recommend the rules specify health care providers have 5 days to request an appeal of a determination to rescind an exemption.

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***Question 8. Under Insurance Code Section 4201.655(a)(2), an issuer seeking to rescind an exemption from preauthorization must make a determination "on the basis of a retrospective review of a random sample of not***

***fewer than five and no more than 20 claims submitted … during the most recent evaluation period." Under Insurance Code Section 4201.656(d), a physician or provider may request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted ... during the relevant evaluation period." Is additional guidance in rules needed to clarify how an issuer or IRO should determine how to select the random sample or the number of claims to consider?***

As mentioned above, if the rule allows health care providers with less than 5 PA claims to qualify for an exemption, we request that TDI clarify that a rescission may be based on a review of all available claims. Such a clarification will allow an exemption to be reviewed to ensure the provider is consistently practicing safe, evidence-based patient care. Without such a clarification, a provider who continually has less than 5 PA claims will maintain an exemption, regardless of whether or not they meet the 90% approval threshold—thus jeopardizing the important patient safety and cost containment measures inherent in the PA process.

For providers with a large number of claims, we would request guidance about who chooses the random sample. Assurances would be needed to maintain statistically significant numbers of claims reviewed.

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***Question 9. Additional comments - Please provide any additional comments or points of clarification that the rule should address.***

During the legislative session, AHIP opposed HB 3459, noting that it would undermine critically important medical management tools that ensure safe and effective patient care, and that it prioritizes provider reimbursement over patient safety. In developing rules to implement this bill, we urge the Texas Department of Insurance (TDI) to consider any opportunity to provide flexibility for health insurance providers, and to allow the ability for insurers to hold providers accountable for inappropriate and costly, or medically unnecessary and unsafe care. Exemptions to PA should not be taken lightly, and broadly limiting the ability to review medical necessity and appropriateness of care before care is delivered will lead to higher premiums and eliminate clinical safety edits designed to ensure patient safety.

Over the last two decades, various landmark reports from the Institute of Medicine (IOM) and the Agency for Healthcare Research and Quality (AHRQ) have brought attention to the significant gaps that exist between evidence-based best practices and the care actually being delivered to patients.

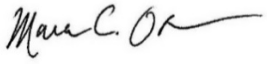
Wide variation in provider performance and the little to no correlation between spending and health care quality have been well-documented by researchers and policy experts at Dartmouth, RAND, and the IOM, among others. Safety concerns also persist, particularly regarding new therapies without a proven track record, therapies prone to overuse, and

treatments that may only be effective for specific conditions or populations. Underscoring the need for tools to support clinical decision-making and strategies to address these challenges, recent findings show beneficiaries in the traditional Medicare program receive a significant amount of "low-value" care –services that have little or no clinical benefit or where the risk of harm from the service outweighs the potential benefit. Numerous other studies have similarly identified "low-value" and unnecessary care as a source of preventable harm and waste. For example, the IOM reported that between $200 and $800 billion is wasted annually on excessive testing and treatment, accounting for 10-30 percent of health care spending.

Health insurance providers are committed to quality care for every patient. To improve patients' experience with their coverage and care, health plans work with doctors, nurses, and patients to make care more efficient, effective, and affordable. Prior authorization helps health insurance providers deliver on that promise and we urge the Department to implement rules that preserve the benefits of this important tool.

AHIP appreciates the Department's consideration of these important patient protection aspects of prior authorization, and stands ready to work with you as rulemaking moves forward. Please contact me at mosman@ahip.org or 202-578-8765 with any questions or to discuss these issues further.

Sincerely,



Mara C. Osman, J.D.
Senior Regional Director, State Affairs
America's Health Insurance Plans
mosman@ahip.org / (202) 578-8765

cc: Billy Phenix

**From:** Villafana, Eva
**To:** LHLComments
**Cc:** Compliance
**Subject:** TDI seeks input on HB 3459
**Date:** Monday, September 20, 2021 4:37:04 PM
**Attachments:** image228545.png

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Good Afternoon,

Community submits the below questions regarding the calculation of the 90 percent:

1. Do we calculate at NPI level or tax-ID?
2. How will providers that are contracted in multiple tax-IDs be handled?

Thank you.

**Eva Villafana**
Sr. Compliance Auditor
Eva.Villafana@CommunityHealthChoice.org
Phone: 713-295-2318
Fax: 713-295-2293

**From:** Gratias, Eric J HHHH
**To:** LHLComments
**Cc:** Estenoz, Brett TN7; Ness, Matthew A TN7; Sanaie, Kandice K HHHH; Wascher, Robert A (Rob) HHHH; Stanton, Katelin E (Kate) 46K
**Subject:** TX HB 3459 questions for TDI
**Date:** Friday, September 17, 2021 4:07:40 PM



Good afternoon and Happy Friday!

Thank you very much for the opportunity to submit questions related to HB 3459. Your rulemaking will be extremely helpful as stakeholders begin operationalizing this new law.

Here are some questions for your consideration that we feel can help to provide the needed clarity and consistency for the law to have the impact that seems intended by the legislature:

1. Can you please provide clarity on the whether the precertification exemption refers to the ordering (or referring) physician, the rendering physician, or both?
    a. Considering the intent of the law, our determination is that the precertification exemption should apply only to the ordering/referring physician who has evaluated the patient and determined the course of treatment, not the physician who receives the case from the referring physician and renders the service.
2. Can you please consider adding rules allowing for plans to revoke exemptions if the provider refuses to participate in the six month claims evaluation period?
    a. A specific example could be a refusal by the provider to provide supporting clinical records for the claims being audited. The statute does provide for a six month re-evaluation period for the exemption, but payers and benefit managers generally do not have direct access to review clinical records for a specific case to determine appropriateness.
    b. If a health plan or benefit manager determines complete case files are needed in order to determine if an exemption is earned and the health plan or benefit manager requests those records, the provider should be expected to comply within a reasonable time period or else forfeit their exemption status.
3. Can you please provide clarity on the clinical context for exemption assignment?
    a. The statute refers to “service”, and considering the intent of the law, our determination is that the “service” is measured at the level of the individual provider, the specific service (CPT, HCPCS, etc.) code, and the specific diagnostic (ICD-10) code.
    b. To clarify this point, a specific service can be provided for a range of possible diagnoses, and the appropriateness of the service can vary widely based on the specific diagnosis.
        i. One example would be the use of the drugs doxorubicin, cyclophosphamide, and paclitaxel for the treatment of cancer. This specific regimen is considered within the standard of care for breast cancer, but would not appropriate be for another cancer type, for example.

ii. If you exclude the diagnosis code from the exemption definition, you remove critical safety barriers for patients who might have common services inappropriately administered for their specific clinical condition.
iii. There are hundreds of examples like this, and as we believe the intention of the law is to reward consistent high quality practice with removal of administrative burden, the measure of that practice scope must be sufficiently specific (individual provider, service code or codes, and diagnostic code) to ensure patient protections are not removed inadvertently.

4. Can you please provide clarity on what constitutes a specific service?
    a. Considering the intent of the law, our determination is that the service is the specific combination of service codes administered for the diagnosis or treatment of the patient.
    b. For example, a request for doxorubicin as a single drug treatment is a qualitatively different request from a plan to use the combination of doxorubicin and cyclophosphamide, and those requests should be considered different services under this law.
    c. Limiting the definition of "service" to a single service code would remove critical patient protections for services that always contain multiple codes.
    d. There are hundreds of examples like this, and as we believe the intention of the law is to reward consistent high quality practice with removal of administrative burden, the definition of that service must be sufficiently specific (unique combinations of codes are considered different services) to ensure patient protections are not removed inadvertently.

We deeply appreciate your partnership and consideration.

**Thank you,**

**Eric J. Gratias, MD, FAAP**
Chief Medical Officer

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September 20, 2021

***Submitted electronically via LHLcomments@tdi.texas.gov***

The Hon. Chris Herrick, Deputy Commissioner
Life and Health Division
Texas Department of Insurance
333 Guadalupe
P.O. Box 12030
Austin, TX 78701

**RE: Comments Regarding Request for Information to Use in Implementation of House Bill 3459 and Stakeholder Notice**

Dear Deputy Commissioner Herrick:

Navitus Health Solutions, LLC ("Navitus") is providing these comments regarding the Texas Department of Insurance's (TDI's) Request for Information[1] regarding implementation of House Bill 3459 (2021).[2]

As background, Navitus is a 100% pass-through, fully transparent, pharmacy benefits manager (PBM). Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits for seven million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business. In Texas, we have approximately 40 clients with over 2.2 million member lives in the State. In addition, we maintain an operations center in Austin, which employs approximately 50 Texans.

We appreciate the opportunity to provide comments and feedback to TDI below regarding the following topics:

- Texas Administrative Medical Licenses
- Preauthorization Requests
- Preauthorization Exemptions
- Rescinding Preauthorization Exemptions
- Additional Comments

**Texas Administrative Medical Licenses.** TDI has requested stakeholder input on their consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a). Navitus currently utilizes the Administrative Medical License to satisfy peer-to-peer requirements. We suggest and believe these licenses do and should continue to satisfy the requirements of Section 4201.206(a). Additionally, Navitus suggests that TDI should reserve peer-to-peer reviews by a same or similar specialty physician for the second level review (appeals process) in order to lower the cost of prior

[1] https://www.tdi.texas.gov/health/hb3459rfi.pdf.
[2] https://capitol.texas.gov/tlodocs/87R/billtext/pdf/HB03459F.pdf#navpanes=0.

authorization review and expedite the availability of outpatient pharmaceuticals supplied to the patient for self-administration by a retail pharmacy.

**Preauthorization Requests.**

*Single Requests or Multiple Request*s. TDI has asked for feedback on supply requests and timelines with regard to determining a provider's approval rate for preauthorization requests. With regard to the pharmacy benefit, Navitus suggests that an order or prescription should be treated as one single request per edit, rather than multiple requests for the duration of the prescription. For example, a request for Humira dosed weekly, would be considered two requests at Navitus (one for the prior authorization, one for an exception to the formulary dosing). While the regulation stipulates that this is an exemption from prior authorization, and not exemption from formulary exceptions, this would be viewed as one request, rather than multiple requests.

*Calculation of Approval Rates*. TDI has asked stakeholders how approval rates should be calculated when some services may be denied while other services may be approved with changes. We believe that based on statutory definitions, within the pharmacy space, "health care service" does not and should not apply to prescription drugs but only to services provided by a pharmacy. Other dosing and dispensing details would be considered exception requests rather than prior authorization requests. Non-services such as prescription drugs (including physician-administered drugs) as well as associated equipment and supplies do not fall within Texas' definition of health care services and thus should not fall under the scope of TDI's rulemaking to implement HB 3459.

**Preauthorization Exemptions.**

*Consideration of Four or Fewer Claims*. TDI has inquired how exemptions should be considered when four or fewer claims have been filed in the previous six months. Navitus recognizes that providers who qualify for an exemption will no longer have claims in the following lookback timeframe following their exemption. In order to reduce the administrative burden of providing a cyclic process to exempt prior authorization requirements (only to have those requirements be subsequently rescinded during the following period), Navitus suggests TDI should remove any requirements for notification of the rescission of an exemption since the regulation already restricts rescission to January or June. After the provider is made aware by the notification of exemption, the provider should understand that they would no longer qualify as a result of not having any requests in the subsequent lookback timeframe. We do argue, however, that rescission for any other reason would still warrant notification of rescission to the provider.

*Automatic Physician Exemptions*. TDI is considering rules that would require physicians or providers to be automatically granted exemptions at the end of the first six-month period unless the 90% threshold was not met. Instead, Navitus believes prescribers should specifically request the exemption rather than be automatically granted. We also question whether the 90% threshold is appropriate since it implies that TDI is willing to accept up to 10% of prescriptions being inappropriate. We believe that threshold is too low – especially as a result of potent and costly medications, regulatory requirements, and mandates with no corresponding ability to ensure high-risk medications are appropriate for the patient through the prior authorization process that warrant higher than a 90% threshold.

*Notice of Exemption Denial from Issuers*. TDI's proposed rules would require issuers to provide notice of a denial of a preauthorization exemption rather than a notice that an exemption was granted to a physician or provider for a particular health care service. We believe the standard should be the reverse. Rather, notice should instead be provided only to those prescribers who qualify for the related exemption, while denial of an exemption request should be assumed unless the provider is notified of their exemption status.

*Initial Notice of Exemption or Denial*. TDI is contemplating instituting a requirement that issuers must provide the initial notice of exemption or denial of exemption to providers in June 2022 as a result of an evaluation of preauthorization requests submitted on or after January 1, 2022. Instead, TDI should require the burden to be on providers to request the exemption as it is unreasonable and inappropriate to send initial notices to all Texas prescribers for each health care service (prescription drug), which would undoubtedly include those prescribers who may not have a patient covered under a specific insurer's benefits.

**Rescinding Preauthorization Exemptions.**

*Timeline for Appeal*. Regarding the appropriate time frame in which a provider must file an appeal after receiving a rescission of an exemption by the issuer, we believe a relatively short period such as fourteen (14) days starting from the date of notification is appropriate since the issuers may only rescind the exemptions two times a year in January or June.

