



## Texas Board of Nursing

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**Katherine A. Thomas, MN, RN, FAAN**  
*Executive Director*

July 27, 2018

Allison Vordenbaumen Benz, R.Ph., M.S.  
Executive Director  
Texas State Board of Pharmacy  
William P. Hobby Building, Suite 3-500  
333 Guadalupe Street  
Austin, Texas 78701

Re: Comments regarding Proposed 22 Texas Admin Code §291.29

Dear Director Benz,

The Board of Nursing is concerned that the proposed rule contains overly broad and vague language that could prevent patients from receiving medications legitimately prescribed by their providers, including advanced practice registered nurses (APRNs) with prescriptive authority. While the Board agrees that appropriate oversight over dispensing practices is needed, the subject matter of the proposal seems better suited to an agency FAQ or position statement than a rule amendment. Further, the Board notes that a 'red flag' checklist containing identical information already appears on the Pharmacy Board website.

The Board makes specific comments on the proposal as follows:

Several portions of the proposal address specific prescriber practices that must be considered and resolved prior to dispensing medications. However, the proposal also identifies several pharmacy practices that must be considered and resolved prior to dispensing medications. These provisions include proposed §291.29(f)(1), (2), and (18) - (24). Essentially, these provisions seem to require a pharmacist to evaluate his/her own employer's dispensing practices prior to deciding whether to dispense a medication. This evaluation should be a prerequisite to being a legitimate pharmacy, not for filling a single prescription. As such, the Board recommends that these proposed provisions be relocated to a more appropriate section.

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Although the Board agrees that a pharmacist should verify a prescription with a prescriber if the pharmacist questions the accuracy or authenticity of a prescription, in some cases, the proposed rule seems to supplant the provider's medical judgment with that of the pharmacist responsible for filling the prescription. This seems to inappropriately encroach upon the scope of practice of the prescribing provider. For example, proposed §219.29(f)(8) contains a list of subjective behaviors that a prescriber may exhibit that constitute a 'red flag' under the proposed rule. However, a legitimate prescriber may be busy with patients and not available to have a comprehensive discussion with a pharmacist who calls his/her office. Further, certain privacy laws, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may prevent a prescriber from having a comprehensive discussion about a patient's treatment, diagnosis, prognosis, etc, with a pharmacist. Legitimate prescribers may also have a differing medical opinion regarding the necessity of the prescribed medications, including its dosage and combination with other medications. The Board recommends striking proposed §291.29(f)(8) from the proposal, as it is overly subjective, broad, and unnecessary. Existing §291.29(a) already provides a pharmacist the authority to verify a questionable prescription with a prescriber prior to dispensing the medication. If the pharmacist is not satisfied with this evaluation, he/she can refuse to dispense the medication.

There are also several proposed provisions that may be inconsistent with existing law. First, proposed §291.29(f)(4) raises privacy concerns under HIPAA. Again, the proposed language is overly broad. What constitutes a non-specific diagnosis? Does an actual diagnosis need to appear on the prescription in order to inform the pharmacist of its necessity? For example, could a prescription read 'as needed for cough' and be sufficient under the proposal? Or, under the proposal, would the prescription be required to also include the underlying condition that is producing the cough? Proposed §291.29(f)(10) also raises concerns in that it does not seem to recognize that only clinics meeting specific statutory requirements are required to register as pain clinics with the Texas Medical Board. Legitimate prescribers may routinely prescribe muscle relaxants, benzodiazepines, or psychostimulants from locations that are not required, by law, to register as a pain clinic. The proposal seems to impose a higher standard than the one imposed by law in this regard. Finally, proposed §291.29(f)(11) seems to again encroach on a prescriber's scope of practice by seeking to limit a prescriber to an area of practice that may not be required under his/her license. A physician is not limited under the law to one area of medical practice. Thus, the proposal again seems to impose a higher standard than that imposed by law. The Board recommends that §291.29(f)(4), (10), and (11) be removed from the rule.

The proposal also includes several proposed provisions that are overly broad not rationally related to non-therapeutic prescribing practices. For example, a prescriber may legitimately prescribe an opioid with an over-the-counter product, such as a laxative. This is not necessarily indicative of non-therapeutic prescribing. The Board recommends that proposed §291.29(f)(6) be removed as an independent 'red flag' factor from the proposal. If retained, the provision should be viewed in conjunction with other objective factors that

are narrowly tailored and objectively related to fraudulent or inappropriate prescribing practices. Likewise, proposed §291.29(f)(12) is too broadly drafted. For example, a prescriber could have a past or current disciplinary order for failure to complete continuing education that would have no bearing on his/her prescribing practices. The Board recommends that this provision be appropriately narrowed so that the prior or current disciplinary action be related to dangerous prescribing practices or conduct rationally related to dangerous prescribing practices. Further, the factors listed in proposed §291.29(f)(15) - (17) are also overly broad and not narrowly tailored to non-therapeutic prescribing practices. First, many families see the same health care provider as their primary care provider. In those instances, several individuals may present prescriptions written by the same prescriber. Such cases would not be out of the ordinary and are not necessarily related to non-therapeutic prescribing. Further, some insurance plans will cover some prescription medications, but some may not. It may be less expensive for a patient to pay for a prescription with cash or a credit card than through insurance. Some patients may not even have insurance. These instances are also not uncommon and are not necessarily indicative of non-therapeutic prescribing. Finally, the conduct specified in proposed §291.29(f)(17) is overly broad and not appropriately tailored to reach non-therapeutic prescribing. Persons are often faced with long lines at pharmacies to pick up medications, particularly if an area has a limited number of pharmacies or it's during a peak traffic period. Patients often know their medications by color or shape and will recognize a departure from those norms in their medications. While some of the conduct specified in these proposed paragraphs could be present in some non-therapeutic prescribing practices, that will not always be the case. The proposal is overly broad in this regard and may impact patients who are seeking to have legitimate prescriptions filled. The Board recommends that these provisions be removed from the rule, but if they are kept, that they be appropriately narrowed to encompass only those behaviors most likely to indicate fraudulent or dangerous prescribing practices.

Lastly, proposed §291.29(g) makes a pharmacist subject to disciplinary action based upon inappropriate dispensing associated with a pattern of the 'red flag' factors contained in the proposal. The proposed 'red flag' factors are overly broad and subjective. The Board is concerned that pharmacists will unnecessarily restrict their dispensing habits in an effort to avoid being scrutinized under the proposed rule. This result may be lessened by removing the overly broad and subjective language from the proposal and retaining the factors that are narrowly tailored and rationally related to non-therapeutic prescribing practices.

Sincerely,



Dusty Johnston, General Counsel  
Board Certified - Administrative Law  
Texas Board of Legal Specialization

# Texas Pharmacy Business Council



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## **TPBC Board**

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## **Executive Director**

Michael J. Wright

July 27, 2018

### **VIA FACSIMILE (512) 305-8061**

Megan G. Holloway  
Assistant General Counsel  
Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500  
Austin, Texas 78701

Re: Comments to the proposed amendments to Texas Administrative Code, title 22, §291.29.

Dear Ms. Holloway:

The Texas Pharmacy Business Council (TPBC) is the legislative advocacy arm of American Pharmacies, the largest buying group of independent pharmacists in Texas. TPBC represents the largest coalition of independent pharmacists in Texas in the legislative and regulatory advocacy arena. TPBC's mission is ensuring that Texas patients receive access to quality pharmacy services and ensuring the economic viability and success of the community pharmacy profession.

On behalf of TPBC, I am submitting the following comments on the Board's proposed amendments to 22 Tex. Admin. Code §291.29. TPBC recognizes the proposed regulations are meant to address concerns over the over-prescribing and improper dispensing of controlled substances.