*Additional Guidance Regarding Random Sample*. TDI has asked whether additional guidance is needed clarifying how to select the random sample or the number of claims to considered. Navitus believes additional guidance should be provided to provide further clarification and assistance to issuers and independent review organizations (IROs)

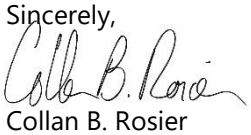
**Additional Comments.** In addition to the specific comments requested above by TDI regarding provisions of the proposed rule, Navitus is including a couple of additional points and thoughts below to be clarified or included.

When a specific provider is granted an exemption from prior authorization requests, does that exemption apply only to the specific or particular client or does it apply across the entire book of business between the provider and Navitus? This is of particular concern given the potential impact in cases where a provider requests a review by an IRO in order to pull claims for a particular client and can impact the volume of requests from a single provider. Our concern stems from the importance of maintaining a consistent internal interpretation for provider eligibility and exemptions regardless of other factors. This is important to providers as well since there is the potential of the same provider getting multiple letters from IROs depending on the client based on whether that client is exempted from the prior authorization requirements or not.

Additionally, the proposed rule has the potential for excessive administrative burden being placed on IROs. This is due to the fact that electronic prior authorizations (ePAs) will not be able to distinguish between individual prescriber-level edits such as those who qualify for a prior authorization exemption. Rather, ePAs are only able to relay the formulary or drug edits for a particular plan. This would require vendor changes for ePAs in order to accommodate this regulatory change.

Thank you for the opportunity to provide feedback on the proposed revisions. If we can provide any additional information for your rulemaking process, please let us know.

Sincerely,



Collan B. Rosier
Director of Government Relations

PCMA

September 20, 2021

Texas Department of Insurance
PO Box 12030
Austin, TX 78711-2030

Via Email: LHLcomments@tdi.texas.gov

**Re: Request for Information on Implementation of HB 3459**

I am writing on behalf of the Pharmaceutical Care Management Association (PCMA) to provide comments to the Texas Department of Insurance (TDI) request for information on implementation of HB3459. PCMA appreciates the opportunity to provide comments as the TDI begins the process of promulgating regulations for this new law.

PCMA is the national association representing America's PBMs, which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the health insurance exchanges established by the Affordable Care Act (ACA).

As drafted and passed, HB3459 creates many implementation questions due to ambiguities and conflicts to current state law. We believe it is imperative for the TDI to provide clear guidance regarding the applicability of and specific requirements for the prior authorization (PA) exemptions and payment mandates.

We believe the TDI rules should confirm and clarify that "service" does not include "products" like prescription drugs obtained from a pharmacy. HB3459 provides no statutory authority to apply the PA exemption and payment requirements to products such as prescription drugs. The law's requirements apply only to "health care services", therefore prescription drugs by definition are not included within health care "services" or pharmacy "services"— they are products.

Pharmaceutical "services" are not the same thing as prescription drugs. The American Medical Association created specific CPT codes for pharmaceutical services and procedures, while prescription drugs are billed using National Drug Codes. The TDI recognizes "pharmacy procedures," and prohibits health plan denial of reimbursement to a pharmacist for *the provision of a service or procedure* within the scope of the pharmacist's license if certain conditions are met. Because "services" and "procedures" clearly differ from and do not include products and supplies such as prescription drugs.

PCMA strongly believes that HB3459 should not be interpreted to require "gold-card" exemptions from PA and payment mandates for prescription drugs. Including prescription drugs will create

confusion, as claims for prescription drugs are submitted by and paid to the dispensing pharmacy not the prescribing physician. In addition to creating practical questions about application of an exemption, this further demonstrates that prescription drugs are not “services.”

Alternatively, if HB3459 applies to pharmaceutical drugs, PCMA believes the spirit of HB3459 is to eliminate unnecessary prior authorization requests when providers demonstrate safe and appropriate use of medicines. In that spirit, we respectfully request TDI impose a requirement establishing a minimum number of prior authorization requests for the particular health care service in a specific time period in order for the prescriber to qualify for an exemption (e.g., 10 prior authorizations for the same service within a 6-month timeframe). PCMA strongly believes that a minimum threshold of prior authorization requests for the particular health care service must be established in order for health plans to reasonably ascertain that the 90 percent approval threshold was met or would have been met. A single prior authorization request should not be sufficient to qualify for an exemption as a single request is not an indicator that 90 percent of requests would have been approved, nor does it meet the spirit of the legislation to eliminate repetitive and burdensome prior authorization requests. Without a minimum threshold to qualify for an exemption, HB3459 creates an undue administrative burden.

In addition, if HB3459 applies to pharmaceutical drugs, additional guidance is needed on the following drug-specific issues:

1. Will high risk medications be exempted from the gold carding program?
2. Are insurers or pharmacy benefit managers expected to determine a provider’s approval rate for prescription drugs by evaluating all requests for all drugs, requests for a specific drug, requests for a particular drug class, or requests for some other grouping of medications?
3. Does this analysis by insurers or pharmacy benefit managers include consideration of prescriber behavior for each health plan?
4. Will there be allowances for additional considerations such as clinical appropriateness and patient safety? For example, the criteria that if 90% of claims pay, then all claims should be paid is not based on clinical appropriateness considerations and may not reflect a complete rational basis to allow coverage. For example, what if that 10% of drug claims which are not being paid are opiate drugs that are being prescribed inappropriately. If the provider is then gold carded, then the drugs being allowed to pay could have safety consequences for the member and provider.
5. If gold carding is granted to a prescriber specific to each drug, would application of gold carding be permitted at the GPI level of the drug (e.g., GPI 14, 12, 10 – all)?
6. Are management of formulary exceptions by insurers or PBMs included in the evaluation of gold-card status when determining a provider’s exceptions approval?
7. The time frame of auditing denials may require additional attention by TDI. We are concerned as the timing of denials does not appear to line up with the six month look back period as denials are only allowed in January and June.

Prior authorizations for prescription drugs are used to encourage the appropriate use of medications, to assist in the reduction of drug costs for all beneficiaries and to promote evidence-based drug therapy utilizations. Prior authorizations are developed by P&T committees using information from the FDA, drug manufacturers, medical literature and through consultations with practicing physicians and appropriate professional organizations. P&T Committees are typically composed of physicians, pharmacists and other qualified health professionals and Committees who help to develop guidelines for prior authorization based on the plan's unique patient population.

During the opioid epidemic, prior authorizations have been one of the primary tools in ensuring appropriate opioid utilization. Beyond opioids, many drugs have harmful side effects or interact adversely with other medications. PAs help ensure appropriate utilization when there are potential safety concerns or complex clinical concerns associated with utilization of a certain drug. A provider's "gold card" status should not exempt them from a plan's ability to implement additional safety checks that are currently in place to ensure appropriate and safe medication utilization.

We oppose efforts to limit the use of managed pharmacy tools that discourage the development of quality, cost effective prescription drug benefits. The fundamental goal of these tools is to promote the appropriate and cost-effective use of medications.

Applying HB3459's PA exemption requirements to prescription drugs would create a very dangerous and expensive new mandate to cover and pay for prescription drugs. For these reasons, we believe prescription drugs should not be included in the implementation of this law and a minimum threshold of services should be established before provisions specific to HB3459 are required.

Sincerely,

Melodie Shrader
Vice President – State Affairs

DATE: September 20, 2021

TO: Texas Department of Insurance; LHLcomments@tdi.texas.gov

FROM: Texas Association of Community Health Plans (TACHP)

RE: HB 3459 Comments

Eleven health plans established by Texas public and non-profit health care systems comprise the membership of the Texas Association of Community Health Plans (TACHP). Our health plans cover over two million Texans, and are committed to supporting and improving the health of people living at low and moderate incomes. TACHP health plans have earned the reputation as leaders in Texas communities through dedication to consumer-focused health care and strong provider relationships.

TACHP has a number of questions and concerns with HB 3459. This legislation mandates sweeping changes to preauthorizations and retrospective reviews, which have been long-standing and integral components of managed care that have protected the safety of consumers and controlled misuse of high-cost services. We hope TDI in its rule-making can clarify the legislation's ambiguities and provide direction that helps simplify operationalization of this challenging bill.

HB 3459 is aimed at rewarding providers who appropriately manage their patients' health care, and is not a blanket disregard of oversight measures. We urge TDI to keep this in mind as it translates the statute into regulation. TDI timeframes for the various requirements are confusing and do not fit together in a workable way. Health plans will need time to calculate exemptions and denials, rescissions and continued exemptions, and provider notifications and engagement. A January 1, 2022 implementation will not be possible because of the substantial modifications to prior authorization and claims systems and business and utilization review processes necessary to implement HB 3459 requirements. These changes cannot be fully designed and executed without more information and discussion with TDI.

TACHP appreciates TDI's willingness to gather input and engage stakeholders. We strived to provide you with reasonable responses to the questions posed in your Request for Information.

**Texas administrative medical licenses**

1. **Insurance Code Section 4201.206(a) requires that before an adverse determination is issued, the ordering health care provider be given the opportunity to discuss the treatment plan with a licensed physician. Please provide input on TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a).**

**TACHP Response:** the only change to the statute made by HB 3459 is to require the physician discussing treatment before adverse determination to be licensed in Texas (and of the same or similar specialty as the ordering/requesting/performing physician). The legislation does nothing to change TDI's allowance of an administrative medical license for utilization review activities. TDI should continue to allow an administrative medical license to fulfill the requirements of Section 4201.206(a).

**Preauthorization requests**

2. **Insurance Code Section 4201.653(a) exempts physicians and other health providers from preauthorization requirements for certain services if the HMO or health plan "has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service."**

    a. **When determining a provider's approval rate for preauthorization requests, should requests for a certain quantity (such as five days of inpatient care) be counted as a single request or multiple requests? What is the approval rate if, using the inpatient care example, three days were approved and two days were denied?**

    **TACHP Response:** TDI's example is one preauthorization request. The number of days is integral in the singular preauthorization request. TDI's existing requirements related to adverse determinations apply to partial denials. Partial denials are not approvals. If some days are denied, then the request is treated as a denial.

    b. **How should approval rates be calculated for preauthorization requests for a treatment regimen (such as three-drug regimen) where some services within the request may be approved and others denied or approved with changes?**

        i. **Should each distinct service be counted as a separate request?**
        ii. **Should a preauthorization request for a drug be treated as the same particular health care service if the prescribed dosage or other dispensing details are different?**

    **TACHP Response:** TDI's questions seems to presume prescription drugs would be included in HB 3459 requirements, but that does not follow from the statutory reference in HB 3459 for "health care services". Sec. 4201.651(b) refers to Sec. 843.002, which defines in (a), "health care services" to include "pharmaceutical services". Physicians and pharmacists provide pharmaceutical services such as medication management, but that is altogether different than products and supplies. TACHP strongly recommends TDI exclude prescription drugs, physician-administered drugs, equipment and supplies from its rule-making.

Our most significant concern with HB 3459 is the possibility of consumers suffering the ill effects of procedures and treatments that compromise their health without the ability of their insurer or health plan to oversee their safety. Prescription drugs in particular can be dangerous because of the fine line that can exist between a prescription drug's efficacy and toxicity. Drugs can also be very expensive, costing tens of thousands of dollars or more per treatment regimen. We suggest TDI interpret the requirements of HB 3459 to exclude non-services.

**Preauthorization exemptions**

3. **Under Insurance Code Sections 4201.655(a)(2) and 4201.656(d), the issuer must make a determination by evaluating a random sample of at least five claims from the most recent six-month evaluation period. Please provide input on how an exemption should be considered when there are four or fewer claims for the particular health care service in the most recent six-month evaluation period.**

   **TACHP Response:** For consideration of a denial or rescission, Sec. 4201(a)(2) refers to a random sample of between 5-20 claims. For an independent review of an exemption determination, 4201.656(d) says a provider may request consideration of *another random sample* of between 5 – 20 claims. That means for determination of an exemption for preauthorization, there must be enough claims to have TWO different random samples of between 5 – 20 claims. A random sample is a SUBSET THAT REPRESENTS the entire population of claims. A random sample is NOT the entire population of claims. Therefore, the number of claims used in the determination of an exemption, denial/rescission and reconsideration of a denial/rescission MUST BE CONSIDERABLY MORE THAN 5 – 20 claims. **Only providers that have enough claims for a random sample of TWICE 5 – 20 claims should be eligible for an exemption.**

4. **Under Insurance Code Section 4201.653(d), a physician or provider is not required to request an exemption to qualify. Under Section 4201.653(c), an issuer may grant an exemption without evaluating whether the physician or provider qualifies. Please provide input on TDI's consideration of rules that would require physicians or providers to be automatically granted an exemption by an issuer at the end of the first six-month evaluation period unless the insurer shows that the 90% threshold was not met during the evaluation period.**

   **TACHP Response:** Nothing in HB 3459, including Section 4201.653(d) and Section 4201.653(c), infers an issuer must provide an automatic exemption at the end of the first six-month period. TACHP would not support any further erosion in the ability of insurers to appropriately manage authorizations and utilization.

5. **Please provide input on TDI's consideration of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician or provider for a particular health care service rather than when the exemption is granted.**

   **TACHP Response:** TACHP supports a rule to require issuers to provide notice of a denial rather than when an exemption is granted.