TPBC shares the Board's concerns and believes that pharmacies should be partners with the Board and other state and federal regulators and law enforcement officials in doing what they can to alleviate these practices.

However, TPBC is concerned that the proposed regulations (1) create vague and unachievable standards; (2) place a great and difficult to achieve burden on pharmacists and pharmacies to assess the patient's condition and the prescriber's intentions; (3) require the pharmacist and pharmacy to assess a prescriber's prescribing history even among patients that are not customers of the pharmacy; and (4) the documentation of consideration of the red flag factors creates a significant burden in staff time and recordkeeping.

Proposed 291.29(f) applies to all prescription drugs, not just controlled substances. requires the pharmacy to document the consideration of 24 separate factors for every prescription that is dispensed by the pharmacy. Even if 291.29(f) were to be revised to be limited only to the dispensing of controlled substances or opioids, it would still constitute an enormous economic burden in staffing and recordkeeping to comply with these provisions, even for pharmacies with no red flags present. TPBC suggests removing the documentation requirement, limiting it to a documentation requirement only when more than x number of red flag factors are present and/or limiting the entire requirement only to the dispensing of controlled substances.

Proposed 291.29(f)(1) creates a red flag for the dispensing by the pharmacy of a “reasonably discernible pattern of prescriptions for the same drugs for numerous persons, indicating a lack of individual drug therapy in prescriptions issued by the practitioner.” Again, this red flag applies to all prescriptions, not just those for controlled substances. Pharmacies near specialists will likely have prescribing patterns that are uniform and tied to their specialty (antibiotics for pharmacies near pediatric practices). This regulation should be limited to controlled substances. In addition, “reasonably discernible pattern” is a vague standard that fails to provide the pharmacy with guidance as to how many prescriptions are sufficient to constitute a reasonably discernible pattern for a particular prescriber. TPBC suggests a more concrete standard that establishes a threshold number of scripts for a prescriber over a threshold period of time (e.g., filling x scripts within the past y months).

With respect to proposed 291.29(f)(3), TPBC suggests a concrete standard of a threshold number of scripts for a prescriber over a threshold period of time. Also, TPBC suggests including the word “only” between “routinely” and “for”.

With respect to proposed 291.29(f)(4), TPBC suggests that any regulation of the requirements in the form of the script be modified in section 22 TAC 315.3 or the form of the prescription for controlled substances such that the prescriber is directed to indicate the diagnosis and provide a sufficient level of specificity as to the diagnosis.

With respect to proposed 291.29(f)(4), TPBC suggests that this be modified to include a minimum threshold number and date range of prescriptions to constitute a sufficient sample on which to assess how common the practice is. In addition, TPBC suggests including the words “by the prescriber for prescriptions filled at the pharmacy” between “prescriptions” and “for controlled substances” to ensure it is clear that the assessment is based on the commonality of a particular prescriber’s prescriptions and only those filled at the pharmacy in question.

With respect to proposed 291.29(f)(6), again TPBC suggests a threshold number and date range of prescriptions to constitute a sufficient sample on which to make an assessment. TPBC also suggests adding the phrase “by the prescriber for prescriptions filled at the pharmacy” between “added and “to”.

With respect to proposed 291.29(f)(7), TPBC is concerned that this standard is dangerously vague, especially where prescriber’s signature is typically in cursive while the other handwriting is typically in print. To the extent that the regulation intends to have the pharmacy pull prior prescriptions by the same prescriber to compare handwriting samples, again, this creates an enormous burden on the pharmacy in terms of time and resources, especially where there is no suspicion of forgery.

With respect to proposed 291.29(f)(8), TPBC is concerned that this standard is dangerously vague. The regulation fails to describe what might constitute a comprehensive discussion versus a non-comprehensive discussion with the prescriber or how to assess the concern of the prescriber. TPBC suggests this factor be removed. TPBC is also concerned that this factor is not limited to controlled substances but places this requirement on every prescription.