6. **Under Insurance Code Section 4201.655, an issuer may rescind an exemption from preauthorization requirements only during January or June of each year. Under Section 6 of HB 3459, Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care services made on or after January 1, 2022. Please provide input on TDI's consideration of rules that would require issuers to provide an initial notice of exemption or denial of exemption in June 2022, based on an evaluation of preauthorization requests that were submitted on or after January 1, 2022.**

   **TACHP Response:** There are obvious drafting errors in HB 3459. TDI must define realistic assumptions about the timeframes for calculation of exemptions and denials/rescissions. As of today, health plans do not have necessary information to make systems and business process changes, which will take several months once requirements are known. Because of the unworkability of timelines in HB 3459, we urge TDI to determine timelines for implementation of the components of HB 3459 based on the publication of final rules.

   We recommend for health plans to be able to determine the six-month evaluation period in 2021 that gives them enough time to calculate exemptions for a January 1, 2022 exemption implementation. However, it may not be likely to begin the initial exemption period on January 1, 2022 because of previously mentioned systems changes required of health plans. If it could be accomplished, that first six-month exemption period would end July 1, 2022, which is after HB 3459's required notice of denial/rescission in June 2022. It would be impossible for TDI to require issuers to provide an initial notice of exemption or denial of exemption in June 2022 with a January 1, 2022 exemption start date.

7. **Starting from the date notification is received, how much time should a physician or provider have to request an appeal of the issuer's determination to rescind the exemption?**

   **TACHP Response:** TACHP recommends for TDI to present a draft timeline at the September 23rd stakeholder meeting of the various timeframes in HB 3459. That would allow for TDI to engage with stakeholders about the timeline possibilities and challenges. According to HB 3459, health plans must give 25 days of advanced notice to providers about a rescission/denial of an exemption, and IROs have 30 days to evaluate an appeal,

with an additional 5 days after IRO decision to uphold a rescission/denial. These requirements add time to the processes, and TACHP has concluded the limitation of rescissions/denials to occur only in January and June is impossible given the other timeline requirements. TACHP concurs with the recommendation from the Texas Association of Health Plans (TAHP) that providers be given 5 business days of the required health plan notice, and must include any request for the IRO to consider another random sample.

8. **Under Insurance Code Section 4201.655(a)(2), an issuer seeking to rescind an exemption from preauthorization must make a determination "on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted . . .during the most recent evaluation period." Under Insurance Code Section 4201.656(d), a physician or provider may request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted . . . during the relevant evaluation period." Is additional guidance in rules needed to clarify how an issuer or IRO should determine how to select the random sample or the number of claims to consider?**

   **TACHP Response:** TACHP recommends for TDI to provide guidance on how to identify a statistically valid random sample, based on commonly accepted standards.

9. **Please provide any additional comments or points of clarification that the rule should address.**

   **TACHP Response:** TACHP recommends TDI focus in its rules on establishing workable and cohesive timelines, appropriately large enough numbers of claims to determine exemptions, and realistic operational requirements for insurers and health plans to implement HB 3459, such as requirements on providers to provide medical records for rescission and IRO determinations.

Thank you for your consideration of our input. You can reach me at the email and phone number shown in my signature block below.

Sincerely,

Kay Ghahremani
President and CEO
Texas Association of Community Health Plans
kay.ghahremani@tachp.org
512/744-3735

Texas Association of Health Plans
1001 Congress Ave., Suite 300
Austin, Texas 78701
P: 512.476.2091
www.tahp.org

September 20, 2021
Texas Department of Insurance
Via email: LHLcomments@tdi.texas.gov

Re: Request for Information on Implementation of HB 3459

The Texas Association of Health Plans (TAHP) is the statewide trade association representing health insurers, health maintenance organizations, and other related health care entities operating in Texas. Our members provide health and supplemental benefits to Texans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid.

We appreciate the Department's efforts to implement House Bill 3459 and provide a stakeholder meeting and opportunity to comment. TAHP supports reasonable regulations designed to protect Texas families and businesses but not those that are overly burdensome with little or no consumer benefit. Prior authorization (PA) is an important tool used to protect patients from overtreatment and prevent care that is inappropriate or dangerous. Regulations should not further undermine important PA tools and quality incentives or create incentives for fraud, waste, and abuse.

HB 3459 as passed has multiple drafting problems and creates many open questions. It is necessary for TDI to provide clear guidance regarding the applicability of and specific requirements for the PA exemptions and payment mandate for health plans to implement the new law. There are several ambiguities and even conflicts in the law that need to be addressed and clarified in rulemaking to avoid mass confusion, potential litigation, and major disruptions to both enrollees and providers. For this reason, we recommend TDI rules provide clarification on several important foundational issues regarding who is eligible for the "gold-card" PA exemption, how and when plans make determinations on these exemptions, and how "health care services" requiring PA should be determined.

Texas statutory construction law and tradition require a "just and reasonable result" and "a result feasible of execution" is intended in statutory adoptions. (Tex. Gov't Code §311.021). Likewise, Texas courts have reiterated multiple times that the plain meaning of a statute may be disregarded if its application would lead to an absurd result. *See, e.g., TGS-NOPEC Geophysical v. Combs*, 340 S.W.3d 432, 439 (Tex. 2011). This is also true when the requirements of two separate statutes, when construed together, would not provide a just and reasonable result. *See FKM P'ship, Ltd. v. Bd. of Regents of Univ. of Houston Sys.*, 255 S.W.3d 619, 633 (Tex. 2008). TDI rules should therefore endeavor to avoid unreasonable and unfeasible interpretations of HB 3459 requirements.

Health plans have worked diligently on implementation of HB 3459, a massive undertaking. Texas health plans have over 40 thousand doctors and over 500 hospitals in their provider networks and pay over 100 million claims a year. Health plans will obviously need time to perform the necessary evaluations to determine which providers meet the 90% standard for PA exemptions. But the bill does not specify or provide guidance on a specific 6-month time period(s) to be used in initial exemption evaluations or for any future evaluations for potential rescissions of exemptions, which can be done only during January or June, based on the prior "evaluation period." Health plans must begin planning and working now if they are required to complete thousands of reviews and have exemptions in place prior to January 1, 2022. TAHP therefore recommends that health plans be given flexibility to determine an appropriate six-month "evaluation" period occurring within the prior year. The evaluation period should not be tied to the exemptions start date.

HB 3459 also creates questions about what is considered a "health care service" requiring PA. This term does not include prescription drugs, particularly those obtained from a pharmacy. Additionally, because of the potential for confusion regarding what is considered a "service" for which PA would be requested (and used for the 90% calculations) we strongly recommend that the rules recognize and confirm that the "services" requiring PA are those that health plans must post as requiring PA pursuant to Insurance Code sections 843.3481 and 1301.1351 and do not include requests for concurrent review.

It is also critical to keep in mind that HB 3459 is aimed at reducing administrative burdens for physicians and providers that are considered exemplary in determining what care is medically necessary and appropriate for each patient's particular circumstances — in other words, providers who excel at directing their personal patients' care. A PA exemption (and its corresponding prohibition on reducing payment based on medical necessity) should be available only for a physician or provider who is directing their personal patient's care (which necessarily includes making determinations that a particular service is medically necessary and appropriate for a particular patient).

TAHP and its member plans appreciate the opportunity to comment on this proposal and look forward to working with the Department on implementation. Please see our responses to the RFI questions below. Please contact me with any questions or to discuss further.

Regards,

Jamie Dudensing, RN
CEO
Texas Association of Health Plans

# Texas Administrative Medical Licenses

1. **Insurance Code Section 4201.206(a) requires that before an adverse determination is issued, the ordering health care provider be given the opportunity to discuss the treatment plan with a licensed physician. Please provide input on TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a).**

## TAHP's Response

**TDI rules should confirm that a Texas administrative medical license meets the requirement that "a physician licensed to practice medicine in the state" be available for peer-to-peer discussions.**

This position is clearly supported by Texas statute, as well as Texas Medical Board and current TDI rules. **Physicians who hold an administrative license issued by TMB are licensed to practice ("administrative") medicine in the state.** Physician applicants for an administrative medical license must meet the same requirements for "full" licensure, including the same exam requirements, with the exception of TMB's "active practice" requirement.

Additionally, under TMB's current "active practice of medicine" requirement, Texas physicians employed full-time as health plan medical directors are ineligible for "full" TMB medical licenses. Therefore, requiring these physicians to obtain full "clinical" licenses rather than allowing administrative medical licenses would result in an unworkable "Catch-22" situation, effectively prohibiting health plan physicians from performing any medical necessity reviews (even for services already received) — this would not be "a result feasible of execution" as required for Texas statutory construction. HB 3450 should not be interpreted to require health plan employed physician reviewers to hold a license that they are prohibited from obtaining under TMB rule.

Requiring only an administrative license for utilization review is a long-standing regulatory requirement at TDI, and nothing in this bill directs this change. Prior to HB 3459, Texas law required that health plans have a physician licensed to practice medicine available for the required peer-to-peer discussion opportunities, and TDI regulations allow this to include an administrative license. The only change made in this portion of the bill is to require that the license be issued by the state of Texas rather than another state.

## Background

- **HB 3459 Amendments**: Tex. Ins. Code §4201.206. OPPORTUNITY TO DISCUSS TREATMENT BEFORE ADVERSE DETERMINATION.
  (a) Subject to Subsection (b) and the notice requirements of Subchapter G, before an adverse determination is issued by a utilization review agent who questions the medical necessity, the appropriateness, or the experimental or investigational nature of a health care service, the agent shall provide the health care provider who ordered, requested,

provided, or is to provide the service a reasonable opportunity to discuss **with a physician licensed to practice medicine <u>in this state</u>** the patient's treatment plan and the clinical basis for the agent's determination.
(b) If the health care service described by Subsection (a) was ordered, requested, or provided, or is to be provided by a physician, the opportunity described by that subsection must be with a physician **licensed to practice medicine <u>in this state</u>** <u>and who has the same or similar specialty as the physician.</u>

- **A physician with an administrative license issued by TMB is "a physician licensed to practice medicine in this state."**
    - **Statute**: Tex. Occ. Code §155.009. LIMITED LICENSE FOR PRACTICE OF ADMINISTRATIVE MEDICINE.
        a) **The board shall adopt rules for the issuance of a license that limits the license holder to the practice of administrative medicine.** The board's rules under this section must include provisions for eligibility for the license, issuance and renewal of the license, the fees applicable to the license, continuing education requirements, and the scope of practice of a person who holds the license.
        b) An applicant for a license under this section must meet all of the requirements for issuance of a license under Section 155.002.
        c) A license holder under this section who seeks to practice medicine under an unrestricted license that is not limited to the practice of administrative medicine must provide proof to the board that the license holder has the clinical competence to practice medicine under that license and must meet all applicable eligibility requirements for that license. The board may require the license holder to pass any examination the board determines necessary.
    - **TMB RULE shows that an administrative license is a "license to practice medicine in this state" and that an applicant must meet the same requirements as for full licensure other than meeting TMB's "active practice" requirement: §172.17 Limited License for Practice of Administrative Medicine**
        a) Pursuant to §155.009, Texas Occupations Code, the board may issue to an applicant a license that is limited to administrative medicine.
        b) **"Administrative medicine," as used in this section means administration or management utilizing the medical and clinical knowledge, skill, and judgment of a licensed physician, and capable of affecting the health and safety of the public or any person.**

c) An administrative medicine license does not include the authority to practice clinical medicine, prescribe dangerous drugs or controlled substances, or delegate medical acts or prescriptive authority.

d) **An applicant for an administrative medicine license must complete the same application and meet the same requirements as an applicant for a full Texas medical license, except that the applicant for an administrative medicine license shall not be required to show that the applicant has been engaged in the active practice of medicine, as defined in §163.11 of this title (relating to Active Practice of Medicine).** Applicants for administrative medicine licenses must demonstrate that they have practiced administrative medicine in either of the two years preceding the date of application or otherwise demonstrate that they are competent to practice administrative medicine.

e) **The holder of an administrative medicine license shall be required to pay the same fees and meet all other requirements for issuance and renewal of the license as a person holding a full Texas medical license.**

f) **The holder of an Administrative Medicine License shall be subject to the Medical Practice Act and the Rules of the board as a person holding a full Texas medical license.**

g) This section shall have no effect on any full Texas medical license issued prior to the effective date of this rule. The license of any physician who has agreed to a board order restricting the license to administrative medicine based solely on the failure to meet the licensure requirement to be engaged in the active practice of medicine, upon request of the physician, may be converted to an administrative medicine license and the board order regarding such physician shall be terminated, provided that the only requirement of the order is the restriction to administrative medicine.

- TMB's own statistics count physicians holding administrative licenses as Texas-licensed physicians
- **TDI UR Rule:** §19.1706 Requirements and Prohibitions Relating to Personnel (a) Qualification requirements. Physicians, doctors, and other health care providers employed by or under contract with a URA to perform utilization review must be appropriately trained, qualified, and currently licensed. **Personnel conducting utilization review must hold** an unrestricted license, **an administrative license**, or be otherwise authorized to provide health care services by a licensing agency in the United States.

- TMB rule prohibits health plan physicians from obtaining a "full" medical license.

- RULE §163.11 **Active Practice of Medicine** (a) All applicants for licensure shall provide sufficient documentation to the board that the applicant has, on a full-time basis, **actively diagnosed or treated persons or has been on the active teaching faculty of an acceptable approved medical school**, within either of the last two years preceding receipt of an application for licensure….

# Preauthorization Requests

2. **Insurance Code Section 4201.653(a) exempts physicians and other health providers from preauthorization requirements for certain services if the HMO or health plan "has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service."**

    a. **When determining a provider's approval rate for preauthorization requests, should requests for a certain quantity (such as five days of inpatient care) be counted as a single request or multiple requests? What is the approval rate if, using the inpatient care example, three days were approved and two days were denied?**

## TAHP's Response

Each PA request should be counted as one request, regardless of whether it involves a request for a certain quantity or number of days. The Department has always required UR agents and health plans to treat a "partial denial" as an adverse determination for one request, with all of the statutory protections afforded an adverse determination, including notice, peer-to-peer discussion opportunity, appeals, independent reviews, etc. HB 3459 rules should be consistent with this long-term understanding.

It is important to have a consistent method of calculating what constitutes a denial or approval, but a requirement that health plans treat these requests as multiple requests and services with some approved and some denied is simply not feasible and was not considered when this bill was drafted. It would also seriously undermine the purpose of having a "gold-card" standard and would lead to exemptions being granted to providers whose requests fail to meet standards of care. As an example, consider a request for ten days of inpatient care. The standard of care for the hypothetical service is nine days, so only nine days are approved. Nevertheless, multiple inappropriate ten-day requests are submitted during a six-month evaluation period. If these inappropriate ten-day requests are each counted as ten individual requests, the provider could appear to have met the 90% standard triggering a PA exemption when in fact 100% of the provider's requests fail to meet the standard of care. This would result in future inappropriate ten-day requests being exempt from preauthorization requirements, despite being above and beyond what the standard of care dictates. Likewise, any request that is only 90% appropriate, if

continuously submitted over a six-month period, would become exempted if the request was considered multiple individual requests.

Additionally, TDI rules should confirm that HB 3459 applies only to PA requirements, and not to concurrent reviews. PA requests and reviews for inpatient services generally occur prior to a patient entering an inpatient facility. Requests submitted while a patient is already inpatient for approval of additional days are “concurrent review” rather than PA requests and, therefore, are outside the scope of applicability to “*pre*authorization” services. The rules should therefore clarify that the PA exemption applies only to preauthorizations and not inpatient concurrent reviews that are extensions of ongoing services. In the question’s example of five days being requested where only three meet the standard of care, the denial should count as one denial and not an approval. However, if instead an initial request for three days was approved and then a later request made during the inpatient stay for an additional two days were ultimately denied, it would count as one PA approval and no denials because concurrent review is not preauthorization.

In the context of an inpatient stay, a PA exemption would apply only to the number of days provided for in the health plan’s applicable PA clinical screening criteria as publicly posted pursuant to Insurance Code sections 843.3481 and 1301.1351. (Under Texas law, health plan PA clinical screening criteria must be objective, clinically valid, compatible with established principles of health care, and flexible enough to allow a deviation from the norm when justified on a case-by-case basis.) A request to extend the stay for additional days is subject to concurrent review and is not a preauthorization request for which an exemption is available under the new law.

## Background

New Sec. 4201.651. DEFINITIONS.

a) In this subchapter, "preauthorization" means a determination by a health maintenance organization, insurer, or person contracting with a health maintenance organization or insurer that health care services proposed to be provided to a patient are medically necessary and appropriate.

b) In this subchapter, terms defined by Section 843.002, including "health care services," "physician," and "provider," have the meanings assigned by that section.

**As distinguished recently by TDI in its mental health parity rules, a preauthorization does not include a reauthorization of ongoing services (concurrent review).**

28 TAC 21.2406 (28) Preauthorization or prior authorization--A utilization review process in which an issuer conditions coverage of a health care service, benefit, or prescription drug on the issuer's approval of the provider's request to provide an enrollee the service, benefit, or drug. For purposes of this rule:

A) preauthorization includes reauthorization of services or benefits that had received preauthorization, but for which the approval period has lapsed;

B) **preauthorization does not include utilization review needed to reauthorize ongoing services or benefits (concurrent review)**; and

C) a request for preauthorization is one received during the reporting period, regardless of the date the claim is incurred.

Sec. 4201.153. SCREENING CRITERIA AND REVIEW PROCEDURES.

a) A utilization review agent shall use written medically acceptable screening criteria and review procedures that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, dentists, and other health care providers.

b) A utilization review determination shall be made in accordance with currently accepted medical or health care practices, taking into account special circumstances of the c

c) **Screening criteria must be:**
   1) **objective;**
   2) **clinically valid;**
   3) **compatible with established principles of health care; and**
   4) **flexible enough to allow a deviation from the norm when justified on a case-by-case basis.**

d) Screening criteria must be used to determine only whether to approve the requested treatment. A denial of requested treatment must be referred to an appropriate physician, dentist, or other health care provider to determine medical necessity.

• • •

**2. b. How should approval rates be calculated for preauthorization requests for a treatment regimen (such as three-drug regimen) where some services within the request may be approved and others denied or approved with changes?**

**i. Should each distinct service be counted as a separate request?**

**ii. Should a preauthorization request for a drug be treated as the same particular health care service if the prescribed dosage or other dispensing details are different?**

# TAHP's Response

As stated above, services should be categorized for purposes of considering what is "a request" for PA consistently with PA requirements posted for various services pursuant to Insurance Code sections 843.3481 and 1301.1351. Each PA request should be counted as one request,

regardless of whether it involves a request for a certain quantity or a certain number of days, visits, or treatments, and regardless of varying dosages or other dispensing details.

**Additionally, TDI rules should confirm and clarify that "service" does not include "supplies" and "products" like medical equipment and prescription drugs, particularly drugs obtained from a pharmacy.** HB 3459 provides no statutory authority to apply the PA exemption and payment requirements to products such as prescription drugs. Under the plain language of the law, the requirements apply only to "health care services." While pharmacy "services" would likely be included, **prescription drugs by plain definition are not included within health care "services" or pharmacy "services"— they are supplies and products. Therefore, the HB 3459 requirements simply do not apply.**

**Pharmaceutical "services" are not the same thing as prescription drugs.** The American Medical Association created specific CPT codes for pharmaceutical services and procedures, while prescription drugs are billed using an entirely different coding system, (National Drug Codes . The Insurance Code also recognizes "pharmacy procedures," and prohibits health plan denial of reimbursement to a pharmacist for *the provision of a service or procedure* within the scope of the pharmacist's license if certain conditions are met. Because "services" and "procedures" clearly differ from and do not include products and supplies such as prescription drugs, HB 3459 should not be interpreted to require "gold-card" exemptions from PA and payment mandates for prescription drugs. Such an interpretation would create confusion and more questions. For example, the prescribing physician generally submits a PA request for prescription drugs, but the claim is submitted by and paid to the dispensing pharmacy. In addition to creating practical questions about application of an exemption in such a scenario, this further demonstrates that prescription drugs are not "services."

Applying 3459's PA exemption requirements to prescription drugs would create a very dangerous and expensive new mandate to cover and pay for prescription drugs, including opioids and other dangerous narcotics, with no ability to check for dangerous drug interactions or to confirm that risky drugs are appropriate for certain patients. For example, the "Houston Cocktail" — a mix of prescribed drugs (an opioid, hydrocodone, and a Xanax) that react with one another to become toxic and deadly — highlights the need for prior authorization checks to remain. When a clinical edit was added to prohibit prescribing this mix of prescriptions, it reduced this deadly interaction by 89%.

Prior authorizations for prescription drugs protect patients from opioid abuse and severe drug interactions or reactions. According to a study by the Institutes of Medicine, most adverse drug events that patients experience are caused by prescriber errors. These adverse drug events (ADEs) account for more than 3.5 million physician office visits and 1 million emergency department visits each year. It is believed that preventable medication errors affect more than 7 million patients and cost almost $21 billion annually. About 30% of hospitalized patients have at least one medication error at discharge. Medication errors and ADEs are an underreported burden that adversely affects patients, providers, and the economy. A study from Johns Hopkins suggests that medical errors, including "unwarranted variation in physician practice patterns that lack accountability," are now the third leading cause of death in the U.S. Prior authorizations not

only ensure appropriate health care, they save lives and protect patients. The overuse of prescription drugs and unsafe care in health care is rampant, resulting in harm to patients and wasted money. Doctors themselves believe that up to 30% of all ordered medical care is unnecessary or unsafe.

Additionally, health plans often suggest more appropriate interchanges during the PA process when there are safety or clinical concerns. This typically results in an approval for a different drug, and so a denial for the initial request would not be appropriately accounted for in calculating the provider's denial rates.

## Background

- HB 3459 uses the term "service": Sec. 4201.653. EXEMPTION FROM PREAUTHORIZATION REQUIREMENTS FOR PHYSICIANS AND PROVIDERS PROVIDING CERTAIN HEALTH CARE SERVICES. (a) A health maintenance organization or an insurer that uses a preauthorization process **for health care services a particular health care service if,** in the most recent six-month evaluation period, as described by Subsection (b), the health maintenance organization or insurer has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service.

- HB 3459 applies to health care services, which includes pharmaceutical *services*, but provides **no statutory authority to apply the PA exemption requirements to prescription drugs.**

    - HB 3459 incorporates the definition of "health care services" from Ins. Code sec. 843.002: "Health care services" means services provided to an individual to prevent, alleviate, cure, or heal human illness or injury. The term includes:
        A. **pharmaceutical *services***;
        B. medical, chiropractic, or dental care;
        C. hospitalization;
        D. care or services incidental to the health care services described by Paragraphs (A)-(C); and
        E. services provided under a limited health care service plan or a single health care service plan.

- **HB 3459 Payment Mandate**: New Sec. 4201.659. EFFECT OF PREAUTHORIZATION EXEMPTION. (a) **A health maintenance organization or insurer may not deny or reduce payment to a physician or provider for a health care service for which the physician or provider has qualified for an exemption from preauthorization requirements under Section 4201.653 based on medical necessity or appropriateness of care** unless the physician or provider: (1) knowingly and materially misrepresented the health care service in a request for payment submitted to the health maintenance organization or insurer with the specific intent to deceive and obtain an

unlawful payment from the health maintenance organization or insurer; or (2) failed to substantially perform the health care service.

- Prescription drugs are not included within “pharmacy services.”
    - House Bill 3441 was passed by the Texas Legislature in 2019, adopting new Section 1451.1261 of the Insurance Code, entitled “Reimbursement **for Certain Services and Procedures** Performed by Pharmacists.” In it the Legislature recognizes that there are billable “pharmacy procedures,” and prohibits denial of reimbursement to a pharmacist for the provision of a service or procedure within the scope of the pharmacist's license if certain conditions are met.
    - Since 2006 there have been three nationally recognized CPT codes to bill for **medication therapy management (MTM) services.**
        - CPT codes 0115T, 0116T, and 0117T describe pharmacist-provided MTM **services** and recognize the initial face-to-face encounter, subsequent visits, and any appointment lasting beyond 15 minutes.
        - Effective 1/1/2008 three new CPT codes developed collaboratively by members of the Pharmacist Services Technical Advisory Coalition (PTSAC) replaced the above category III codes. **The CPT codes that are used to report Pharmacy services** and its full description are as follows
            - 99605 **Medication therapy management service(s) provided by a pharmacist,** individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient
            - 99606 **Medication therapy management service(s) provided by a pharmacist,** individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient
            - 99607 **Medication therapy management service(s) provided by a pharmacist,** individual, face-to-face with patient, with assessment and intervention if provided; each additional 15 minutes
    - Prescription drugs are not included within the HMO “basic health care services" that, according to statute (Sec. 843.002), TDI has determined an enrolled population might reasonably need to be maintained in good health. (See TDI Rule §11.508 Basic Health Care Services and Mandatory Benefit Standards: Group, Individual, and Conversion Agreements.)
    - The recent passage of HB 2090 reflects that health care services do not include products like drugs. This transparency law consistently refers to “health care

services **or supplies**," and creates a definition for a "health care service ***or supply***" in order to obtain data on health care supplies that are not health care services. Because HB 3459 does not similarly specify applicability to health care "supplies," it does not apply to PA requests or claims for prescription drugs or other supplies and products.

# Preauthorization Exemptions

3. **Under Insurance Code Sections 4201.655(a)(2) and 4201.656(d), the issuer must make a determination by evaluating a random sample of at least five claims from the most recent six-month evaluation period. Please provide input on how an exemption should be considered when there are four or fewer claims for the particular health care service in the most recent six-month evaluation period.**

## TAHP's Response

HB 3459 does not specify the minimum number of services needed for calculation of the 90% standard for an initial determination of whether an exemption should be granted or denied. TDI rules cannot create a situation where a health plan must provide a PA exemption based on less than 5 services or claims but cannot rescind that exemption based on fewer than 5. In other words, health plans should not be required to issue a PA exemption for a provider that submits only a few claims for a certain service during each evaluation period that can never be rescinded even if the provider fails to meet the 90% approval standard.

A valid evaluation of a specific provider in relation to their capability to adequately perform a specific service must necessarily rely on review of multiple incidents of the service. For example, a review of a service that a provider has performed and submitted only once or twice during the evaluation period would not be statistically valid.