With respect to proposed 291.29(f)(9), TPBC is concerned that this standard is dangerously vague. The proposed regulation fails to specify a specific standard for establishing the validity of a prescription. Again, TPBC is also concerned that this factor is not limited to controlled substances but places this requirement on every prescription.

With respect to proposed 291.29(f)(10), TPBC is concerned that this factor raises a concern over “routine” prescribing practices but fails to state what quantity over what period of time might be considered routine.

With respect to proposed 291.29(f)(12), TPBC is concerned that this factor will be difficult and time consuming for the pharmacy to verify the disciplinary history and criminal history of the prescriber. The regulation is also not limited to a disciplinary or criminal history associated with controlled substances. TPBC believes the factor should be removed or modified because, as drafted, the regulation itself applies to all prescriptions, not just those for controlled substances.

With respect to proposed 291.29(f)(14), TPBC is concerned that this factor is dangerously vague in failing to describe how far a “significant distance” is from the pharmacy or prescriber. TPBC suggests a more concrete definition of a distance that would be considered a red flag. TPBC believes the factor should be removed or modified because, as drafted, the regulation itself applies to all prescriptions, not just those for controlled substances.

With respect to proposed 291.29(f)(15), TPBC believes this factor should be limited to controlled substance prescriptions and not all prescriptions as currently drafted.

With respect to proposed 291.29(f)(16), TPBC believes this factor should be limited to controlled substance prescriptions and not all prescriptions as currently drafted.

With respect to proposed 291.29(f)(17), TPBC believes that this factor creates a dangerously vague and subjective standard. However, TPBC does not object to the specific examples of persons arriving in the same vehicle with prescriptions from same practitioner, one person seeking to pick up prescriptions for multiple others and drugs referenced by street names as sufficiently clearly stated.

With respect to proposed 291.29(f)(23), TPBC believes that this factor improperly stigmatizes pharmacies employing prudent practices such as hiring security personnel to secure the pharmacy and its inventory.

TPBC’s concern is raised further by the fact that violation of these standards could lead to Board disciplinary action, including a permanent public record associated with the disciplinary action.

TPBC urges the Board to accept additional input from pharmacy interest groups and, if the Board deems appropriate, a formal or informal meeting to discuss pharmacy best practices to deal with the very significant opioid epidemic facing our state and country.

I welcome the opportunity to visit with you, the Board and its staff to discuss these important issues.

Please do not hesitate to contact me if you need additional information or clarification.

Yours truly,

A handwritten signature in cursive script that reads "Michael J. Wright". The signature is written in black ink and is positioned above the typed name and title.

Michael Wright  
Executive Director  
Texas Pharmacy Business Council



Physicians Caring for Texans



July 27, 2018

Megan G. Holloway  
Assistant General Counsel  
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**Via email to [Megan.Holloway@pharmacy.texas.gov](mailto:Megan.Holloway@pharmacy.texas.gov)**

*Re: Comments on Proposed Rule 22 TAC §291.29*

Dear Ms. Holloway:

The Texas Medical Association (TMA), the Texas Pain Society (TPS), and the Texas Orthopaedic Association (TOA) (collectively the “Medical Associations”) write to provide comments on the rules proposed by the Texas State Board of Pharmacy (TSBP), as published in the Texas Register on June 29, 2018 (43 TexReg 4298). TMA is a private, voluntary, nonprofit association founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health and represents over 51,000 Texas physicians and medical residents and students. TPS is a non-profit organization of over 350 pain practitioners that are involved in acute and chronic pain management of patients in Texas. TPS’s mission is to improve the quality of life of Texans who suffer from pain. TOA is a voluntary organization founded in 1936 that represents over 1,400 orthopaedic surgeons. TOA’s mission is to ensure outstanding musculoskeletal care for Texans.