For these reasons, TAHP recommends that the rules require a minimum of 5 claims for an initial exemption and also clarify that a rescission may be based on a review of all claims or PA requests for a particular service if there are less than 5 for a particular provider.

Additionally, HB 3459 uses the term "random sample" but refers to a review of only 5-20 claims for exemption rescissions. A random sample is meant to be an unbiased representation of a larger population. In many instances, a sample of 5-20 claims is not statistically valid to represent the entire population of a service performed by a particular provider. A valid evaluation must be based on a minimum number of claims.

TAHP therefore recommends that the rules require a minimum of 5 claims for an initial exemption and clarify that a rescission may be based on a review of all claims or PA requests for a particular service if there are less than 5 for a particular provider.

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4. **Under Insurance Code Section 4201.653(d), a physician or provider is not required to request an exemption to qualify. Under Section 4201.653(c), an issuer may grant an exemption without evaluating whether the physician or provider qualifies. Please provide input on TDI's consideration of rules that would require physicians or providers to be automatically granted an exemption by an issuer at the end of the first six-month evaluation period, unless the insurer shows that the 90% threshold was not met during the evaluation period.**

## TAHP's Response

First, Section 4201.653(c) provides that a health plan issuer may "continue" an existing exemption without completing the evaluation and showing that the 90% threshold was not met during a later evaluation period. TAHP is not opposed to exemptions being granted or extended by health plans that may choose to grant or extend an exemption without performing the evaluations in order to calculate whether the 90% approval rate has been met. We would oppose a requirement that providers automatically receive an exemption at the end of the 1st 6-month evaluation period because it would undermine the purpose of important PAs that protect patient safety. **Additionally, rules addressing this issue must be very clear that the exemption is available only for services for which the health plan requires PA.**

• • •

5. **Please provide input on TDI's consideration of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician or provider for a particular health care service rather than when the exemption is granted.**

## TAHP's Response

TAHP supports allowing health plans to send notices of exemption denials rather than approvals. The rules should allow health plans the flexibility to decide which is appropriate. But rules addressing this issue must be very clear that the exemption is available only for services for which the health plan requires PA and only for physicians and providers who met the 90% threshold for each particular service with a PA requirement during the evaluation period.

• • •

6. **Under Insurance Code Section 4201.655, an issuer may rescind an exemption from preauthorization requirements only during January or June of each year. Under Section 6 of HB 3459, Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care service made on or after January 1, 2022. Please provide input on TDI's consideration of rules that would require issuers to provide an initial notice of exemption or denial of exemption in June 2022, based on an evaluation of preauthorization requests that were submitted on or after January 1, 2022.**

## TAHP's Response

TAHP would support an interpretation that the January 1st date in HB 3459 refers to PA requests submitted on or after that date for purposes of evaluating whether the 90% standard has been met. This is appropriate given potential plan changes with respect to preauthorization requirements that may occur on January 1, 2022. We would also support delayed applicability and implementation of the HB 3459 exemption requirements based on the number of open questions and the extensive resources required for implementation. However, we do not understand the details of this question, which indicates that a health plan would use an evaluation period of less than six months and does not account for the time needed to perform the necessary evaluations.

HB 3459 requires a health plan to provide an exemption from PA requirements (and essentially mandates payment) for any provider for any particular service requiring PA for which the provider meets the 90% approval threshold established in the bill during a six-month "evaluation" period. Health plans are required to give notice of an exemption within only 5 days of a provider "qualifying" for it based on the evaluation. But the bill does not specify or provide guidance on a specific 6-month time period(s) to be used in initial exemption evaluations or for any future evaluations for potential rescissions of exemptions, which can be done only during January or June, based on the prior "evaluation period."

To perform the evaluations required to determine whether the 90% approval threshold has been met, health plans will be required to review **every PA request or every claim for each service** requiring PA. Performing these evaluations will obviously require extensive employee time and IT resources. Health plans cannot just "turn off" PA requirements for specific providers. Texas health plans have over 40 thousand doctors and over 500 hospitals in their provider networks and pay over 100 million claims a year. Requiring a specific time period that is too close to the date the exemptions must be in place will create an unworkable process. It is simply not feasible to create a system that measures the 90% standard for meeting medical criteria for every provider in Texas twice each year at the same time for every service that needs clinical review.

**Health plans must begin planning and working now** in order to complete their potentially thousands of reviews and have exemptions in place prior to January 1, 2022. TAHP therefore recommends that health plans be given flexibility to determine an appropriate six-month evaluation period occurring within the prior year. Such an approach would allow health plans to use different time periods for various provider types and services so that they would not be required to perform the evaluations (and send notices within 5 days) for every service and every provider in the same limited time frame. Without this flexibility in timing, there is no way for health plans to implement this requirement. The evaluation period should not be tied to the exemptions start date.

Additionally, HB 3459 specifies that exemption evaluations be performed every six months, that rescission notices be sent at least 25 days in advance, and that rescissions of exemptions can only occur in January or June of each year. The extended notice time and apparent drafting error (January through June is a 5 month—not a 6 month—time period) necessarily require that

additional time must be provided between the end of the “evaluation” period and the time that the exemption must be in place.

## Background

- New 4201.653

    a) A health maintenance organization or an insurer that uses a preauthorization process for health care services **may not require** a physician or provider **to obtain preauthorization** for a particular health care service **if**, **in the most recent six-month evaluation period,** as described by Subsection (b), the health maintenance organization or insurer **has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service.**

    b) Except as provided by Subsection (c) *[which allows a health plan to simply continue an exemption]*, a health maintenance organization or insurer shall evaluate whether a physician or provider qualifies for an exemption from preauthorization requirements under Subsection (a) once every six months.

- Notice of Exemption: Health plans are required to give notice of an exemption within only 5 days of a provider “qualifying” for it: new 4201.658(d) provides that “Not later than five days after qualifying for an exemption," a health plan must provide notice to the provider that includes a list of all services exempted. To deny an exemption, the health plan must provide "actual statistics and data for the relevant preauthorization request evaluation period and detailed information sufficient to demonstrate" that the provider does not meet the criteria for an exemption for each service.

- Once an exemption is issued, it can only be rescinded in January or June under new Sec. 4201.655: DENIAL OR RESCISSION OF PREAUTHORIZATION EXEMPTION.

    a) A health maintenance organization or insurer **may rescind an exemption from preauthorization requirements under Section 4201.653 only**

        1) **during January or June of each year;**

        2) if the health maintenance organization or insurer makes a determination, on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims **submitted by the physician or provider during the most recent evaluation period described by Section 4201.653(b),** that less than 90 percent of the claims for the particular health care service met the medical necessity criteria that would have been used by the health maintenance organization or insurer when conducting preauthorization review for the particular health care service during the relevant evaluation period; and….

# Rescinding Preauthorization Exemptions

7. **Starting from the date notification is received, how much time should a physician or provider have to request an appeal of the issuer's determination to rescind the exemption?**

## TAHP's Response

TAHP recommends that providers requesting an appeal of an exemption rescission or denial be required to do so within 5 business days of the required health plan notice and must include any request for the IRO to consider another "random" sample. Under new Section 4201.655, a health plan may rescind a PA exemption only in the months of January or June, and only after providing at least 25 days' advance notice of the rescission or denial, including the sample information used to make the determination and a plain language explanation of how to appeal to an IRO. The IRO has up to 30 days to complete the review, including when the appealing provider has requested the IRO to make its determination based on another claim sample. Even when the IRO confirms a health plan's determination to rescind an exemption, the exemption stays in place for 5 days after the IRO's decision. Because of HB 3459's requirements for 25 days' advance notice of a rescission and to maintain the exemption during the 30-day IRO appeal time frame, the rules should allow no more than 5 days for the provider to submit an appeal in order for the six-month exemption to not extend far beyond 6 months.

If more time is allotted for providers to submit appeals, the rules should then clarify that the PA exemption and prohibition on reducing claim payment based on medical necessity do not apply beyond the date that the rescission would have been effective without an appeal. Extending an exemption far beyond the six-month period specified in the bill for providers who are no longer meeting the 90% standard creates patient safety issues and increases opportunities for fraud, waste and abuse.

## Background

New Sec. 4201.653. EXEMPTION FROM PREAUTHORIZATION REQUIREMENTS FOR PHYSICIANS AND PROVIDERS PROVIDING CERTAIN HEALTH CARE SERVICES….

b) Except as provided by Subsection (c), **a health maintenance organization or insurer shall evaluate whether a physician or provider qualifies for an exemption from preauthorization requirements** under Subsection (a) **once every six months.**

c) A health maintenance organization or insurer may continue an exemption under Subsection (a) without evaluating whether the physician or provider qualifies for the exemption under Subsection (a) for a particular evaluation period.

New 4201.656. INDEPENDENT REVIEW OF EXEMPTION DETERMINATION.

a) A physician or provider has a right to a review of an adverse determination regarding a preauthorization exemption be conducted by an independent review organization. A health maintenance organization or insurer may not require a physician or provider to engage in an internal appeal process before requesting a review by an independent review organization under this section,

c) **An independent review organization must complete an expedited review of an adverse determination regarding a preauthorization exemption not later than the 30th day after the date a physician or provider files the request for a review under this section.**

New Sec. 4201.654. DURATION OF PREAUTHORIZATION EXEMPTION.

a) A physician's or provider's exemption from preauthorization requirements under Section 4201.653 remains in effect until… (2) **if the physician or provider appeals the determination, the fifth day after the date the independent review organization affirms** the health maintenance organization's or insurer's determination to rescind the exemption.

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8. **Under Insurance Code Section 4201.655(a)(2), an issuer seeking to rescind an exemption from preauthorization must make a determination "on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted … during the most recent evaluation period." Under Insurance Code Section 4201.656(d), a physician or provider may request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted ... during the relevant evaluation period." Is additional guidance in rules needed to clarify how an issuer or IRO should determine how to select the random sample or the number of claims to consider?**

## TAHP's Response

TAHP recommends that the rules provide for the health plan to select a random sample in a blind manner in accordance with written procedure that describes the methodology for the random sampling.

# Additional comments

9. **Please provide any additional comments or points of clarification that the rule should address.**

## TAHP Response

1. Please provide in the rules that the 5-day notice time period in Sec. 4201.659(d) refers to business days.

2. It would be very helpful for TDI to provide model language for notices of exemption rescissions or denials and appeal rights.

3. TAHP requests and strongly recommends that the rules require physicians and providers to cooperate in the evaluations. Medical records will often be required, and providers should be compelled to comply with requests for copies of those records within a reasonable time period (such as 30 days) in order to maintain an exemption. A provider's refusal to cooperate in the evaluations should not form the basis for an exemption. We therefore request that the rules clarify that health plans are not required to grant or maintain exemptions in documented instances where the provider has failed to cooperate with reasonable requests for necessary information.

4. TAHP requests that TDI confirm its ability to assign appeals to IROs and for Texas-certified IROs to perform rescission appeals. Specifically, will all certified IROs be required to also review physician appeals? Is there sufficient capacity with current licensed IROs to provide these services? Will TDI propose rules to address the fee structure for IRO review of rescission appeals and assignment (per 28 TAC 12.401 et seq )and random assignment of an IRO (per 28 TAC 12.501 et seq.)?

5. TAHP recommends that the rules clarify that a PA exemption (and its corresponding prohibition on retrospective reviews and denials based on lack of medical necessity) is available only to physicians and providers **that order and submit PA requests and** direct the care of their patient. As noted above, HB 3459 is aimed at reducing administrative burden for physicians and providers that are considered exemplary in determining what care is medically necessary and appropriate for each patient's particular circumstances; in other words, providers who excel at directing patient's care. In many situations, the same physician or provider will order/direct, request a PA for, render, and bill for health care services. In these scenarios, the determination and application of a PA exemption (and its corresponding prohibition on reducing payment based on medical necessity) is fairly straightforward. But there are many scenarios where one provider is deciding what care is appropriate (and requesting a PA for the care) but another provider is rendering the services and billing for them. In that situation, the ordering provider who would typically be requesting a PA may be eligible for a PA exemption, but the rendering and billing provider should not be.

   TAHP recommends that TDI rules clarify that the prohibition on reducing payment based on medical necessity does not apply to the rendering provider based on the ordering provider's PA exemption. A PA exemption (and its corresponding prohibition on reducing payment based on medical necessity) should be available only for providers who are directing the patient's care (including determinations that a service is medically necessary and appropriate). Allowing one physician or provider's PA exemption to form

the basis of a prohibition on reducing payment to another provider would invite manipulation of the process, allowing treating or dispensing providers to “shop around” for providers with PA exemptions in order to inappropriately avoid health plan PA requirements.

## Background

**PA Exemption**: Sec. 4201.653. EXEMPTION FROM PREAUTHORIZATION REQUIREMENTS FOR PHYSICIANS AND PROVIDERS PROVIDING CERTAIN HEALTH CARE SERVICES.

a) A health maintenance organization or an insurer that uses a preauthorization process for health care services **may not require a physician or provider to obtain preauthorization for a particular health care service if,** in the most recent six-month evaluation period, as described by Subsection (b), the health maintenance organization or insurer has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service.

b) Except as provided by Subsection (c), a health maintenance organization or insurer shall evaluate whether a physician or provider qualifies for an exemption from preauthorization requirements under Subsection (a) once every six months.

c) A health maintenance organization or insurer may continue an exemption under Subsection (a) without evaluating whether the physician or provider qualifies for the exemption under Subsection (a) for a particular evaluation period.

d) A physician or provider is not required to request an exemption under Subsection (a) to qualify for the exemption.

**Payment Mandate**: New Sec. 4201.659. EFFECT OF PREAUTHORIZATION EXEMPTION. (a) A health maintenance organization or insurer may not deny or reduce payment to a physician or provider for **a health care service for which *the physician or provider* has qualified for an exemption from preauthorization requirements** under Section 4201.653 based on medical necessity or appropriateness of care unless the physician or provider:

1) knowingly and materially misrepresented the health care service in a request for payment submitted to the health maintenance organization or insurer with the specific intent to deceive and obtain an unlawful payment from the health maintenance organization or insurer; or

2) failed to substantially perform the health care service.

TEXAS ONCOLOGY

More breakthroughs. More victories.®

September 20, 2021

Texas Department of Insurance

Commissioner Cassie Brown

PO Box 12030

Austin, TX 76711

Dear Commissioner Brown,

On behalf of Texas Oncology, we appreciate the opportunity to submit comments and participate in the stakeholder process regarding the implementation of House Bill 3459.

Texas Oncology is an independent, physician-led practice conducting innovative research and delivering leading-edge technology and treatment options. Texas Oncology's community-based approach of integrated sub-specialty oncology care enables patients to receive leading-edge treatment while living at home and receiving critical support from family and friends. Texas Oncology has over 500+ physicians in over 210 locations across the state of Texas treating more than 55,000 new cancer patients annually.

The rising use of prior authorization continues to burden physicians and clinical staff, increase practice operating costs, and delay time-sensitive care for patients. Such policies, when not appropriately controlled, are a direct threat to integrated care. Texas took a huge step in amending the Insurance Code 4201.26 to require physicians participating in a peer-to-peer review on behalf of a health benefit plan issuer to be Texas-licensed physicians with the same or similar specialty as the physician or provider requesting the service. We applaud Senator Buckingham for her leadership on this legislation. Efforts such as hers and HB 3459 help to ensure physicians and clinical staff aren't overburdened with administrative processes.

We are grateful for the opportunity to provide input for TDI's consideration when promulgating rules to satisfy the following requirements of HB 3459:

**Texas Administrative Medical Licenses:**

A) **Insurance Code Section 4201.206(a) requires that before an adverse determination is issued, the ordering health care provider be given the opportunity to discuss the treatment plan with a licensed physician.**

   I. **Please provide input on TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206 (a):**

Texas Oncology is opposed to TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a) of the Texas Insurance Code regarding the "peer-to-peer" call prior to an adverse determination.

Texas Oncology is concerned that the use of an Administrative Medical License is inconsistent with the statutory intent of HB 3459. We are aligned with the Texas Medical Association's (TMA) comments and agree the legislative intent is for physicians who perform peer-to-peer under Section 4201.206, to have a full Texas medical license.

**Preauthorization Requests:**

**Insurance Code Section 4201.653 (a) exempts physicians and other health providers from preauthorization requirements for certain services if the HMO or health plan "has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service."**

**A) When determining a provider's approval rate for preauthorization requests, should requests for a certain quantity (such as five days of inpatient care) be counted as a single request or multiple requests?**

Not applicable to Texas Oncology.

**I. What is the approval rate if, using the inpatient care example, three days were approved, and two days were denied?**

Not applicable to Texas Oncology.

**B) How Should approval rates be calculated for preauthorization requests for a treatment regimen (such as three-drug regimen) where some services within the request may be approved and others denied or approved with changes?**

**I. Should each distinct service be counted as a separate request?**

Transparency from the payer on how to handle requests is needed. We encounter some payers that prefer authorizations for everything at once, while some, for example, do antineoplastics and antiemetics separately. Texas Oncology aligns with the Texas Medical Association's (TMA) comments and support that for the three-drug treatment regimen referenced above, each drug would be treated separately.

**II. Should a preauthorization request for a drug be treated as the same particular health care service if the prescribed dosage or other dispensing details are different?**

Texas Oncology believes it is responsible to request that dosing is removed from prior authorization requirements. Dosing, especially with chemotherapy is not just the practice of medicine but is also complicated and actual dosing decisions should lie in the hands of the treating oncologist.

**Preauthorization Exemptions**

**A) Under Insurance Code Sections 4201.655(a)(2) and 4201.656(d), the issuer must make a determination by evaluating a random sample of at least five claims from the most recent six-month evaluation period.**

**I. Please provide input on how an exemption should be considered when there are four or fewer claims for the particular health care service in the most recent six-month evaluation period.**

If a provider has fewer than 5 claims in a 6-month period, Texas Oncology believes they should be exempt as a below threshold provider.

**B) Under Insurance Code Section 4201.653(d), a physician or provider is not required to request an exemption to qualify. Under Section 4201.653(c), an issuer may grant an exemption without evaluating whether the physician or provider qualifies.**

I. **Please provide input on TDI's consideration of rules that would require physicians or providers to be automatically granted an exemption by an issuer at the end of the first six-month evaluation period, unless the insurer shows that the 90% threshold was not met during the evaluation period.**

Texas Oncology agrees that payers should have the opportunity to grant exemptions without review but must provide notice if the exemption does not apply within a reasonable time frame.

**C) Please provide input on TDI's consideration of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician or provider for a particular health care service rather than when the exemption is granted.**

Texas Oncology would prefer providers receive notice when exemptions are both either granted or denied. This would protect the provider from inadvertently thinking they are exempt, ordering tests, and not requesting prior authorization. Payer notifications are inevitably lost or sent directly to the provider and not forwarded to the people who need them to adjust workflows. If they receive advance notice of the exemption, the practice can retain that documentation and protect themselves against possible denials due to lack of prior authorization.

**D) Under Insurance Code Section 4201.655, an issuer may rescind an exemption from preauthorization requirements only during January or June of each year. Under Section 6 of HB**

**3459, Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care service made on or after January 1, 2022.**

I. **Please provide input on TDI's consideration of rules that would require issuers to provide an initial notice of exemption or denial of exemption in June 2022, based on an evaluation.**

Texas Oncology agrees and supports that payers must provide an initial communication to all providers that clearly states what services the provider will or will not be exempt from submitting prior authorization. We feel a provider should be notified for example on 12/15/20xx or 5/15/20xx of the notice to rescind an exemption. Providers need notification early enough to make sure we have the processes in place prior to recission. This is important communication that will establish a baseline with each provider.

**Rescinding Preauthorization Exemptions**

A) **Starting from the date notification is received, how much time should a physician or provider have to request an appeal of the issuer's determination to rescind the exemption?**

Texas Oncology supports that a physician should have 60 days to request an appeal of the issuer's determination to rescind exemption. In our experience, 30 days will not be enough time to receive the notice, circulate it internally, and formulate a response.

B) **Under Insurance Code Section 4201.655(a)(2), an issuer seeking to rescind an exemption from preauthorization must make a determination "on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted … during the most recent evaluation period." Under Insurance Code Section 4201.656(d), a physician or provider may request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted ... during the relevant evaluation period."**

I. **Is additional guidance in rules needed to clarify how an issuer or IRO should determine how to select the random sample or the number of claims to consider?**

Texas Oncology believes that if a provider fails a 5-chart review, they should be able to request a review of up to 20 charts. In the example of reviewing 5 charts, if the provider has one order that is non-concordant with guidelines, they will fail the 90% threshold.

**Additional Comments:**

- Each payer needs to provide quarterly performance reports so providers, like Texas Oncology, can make proactive adjustments before losing exemption or to help them gain future exemption.
- Upon request, payers need to supply provider with itemized raw data of patient name, DOB, payer ID, requested service, PA determination (approve/deny), and reason for denial (if applicable).

Data must be provided within 45 days. This is important to support continuous quality improvement efforts and education.

- Exemptions should be determined at a high-level and not at a CPT code level (i.e., CT chest, CT abdomen, CT pelvis should all be calculated within the same category.
- What happens when a provider submits a request but then changes that request prior to administration of drug? Will the provider be penalized?

Thank you for your consideration of our comments regarding the implementation of House Bill 3459. We appreciate the opportunity to be a resource for you. Please let us know if we can provide additional information.

Sincerely,

Debra Patt, MD

Executive Vice President, Policy and Strategic Initiatives, Texas Oncology

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Texas Hospital Association

1108 Lavaca Street, Suite 700, Austin, Texas 78701
512/465-1000
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September 20, 2021

*Via electronic submission to:* LHLcomments@tdi.texas.gov

Cassie Brown
Commissioner
Texas Department of Insurance
333 Guadalupe
Austin, TX 78701

Re: Texas Hospital Association Comments on Implementation of House Bill 3459

Dear Commissioner Brown:

On behalf of our more than 470 member hospitals, the Texas Hospital Association is pleased to submit comments to the Texas Department of Insurance on the implementation of House Bill 3459, 87th Regular Session. The underlying goal of HB 3459 is to create efficiency in health care. THA encourages TDI to ensure that the implementation of HB 3459 prevents processes that would create an additional burden for hospitals, physicians or payors. THA looks forward to a detailed stakeholder discussion on items one through eight of its request for information and offers the following comments on item nine:

In implementing HB 3459, it is important to protect historical payor peer-to-peer processes in an effort to timely secure authorization for continued inpatient stays, services or transfers to post-acute providers. Specialty reviews should not take the place of standard peer-to-peer review processes. If a routine peer-to-peer review occurs and the parties remain at an impasse (and there is an ongoing denial), only then should a specialty physician review occur. HB 3459 was developed to support providers in ensuring that coverage decisions rendered by payors are made after exhaustive efforts and thorough review with all available information and expertise. Most prior authorization requests can be handled through established processes. Specialty reviews should be based on the best interest of the patient and not be used to delay treatment decisions pending the location of a specialty provider. Hospitals want to ensure that HB 3459 is implemented in good faith and that specialty physician reviews are used appropriately. Historically, these reviews have occurred in situations related to complex clinical scenarios or diverse medical opinions.

In addition, peer-to-peer reviews should not require discussion with only the attending physicians. Hospitals designate certain physicians and employees familiar with the patient record, documentation and care to assist with peer-to-peer reviews. The utilization review process should include these professionals, in addition to the attending physician.

Thank you for your consideration of these comments. We look forward to working with you on the implementation of this important legislation. Should you have any questions, please do not hesitate to contact me at cduncan@tha.org or 512/465-1539.

Respectfully submitted,

Cameron Duncan
Associate General Counsel
Texas Hospital Association

September 20, 2021

Cassie Brown
Commissioner
Texas Department of Insurance
Austin, Texas 78744-9104

Via email: LHLcomments@tdi.texas.gov

Re: TDI Request for information to use in implementation of House Bill 3459

Dear Commissioner Brown:

On behalf of our collectively more than 55,000 physician and medical student members, the Texas Medical Association (TMA), Texas Orthopaedic Association, Texas Society for Gastroenterology and Endoscopy, Texas Society of Anesthesiologists, Texas Chapter of the American College of Physicians, Texas Academy of Family Physicians, Texas Chapter, American College of Cardiology, Texas Dermatological Society, Texas Pediatric Society, Texas College of Emergency Physicians, Texas Radiological Society, Texas Society of Pathologists, Texas Osteopathic Medical Association, and Federation of Texas Psychiatry (hereinafter the "Associations") appreciate the opportunity to submit these comments on the Texas Department of Insurance's (TDI)'s "Request for information to use in implementation of House Bill 3459."

As TDI is aware, our organizations have a well-demonstrated interest in reducing the burdens and increasing the transparency of health plan preauthorization requirements. Accordingly, we strongly supported HB 3459 last regular legislative session. We appreciate TDI's efforts to implement this important legislation. In response to the specific questions posed, we offer the comments, below.

**Texas administrative medical licenses**

**1. Insurance Code Section 4201.206(a) requires that before an adverse determination is issued, the ordering health care provider be given the opportunity to discuss the treatment plan with a licensed physician. Please provide input on TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a).**

In response to the first question posed by TDI, the Associations are opposed to TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a) of the Texas Insurance Code regarding the "peer-to-peer" call prior to an adverse determination.

The Associations are concerned that the: (1) limitations placed on this type of Texas license make the license ill-suited for the functions performed by the Texas-licensed physician who conducts the peer-to-peer call; and (2) use of a limited license for the practice of administrative medicine is inconsistent with the statutory intent of HB 3459.

More specifically, under Section 155.009 of the Texas Occupation Code and 22 Tex. Admin. Code § 172.17, the Texas Medical Board (TMB) is authorized to issue a license that is limited to administrative medicine. "Administrative medicine" is defined under the rule as "administration or management utilizing the medical and clinical knowledge, skill, and judgment of a licensed physician, and capable of affecting the health and safety of the public and any person." However, the rule continues by stating that "[a]n administrative license ***does not include the authority to practice clinical medicine***, ***prescribe dangerous drugs or controlled substances, or delegate medical acts or prescriptive authority***." (emphasis added).