There are some parts of §291.29 that need to be updated that TSBP does not propose amending,<sup>1</sup> but the Medical Associations provide comment particularly on proposed §291.29(f), in which the TSBP seeks to clarify “red flag factors” that a pharmacist is to consider when dispensing prescription drugs to judge whether the prescription is legitimate. The Medical Associations recognize the important role that pharmacists play in ensuring that prescriptions are not fraudulent and forged, and further recognize that providing a list of considerations for pharmacists may be helpful in this effort. In fact, physicians and pharmacists should have a

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<sup>1</sup> See §291.29(b)(3), relating to the circumstances under which there is no need for a physician-patient relationship. TSBP makes no proposed amendment to this section, but this section does not reflect the current exceptions under Texas Medical Board rule. Specifically, while the TSBP rule states that there is no need for a professional relationship with a patient for a patient’s family members if the patient has an illness that has been determined to be pandemic, the Texas Medical Board rule in 22 TAC §190.8(1)(L)(ii) as amended in 2016 provides for a much broader exception.

shared responsibility based on collaboration and communication in curbing drug abuse and diversion.<sup>2</sup>

Though the Medical Associations recognize that these red flag factors have a noble and necessary intention, the Medical Associations nevertheless have concerns with how some of these factors are articulated. Essentially, as explained in greater detail below, the Medical Associations are concerned that the proposed rules undermine the shared responsibility between physicians and pharmacists and also that the rules are drafted vaguely so that they may cause pharmacists to erroneously reject legitimate prescriptions. As a result, the Medical Associations encourage the TSBP to:

1. withdraw the proposed rules and convene a stakeholder group<sup>3</sup> composed of prescribers and pharmacists to jointly discuss how to address these issues; or
2. alternatively, amend the proposed rules to remove vagueness from the factors and to be clearer regarding the intent of the listed factors.

The Medical Associations' first main concern is that the proposed rules undermine cooperation between prescribers and pharmacists in fulfilling a shared responsibility to curb drug abuse and diversion. The Medical Associations note that many of the red flag factors listed in the proposed rules involve the pharmacist's scrutiny of the prescriber or the prescriber's clinic. As already noted, pharmacists and prescribers have a *shared* responsibility for eliminating drug abuse and diversion and should be working together in cooperation, but emphasizing too strongly a pharmacist's scrutiny of the prescriber may sow distrust and discord between the two professionals. To be fair, some factors that relate to the prescriber do appropriately capture an indication of a fraudulent prescription, such as if the physician has had the physician's DEA registration revoked or suspended. But other factors that encourage probing the physician's prescription patterns may not be as enlightening as they would undermine the shared responsibility between pharmacists and prescribers.<sup>4</sup> One factor that is particularly puzzling is that found in proposed 291.29(f)(9), which indicates that a pharmacist should not be able to rely on a physician's representation that a prescription is legitimate. This factor is vague and seems to suggest that physicians and other prescribers cannot or should not ever be trusted.

As an example of what could foster and demonstrate a more proper and cooperative relationship, the National Association of Boards of Pharmacy released a consensus document that represents collaboration between pharmacy and physician stakeholder groups to address challenges each group faces with respect to the issue of prescription drug abuse.<sup>5</sup> The document further lists "red flag warning signs" for each group—pharmacists *and* prescribers—to consider. Rather than

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<sup>2</sup> See e.g., 21 C.F.R. §1306.04(a): "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

<sup>3</sup> In addition to soliciting comments in response to proposed rules, many other state agencies, including the Texas Medical Board, the Texas Board of Chiropractic Examiners, and the Texas State Board of Examiners of Psychology, conduct stakeholder meetings in the pre-proposal rulemaking process in order to get early feedback and avoid proposing rules that have significant problems.

<sup>4</sup> See e.g. proposed §291.29(f)(1), (3), (5), (6), (8), (9), (10), (11), and (12).