We are concerned with these administrative medical licensure limitations regarding clinical practice, given that under the applicable Insurance Code provision (Section 4201.206), the physician reviewer would be performing very clinically driven functions. For example, the physician would be discussing the patient's treatment plan and the clinical basis for the agent's determination concerning the medical necessity, appropriateness or the experimental or investigational nature of a health care service. Thus, for the functions performed by the physician to truly be "peer-to-peer," the reviewing physician must have full authority to practice clinical medicine in this state.

Peer reviews (in other medical contexts) are traditionally performed by individuals who have the authority to engage in the same type of practice as the physician or health care professional being reviewed. TMA policy 225.019 acknowledges this and, therefore, expressly provides that:

> [t]he Texas Medical Association advocates that physicians who conduct review for health care decisions in Texas should (1) be in an active practice; (2) possess a nonrestricted license to practice in Texas; and (3) be experienced in the procedures or treatment under review. (For example, not all orthopedic surgeons perform spinal surgery.)

In the context of conducting utilization reviews, maintaining full regular licensure to practice medicine in Texas as a requirement is equally important. While the physician is not being peer reviewed for disciplinary purposes under Section 4201.206, the physician reviewer can significantly impact the enrollee/patient's care. Thus, TMA policy 160.107 provides, in part, that "… adverse utilization review determinations [should] be made only by physicians who are ***fully licensed*** by the Texas Medical Board … ." (emphasis added).

For a reviewing physician on a peer-to-peer call to recommend denying coverage to an enrollee/patient based upon a determination that a drug being prescribed is medically unnecessary when that physician has no authority to prescribe that drug himself or herself makes little sense from either a clinical or a public policy perspective. And, if an adverse determination is issued due to this disconnect in clinical authority, it is likely to cause unnecessary delay in the patient's care, as the ordering physician would then have to appeal the determination. **Time is of the essence for many patients who are seeking preauthorization for medical services. Injecting further delay into the system is wasteful, at best, but harmful to patient care, at worst.**

Furthermore, the use of a limited administrative medicine license is inconsistent with the statutory intent of HB 3459. HB 3459 was designed to ensure that physicians who perform peer-to-peer calls are: (1) accountable to the Texas Medical Board; and (2) the most familiar with the standard of care/delivery of care in this state. A limited license to practice administrative medicine in Texas might aid, to a limited extent, in promoting the first goal. But it does not support the second goal (and certainly does not to the extent that a regular full Texas medical license would).

The bill author's/sponsor's statement of intent expressly provides that:

> [t]here are concerns that the preauthorization and utilization review processes for health care benefit plan coverage may be burdensome to physicians and providers and may have the potential to prevent patients from receiving the care they need. ***H.B. 3459 seeks to address this issue by ensuring that physicians who are the most familiar with the delivery of health care in Texas are involved in utilization reviews for health benefit plan coverage.*** (emphasis added).

Put simply, requiring physicians who perform peer-to-peer calls under Section 4201.206 to have a full Texas medical license is much more aligned with legislative intent in adding the Texas licensure requirement to the peer-to-peer requirements under the law. The Legislature's goal in amending Section 4201.206 was not to reduce the licensure requirements under prior law (i.e., to move it from a full license in one state to an administrative medicine only license in another), but to make it a ***Texas-specific full*** licensure requirement. The Associations urge TDI to act consistently with this intent, which will promote access to timely, medically appropriate patient care.

We also note that the Texas Association of Health Plan (TAHP) representatives have stated in news articles that "[h]ealth plans are often the only ones with a 360-degree view of a patient's treatment, and safety edits can help stop dangerous interactions for care or prescriptions supplied by multiple providers." If this statement were true, then we argue that the health plans should be supportive of having a physician with the

most appropriate training, experience and licensure (which would include being authorized to prescribe the reviewed drugs in this state) performing the peer-to-peer calls for utilization reviews.

Additionally, if TDI is considering an administrative medicine only license out of concern that it may be difficult to find fully-licensed Texas physicians to perform the peer-to-peer calls, then it is important for TDI to be aware that, based upon data received from the TMB, it is our understanding that Texas licensed 5,304 new physicians in fiscal year 2021. This is the highest annual number since we began collecting these data in 1981 and likely in the state's history. Therefore, any supply concern may be unfounded in light of this substantial new physician licensure increase.

Further, with the passage of HB 1616 (the Interstate Medical Licensure Compact), these numbers should continue to grow. We expect expedited access to a full medical license to be greatly facilitated through use of the Compact. Also, we note that the process and criteria for obtaining a full medical license under Texas' normal licensure process are largely the same as for an administrative medicine license (with the exception of the active practice of medicine requirements). Thus, it is not much more burdensome for a physician to obtain a full medical license, rather than a limited administrative medicine license. The number of administrative medicine only licenses also is likely nominal compared to the number of fully-licensed physicians in Texas, so expanding the licensure requirement to permit the use of administrative medicine only licenses would do little to address any supply concern that TDI may have.

For all the foregoing reasons, we strongly urge TDI to require a full license to practice medicine in Texas for a physician performing the peer-to-peer call under Section 4201.206, Texas Insurance Code.

**Preauthorization requests**

**2. Insurance Code Section 4201.653(a) exempts physicians and other health providers from preauthorization requirements for certain services if the HMO or health plan "has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service."**

**a. When determining a provider's approval rate for preauthorization requests, should requests for a certain quantity (such as five days of inpatient care) be counted as a single request or multiple requests? What is the approval rate if, using the inpatient care example, three days were approved and two days were denied.**

Prior authorizations are generally reviewed on a Current Procedural Terminology (CPT®) code basis, either the specific CPT code or groups of CPT codes within the same family (i.e., inpatient E/M codes). Therefore, it makes sense to review on the basis of the primary CPT code. The Associations also urge TDI to ensure that any method TDI selects to address the questions in RFI No. 2 is fully transparent to all stakeholders.

**b. How should approval rates be calculated for preauthorization requests for a treatment regimen (such as three-drug regimen) where some services within the request may be approved and others denied or approved with changes?**

**i. Should each distinct service be counted as a separate request?**

For the three-drug treatment regimen, referenced above, we would support each drug being treated separately.

**ii. ii. Should a preauthorization request for a drug be treated as the same particular health care service if the prescribed dosage or other dispensing details are different?**

The Associations contend that for drug approvals, the drug should be the basis for the preauthorization exemption determination (rather than the dosage). Although medications may have different indications for different dosages and there may be different dosages used for different conditions, dosing will be more difficult to parse and apply in the context of this bill. Dosing issues will also be addressed by the standard of care, which is enforceable through other mechanisms outside of preauthorization (e.g., the Texas Medical Board and medical professional liability). Use of a drug in the context of a general medical condition could also be considered (rather than the dosage).

**Preauthorization exemptions**

**3. Under Insurance Code Sections 4201.655(a)(2) and 4201.656(d), the issuer must make a determination by evaluating a random sample of at least five claims from the most recent six-month evaluation period. Please provide input on how an exemption should be considered when there are four or fewer claims for the particular health care service in the most recent six-month evaluation period.**

For this question, it may be helpful to separate this issue by denials and recissions, because the Associations believe this question is answered by the express language of the law. For denial of an exemption when there are four or fewer claims, Section 4201.655(c) states:

> (c) A health maintenance organization or insurer may deny an exemption from preauthorization requirements under Section 4201.653 only if:
>
> (1) the physician or provider does not have the exemption at the time of the relevant evaluation period; and
>
> (2) the health maintenance organization or insurer provides the physician or provider with actual statistics and data for the relevant preauthorization request evaluation period and detailed information sufficient to demonstrate that the physician or provider does not meet the criteria for an exemption from preauthorization requirements for the particular health care service under Section 4201.653.

In relevant part, Section 4201.653 states:

> (a) A health maintenance organization or an insurer that uses a preauthorization process for health care services may not require a physician or provider to obtain preauthorization for a particular health care service if, in the most recent six-month evaluation period, as described

by Subsection (b), the health maintenance organization or insurer has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service.

So in order to grant or deny an exemption for a particular health care service for which the physician has submitted four or fewer claims, the law states that the general 90 percent approval threshold from Section 4201.653(a), Texas Insurance Code would apply. To clarify further, the initial preauthorization exemption for a particular health care service is not based upon a random sample of claims. For example, if a physician had four claims and all were approved for that particular service, the physician would receive a preauthorization exemption for that service from the HMO or insurer, because the physician would have a 100 percent approval rate for those claims.

Alternatively, under the bill, the random sampling of claims comes into play when an HMO or insurer is attempting to rescind a preauthorization exemption that has already been granted. More specifically, Section 4201.654 provides that an HMO or insurer may rescind an exemption from preauthorization requirements under Section 4201.653 ***only if*** certain requirements are met. One of those requirements is that the HMO or insurer must have made a determination, on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted by the physician or provider during the most recent evaluation period, that less than 90 percent of the claims for the particular health care service met the medical necessity criteria that would have been used for the service.

If there are four or fewer claims, *ipso facto,* this recission criterion cannot be satisfied and the physician or provider's gold card exemption continues for that particular service. This is made clear through the language in Section 4201.654, which provides that "[i]f a health maintenance organization or insurer does not finalize a recission determination as specified in Subsection (a) [which is an impossibility given the inadequate sampling number in cases of 4 or fewer claims], then the physician or provider is considered to have met the criteria under Section 4201.653 to continue to qualify for the exemption."

The bill's default status of a continuation of an exemption (when four or fewer claims are submitted in a six-month evaluation period) makes sense from a policy perspective, because the physician has already had a history of submitting claims that met the 90 percent approval threshold for that particular service and there are too few claims to present a waste or abuse concern. (Note that fraud should not be a concern either, because even with an exemption in place, there is a separate provision designed to address fraud under the law (i.e., Section 4201.659).

**4. Under Insurance Code Section 4201.653(d), a physician or provider is not required to request an exemption to qualify. Under Section 4201.653(c), an issuer may grant an exemption without evaluating whether the physician or provider qualifies. Please provide input on TDI's consideration of rules that would require physicians or providers to be automatically granted an exemption by an issuer at the end of the first six-month evaluation period, unless the insurer shows that the 90% threshold was not met during the evaluation period.**

The Associations support automatically granting of an exemption by an issuer at the end of the first six-month evaluation period, unless the issuer shows that the 90 percent threshold was not met during the evaluation period. This would present the least amount of burden in terms of a review for an issuer and defaults to granting an exemption (presuming high approval as authorized under Section 4201.653(c)) which is appropriate.

The Associations contend, however, that it will be important that: (1) the HMO or insurer complies with the requirements in Section 4201.655(c) regarding the provision of data and statistics to support any denial; and (2) for the appeal rights under the bill to continue in the scenario where an issuer claims that the 90 percent threshold was not met during the evaluation period. And, for transparency, it will be important for the HMO or insurer to provide the exemption qualification notice under Section 4201.659(d), so that a physician knows the scope and duration of the exemption. Physician practices process preauthorization requests from numerous plans (both state-regulated and self-funded). It is important for physicians to be on notice as to which plans and services the preauthorization exemption applies. Otherwise, the physician may be under the mistaken impression that a preauthorization exemption applies to a particular plan for a particular service, fail to submit a preauthorization request for that plan, and have an enrollee's coverage for the service denied. Such a result creates bad public policy because it would unnecessarily punish the physician and the patient. Thus, transparency in process will be key to the proper implementation of the law.

**5. Please provide input on TDI's consideration of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician or provider for a particular health care service rather than when the exemption is granted.**

The Associations are very supportive of TDI's promulgation of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician (as this would be important for the physician to know in order to exercise the physician's appeal rights under Section 4201.656). However, we do not think that the denial notice should be in lieu of notice when an exemption is granted. It needs to be a requirement *in addition to* when an exemption is granted. As stated in response to RFI No. 4, transparency in the process will be key to proper implementation of the law.

**6. Under Insurance Code Section 4201.655, an issuer may rescind an exemption from preauthorization requirements only during January or June of each year. Under Section 6 of HB 3459, Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care service made on or after January 1, 2022. Please provide input on TDI's consideration of rules that would require issuers to provide an initial notice of exemption or denial of exemption in June 2022, based on an evaluation of preauthorization requests that were submitted on or after January 1, 2022.**

The Associations are generally supportive of TDI's stated timeframe for implementation of the law. A conservative reading of the bill would be that the "Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care service made on or after January 1, 2022" includes the claims being reviewed for eligibility for the preauthorization exemption. Under this approach, our assumption is that TDI would require insurers and HMOs to provide initial notices either granting or denying exemptions in June 2022 (based upon a review of claims from January 1, 2022 until June

2022). Any granted exemptions would go into effect immediately after qualifying for the exemption (as the law requires notice to be provided not later than five days after the physician qualifies for the exemption). And any exemption would not be subject to potential recission until completion of the next six-month evaluation period, consistent with the timeframe (i.e., January 2023) and other requirements set forth in the law. Any denied exemptions would be subject to appeal rights under the law.

Alternatively, we note that a more liberal reading of the bill's timing requirements (under SECTION 6 of the bill and Section 4201.655, Texas Insurance Code) would potentially permit plans to grant preauthorization exemptions based upon a review of requests submitted prior to January 1, 2022, since the status of any preauthorization request would not be impacted until the first exemption is granted. The Associations would be supportive of that approach as well. We would not be supportive of any further delay beyond that included in this RFI.