<sup>5</sup> National Association of Boards of Pharmacy, "Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances," <https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf>.



having pharmacists scrutinize prescribing physicians, their clinics, and prescription patterns, the red flag warning signs for pharmacists focus on how the prescription is presented and on the *patient's* behavior. This document could provide the TSBP with ways of refocusing pharmacists' attention in a constructive way that can invite cooperation with prescribers and the collaboration between national prescriber and pharmacy groups evidenced by this document could be a model for collaboration that could take place on a state level. The Medical Associations thus reiterate their recommendation for a stakeholder meeting where representatives from both groups of professionals can collaborate to come up with solutions that can work without imposing undue burdens on prescribers or patients.

The Medical Associations' second main concern is that some of the red flag factors in the proposed rule are not thoughtfully articulated and could actually have a negative impact. Overly broad red flag factors impose heavier administrative burdens on prescribers without yielding helpful results and, more importantly, could cause pharmacists to erroneously label legitimate prescriptions as possibly forged or fraudulent. All of this means depriving patients of medication when they have a genuine need.

The Medical Associations thus encourage TSBP to ensure that the red flag factors are carefully tailored to mitigate the possible negative effects the rules may have on patients' ability to have legitimate prescriptions filled.

The Medical Associations' concerns are most evident in the following red flag factors listed in the proposed rule. As demonstrated here, most of the factors raise concern, which highlights the need to pause the progression of the rule proposal in order to gather further stakeholder input.

1. Subdivision (1): This red flag factor requires pharmacists to consider whether there exists a pattern of prescriptions for the same drugs for numerous persons. There could be, however, very legitimate reasons for which a physician consistently prescribes the same drugs to several patients. Specialists or even subspecialists, for instance, may frequently treat patients with the same or similar conditions. Further, national treatment guidelines or insurance step therapy protocols may even *require* consistently prescribing the same drugs for numerous persons. The Medical Associations assert that the existence of such patterns is itself not a sufficient indication of the physician's lack of individual drug therapy. Instead, the pharmacist could consider this pattern if there is some other, independent indication of a lack of tailored or individualized drug therapy.
2. Subdivisions (3) and (5): These factors relate to regular prescriptions for commonly abused drugs and high-strength drugs. These are important considerations, especially in light of the national opioid epidemic that is currently hanging over the nation. The Medical Associations reiterate their support of pharmacists' role in curbing this epidemic. Criteria like these are certainly relevant, but the existence of these criteria should not necessarily be dispositive because there are numerous legitimate reasons for prescribing high-strength drugs and controlled substances (which are controlled *because* of their potential for abuse). There are, for example, a significant number of chronic conditions that cause severe episodic pain that require high dose narcotics. Sickle cell patients will episodically suffer a sickling crisis, which causes tremendous pain and requires a strong prescription to treat the pain. As another example, orthopedic surgeons frequently and

perhaps even routinely prescribe opioids for acute pain, and may also prescribe the highest strength of a drug. The Medical Associations thus encourage the TSBP to amend the rules to ensure that pharmacists consider the totality of circumstances to avoid depriving patients in acute pain or in other legitimate circumstances of needed medication.