**Rescinding preauthorization exemptions**

**7. Starting from the date notification is received, how much time should a physician or provider have to request an appeal of the issuer's determination to rescind the exemption?**

The Associations contend that the physician should have, at the very least, 30 business days to request an appeal of the issuer's determination to rescind the exemption. We would be supportive of any timeframe greater than that. It will take time for the physician to review the recission determination, assess whether to appeal, and submit the appeal. Any less time will be insufficient for a physician to make the assessment of a need for an appeal. We also strongly recommend that TDI promulgate rules that require the HMO or insurer to provide any notifications required by the law or TDI rule to the physician using the method and contact information preferred by the physician (e.g., preferred email address) so that the physician is able to ensure proper receipt of any notifications or dedicate an email solely to receiving these notifications to ensure the notifications do not get lost.

**8. Under Insurance Code Section 4201.655(a)(2), an issuer seeking to rescind an exemption from preauthorization must make a determination "on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted … during the most recent evaluation period." Under Insurance Code Section 4201.656(d), a physician or provider may request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted ... during the relevant evaluation period." Is additional guidance in rules needed to clarify how an issuer or IRO should determine how to select the random sample or the number of claims to consider?**

The Associations support additional guidance to clarify how a "random sample" must be collected to ensure uniformity in decisions are made. As a guide, we believe that the dictionary definition of "random" is fairly straightforward. For example, according to Merriam Webster, "random," may is defined as:

> **1a:** lacking a definite plan, purpose, or pattern
> **b:** made, done, or chosen at random read *random* passages from the book

**2a:** relating to, having, or being elements or events with definite probability of occurrence *random* processes
**b:** being or relating to a set or to an element of a set each of whose elements has equal probability of occurrence a *random* sample
*also* **:** characterized by procedures designed to obtain such sets or elements *random* sampling

It is important that, consistent, with general definitions of "random," the insurer or HMO not exhibit a plan, purpose, or pattern in selecting the samples. Each claim should have an equal probability of being selected. And, at no point should specific metrics be applied by the issuer such as, specific patient cohorts or site of service, which may favor the issuer's decision-making.

Further, under Section 4201.655, where the law provides that a the recission determination shall be based on "a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted … during the most recent evaluation period," TDI should require the issuer to review the maximum amount of claims available within that range. For example, if only five claims have been submitted during the relevant period for the particular service, that would be sufficient for the determination. If twenty or more claims have been submitted for the particular service during the relevant evaluation period, then the issuer should be required to review twenty claims prior to making the determination. This will promote having that most robust data set within the statutory range reviewed.

Also, when under Insurance Code Section 4201.656(d), a physician or provider is permitted to request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted ... during the relevant evaluation period," it is important that TDI clarify that if the same claims are selected in this second random sample, the duplicates only are reviewed once and another claim can be randomly selected (if available). The intent of the law is to review the claims originally reviewed, plus a new sample (as provided expressly in Section 4201.656(d)).

However, TDI should provide that if the physician or provider feels the "random" sample used in either Section 4201.655 or 4201.656 is biased, the physician may request that the identified biased metric, such as specific patient cohorts or site of service, be removed. The physician or provider should also be able to file a complaint with TDI to assess the "randomness" of selection procedures utilized by issuers.

**Additional comments**

**9. Please provide any additional comments or points of clarification that the rule should address.**

Additional areas of clarification that would be useful in rulemaking include:

- imposing express requirements on issuers to provide notice of denials of preauthorization exemptions (along with information on how to appeal);
- (as stated above), requiring issuers to solicit the preferred contact method/information for notices provided under the law and rules;

- clarifying that the final preauthorization decision is what is utilized to assess the approval rate (i.e., after all appeals, including any external reviews, are conducted). An initial denial that is subsequently overturned should still count as an approval for preauthorization exemption purposes;
- clarifying that a preauthorization exemption may be granted to both an individual physician and the physician's practice (consistent with the definition of a "physician" under the law). If a preauthorization exemption is granted to a physician's practice, then the rule should provide that the exemption would apply to all the physicians in the practice regardless of whether they individually qualify for an exemption. As provided under Subchapter N, Chapter 4201, Texas Insurance Code, terms defined by Section 843.002, including "physician" and "provider" have the meanings assigned by that section. Importantly, the definition of a "physician" under Section 843.002 is not limited to an individual licensed to practice medicine in this state. It also includes, among other things,: (1) a professional association organized under the Texas Professional Association Act; and (2) another person wholly owned by physicians. Thus, the HB 3459 provision authorizing a preauthorization exemption should apply to both individual physicians and their practices that fall within the definition of a "physician." The definition of "provider" is also broad and should be reflected in the rules accordingly; and
- requiring the physician reviewer (under Section 4201.206(b)'s peer-to-peer utilization review provision and Section 4201.655(b)'s preauthorization exemption review provision) to timely provide the physician who is being reviewed with information concerning the reviewer's specialty so that the reviewed physician is able to file a complaint with TDI if he or she believes the reviewing physician is not truly of the same or similar specialty.

The Associations thank TDI for the opportunity to comment. If you have any questions, please do not hesitate to contact Kelly Walla, Associate Vice President and Deputy General Counsel of the Texas Medical Association, at kelly.walla@texmed.org

Respectfully,

E. Linda Villarreal, MD
President, Texas Medical Association

Kenneth J. Kaminski, MD
President, Texas Orthopaedic Association

Louis J. Wilson, MD
President, Texas Society for Gastroenterology and Endoscopy

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President, Texas Society of Anesthesiologists

John Flores, MD, FACP
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Amer Shakil, MD, MBA
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Kenneth M. Shaffer, MD
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President, Texas College of Emergency Physicians

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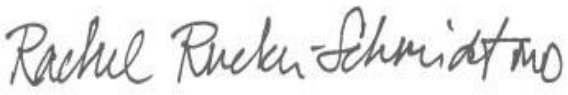

Rachel Rucker-Schmidt, MD
President, Texas Society of Pathologists

Heather Aguirre, DO
President, Texas Osteopathic Medical Association

J. Clay Sawyer, MD
Chairman, Federation of Texas Psychiatry

September 16, 2021

Cassie Brown
Commissioner
Texas Department of Insurance
Austin, Texas 78744-9104

Via email: LHLcomments@tdi.texas.gov

Re: TDI Request for information to use in implementation of House Bill 3459

Dear Commissioner Brown:

TSAOG Orthopaedics appreciate the opportunity to submit comments on the Texas Department of Insurance's (TDI)'s "Request for information to use in implementation of House Bill 3459."

TSAOG Orthopaedics is a physician owned, multi-specialty orthopaedic practice located in the greater San Antonio, TX area. We are proud to have been caring for our community since 1947.

We strongly support the HB 3459 and appreciate the efforts of TDI to implement this important legislation.

In response to the questions posed, our comments are below.

**Texas administrative medical licenses**

1. Insurance Code Section 4201.206(a) requires that before an adverse determination is issued, the ordering health care provider be given the opportunity to discuss the treatment plan with a licensed physician. Please provide input on TDI's consideration of a rule providing that an Administrative Medical License could satisfy the requirements of Section 4201.206(a).

***Answer**: We do not feel comfortable discussing a patient's treatment plan with a non-practicing physician. As defined by the Texas Medical Board, an administrative medical license "allows physicians to use the medical and clinical knowledge skill and judgment in ways which may affect the health and safety for the public or any person". This definition does not include the development of a treatment plan. A physician who holds an administrative license is not considered a 'peer' when developing a treatment plan for any one patient. A 'peer' must be a physician whose scope of practice includes developing and executing treatment plans.*

**Preauthorization requests**

2. Insurance Code Section 4201.653(a) exempts physicians and other health providers from preauthorization requirements for certain services if the HMO or health plan "has approved or would have approved not less than 90 percent of the preauthorization requests submitted by the physician or provider for the particular health care service."

a. When determining a provider's approval rate for preauthorization requests, should requests for a certain quantity (such as five days of inpatient care) be counted as a single request or multiple requests? What is the approval rate if, using the inpatient care example, three days were approved and two days were denied?

*Answer: Single Request. Requests should not be unbundled. The approval rate should be measured by the approval of the primary code. Therefore, the answer to the above question is the approval rate should be 100%.*

b. How should approval rates be calculated for preauthorization requests for a treatment regimen (such as three-drug regimen) where some services within the request may be approved and others denied or approved with changes?

i. Should each distinct service be counted as a separate request?

*Answer: No. The approval rate should be calculated based on the primary CPT code. There should not be individual approvals for each code; the approval rate needs to be based off the primary CPT code requested. "Was the primary CPT code approved?" Yes (approved) – No (Denied).*

*The approval rate should be based on the final decision; after all appeals, external reviews, peer reviews, etc. have been exhausted. If the authorization is initially denied and that decision is overturned with a peer-to-peer, additional medical records, etc., it is the final decision of the authorization that must be counted.*

ii. Should a preauthorization request for a drug be treated as the same particular health care service if the prescribed dosage or other dispensing details are different?

*Answer: No. It is the drug being approved, not the dosage.*

**Preauthorization exemptions**

3. Under Insurance Code Sections 4201.655(a)(2) and 4201.656(d), the issuer must make a determination by evaluating a random sample of at least five claims from the most recent six-month evaluation period. Please provide input on how an exemption should be considered when there are four or fewer claims for the particular health care service in the most recent six-month evaluation period.

*Answer: If there are lest than five claims, then the physician should be automatically placed in an 'exempt' status. The intent of prior authorizations is to weed out fraud, waste, and abuse; if a physician has less than five claims, then they are not a problem.*

4. Under Insurance Code Section 4201.653(d), a physician or provider is not required to request an exemption to qualify. Under Section 4201.653(c), an issuer may grant an exemption without evaluating whether the physician or provider qualifies. Please provide input on TDI's consideration of rules that would require physicians or providers to be automatically granted an exemption by an issuer at the end

of the first six-month evaluation period, unless the insurer shows that the 90% threshold was not met during the evaluation period.

*Answer: Agree, all providers should be given an exemption status until the issuer can prove trends of abuse.*

5. Please provide input on TDI's consideration of rules that would require issuers to provide notice of a denial of a preauthorization exemption to a physician or provider for a particular health care service rather than when the exemption is granted.

*Answer: Providers must be notified of their status; exempt or not. Transparency is vital to ensure accurate authorization and claim processing. One option for storing this status is in the CAQH database.*

6. Under Insurance Code Section 4201.655, an issuer may rescind an exemption from preauthorization requirements only during January or June of each year. Under Section 6 of HB 3459, Subchapter N of Chapter 4201 applies only to a request for preauthorization of health care service made on or after January 1, 2022. Please provide input on TDI's consideration of rules that would require issuers to provide an initial notice of exemption or denial of exemption in June 2022, based on an evaluation of preauthorization requests that were submitted on or after January 1, 2022.

*Answer: Agree.*

**Rescinding preauthorization exemptions**

7. Starting from the date notification is received, how much time should a physician or provider have to request an appeal of the issuer's determination to rescind the exemption?

*Answer: 30 days*

8. Under Insurance Code Section 4201.655(a)(2), an issuer seeking to rescind an exemption from preauthorization must make a determination "on the basis of a retrospective review of a random sample of not fewer than five and no more than 20 claims submitted … during the most recent evaluation period." Under Insurance Code Section 4201.656(d), a physician or provider may request that the independent review organization (IRO) "consider another random sample of not less than five and no more than 20 claims submitted ... during the relevant evaluation period." Is additional guidance in rules needed to clarify how an issuer or IRO should determine how to select the random sample or the number of claims to consider?

*Answer: We are deeply concerned about the paucity of information describing the criteria payers may use to determine the gold member status. By our own estimates, we believe that at least 375 authorization requests would need to be reviewed, per physician, to determine that 10% of authorization requests were appropriately denied, assuming 95% confidence intervals and a 3% margin of error. Sampling only twenty authorization requests grossly underpowers the payer's ability to draw any reasonable conclusion regarding adherence to the 90% approval standard. In fact, if you select a random sample of 20 from a population (assuming that 10% of authorization requests are appropriately denied), you would only be 52.5% confident that between 5% and 15% of authorization requests were denied in the entire sample. That's basically a coin flip! An independent review organization will be similarly handicapped if the 5-20 sample rule remains in place, rendering independent review as feckless as the payer's original analysis. We adamantly recommend compelling the largest allowable sample of*

*authorizations requests submitted and advise that clear statistical methods be outlined and published regarding any compliance calculations, including explicit language around sampling strategy.*

*A fair evaluation should afford providers the opportunity to independently evaluate a payer's conclusions by obligating the payer to "show their work" with pre-registered, transparent, reproducible sampling and analysis methods.*

**Additional comments**

9. Please provide any additional comments or points of clarification that the rule

*1. Sample size: Please see comments on answer #8 regarding our grave concerns with the sampling methodology to 90% compliance.*

*2. Claims being reviewed: The word 'claim' is being used throughout the bill and these clarifications; however, these authorizations will be considered requests or tasks by the insurance carrier and (issuer) and not yet a claim. The use of the terminology 'claim' vs. 'authorization request' should be clarified.*

*3. How are the 'claims' being measured? Will this be by TIN, Provider NPI, CPT code? What will be included in the sample for approval?*