3. Subdivision (4): This factor requires a pharmacist to consider whether a prescription for a controlled substance has nonspecific or no diagnoses, but this factor is vague and does not reflect current prescription practices. There is no requirement for physicians to include diagnoses on prescriptions and further, some electronic medical records do not even have a field for indication of the applicable international classification of disease codes. This factor should thus be removed or significantly modified to come in line with current prescription practices.
4. Subdivision (6): This red flag factor, considering whether dangerous drugs or other over-the-counter prescriptions are consistently added to controlled substance prescriptions, is also vague and does not reflect reality. There are many legitimate reasons for which a physician might prescribe other dangerous drugs while prescribing a controlled substance. Laxatives, for instance, are commonly prescribed with opioids because opioids cause constipation. The Medical Associations thus encourage TSBP to remove this factor or modify it so that it does not flag legitimate prescriptions.
5. Subdivision (8): This factor would require physicians to “engage in a comprehensive discussion” with the pharmacist and to “demonstrate concern regarding the pharmacist’s apprehension” regarding the physician’s prescriptions. This is troublesome for several reasons. This factor establishes subjective standards for a conversation and for a level of concern of the physician. It also would impose a significant administrative burden on physicians, who would have to pull files for each patient of concern and explain the treatment goals and the prognosis to the pharmacist. And for some physicians, like surgeons, who may be occupied in a procedure for a number of hours and are thus unable to immediately respond to a pharmacist’s inquiry, consideration of this factor could delay a patient from receiving their needed medication. Additionally, such a conversation would be out of the scope of practice of a pharmacist. The Medical Associations encourage TSBP to remove this factor or modify it to address these concerns.
6. Subdivision (9): As noted above, this factor seems to indicate that prescribers should not ever be trusted. While a pharmacist should at least exercise professional judgment when “taking a prescriber’s word for it” that a prescription is legitimate, this factor as proposed invites pharmacists to overstep their authority and override a physician’s prescription, even when a physician can affirm the legitimacy of it. This factor must be made clearer as to what the pharmacist should consider, without undermining what should be a cooperative relationship between physician and pharmacist.
7. Subdivision (10): This factor promotes consideration of whether a clinic should actually be certified as a pain management clinic because of routine prescriptions for opioids and other drugs. First, this factor misstates the standards for pain management clinics, which must be certified as such by the Texas Medical Board only if a *majority* of patients are issued prescriptions for opioids, benzodiazepines, barbiturates, or carisoprodol. Further, it is possible for a clinic to be “routinely” prescribing opioids and these other drugs without reaching the threshold required for pain management clinic certification. The Medical Associations suggest that this criterion be removed.

8. Subdivision (11): Under this red flag factor, a pharmacist would question the physician's specialty or area of medical practice. It is unclear how this is within the scope of a pharmacist's education and expertise to make a judgement as to whether a physician of a particular specialty should or should not issue a particular prescription. Again, this undermines the collaboration that should exist between pharmacists and physicians and should be removed or modified.
9. Subdivision (12): This red flag factor appears to encourage a pharmacist to consider whether the practitioner has been subject to disciplinary action by the appropriate licensing board, but without consideration of whether that disciplinary action had any relation to the practitioner's prescribing practices. As proposed, this factor is overly broad. Physicians and other practitioners can be disciplined for any number of things—for even minor violations such as administrative or technical mistakes. A more relevant consideration would be whether the practitioner has been disciplined for actions specifically relating to inappropriate prescribing. The Medical Associations encourage the TSBP to further clarify this factor accordingly.
10. Subdivision (14): This red flag factor would have pharmacists consider whether a patient travelled a "significant" distance to a physician's office. Measurement of a "significant" distance is purely subjective and could also cause a pharmacist to erroneously stop a legitimate prescription. This is because patients may often travel "significant" distances to physicians for a variety of legitimate reasons, whether it is because of a positive physician-patient relationship or because the physician practices in a specialty that has more significant access issues. It is also possible that patients get injured while they are traveling out of town and may seek treatment in an area away from home. Consideration of this factor could prevent these patients from receiving needed therapy.

In sum, The Medical Associations understand the TSBP's intent in creating a list of red flag factors for pharmacist consideration, as the pharmacists do have a shared responsibility to ensure that prescriptions are legitimate. But The Medical Associations caution that the rules as proposed could have significant negative effects. These rules could create distrust between physicians and pharmacists when there should be collaboration and cooperation, and the lack of clarity of these rules could also mean more patients with legitimate prescriptions will be denied access to their medication. **The Medical Associations thus urge the TSBP to halt the rule adoption process for these rules to allow for further stakeholder involvement and input**, or to at least make necessary amendments, some of which are detailed in the list of red flag factors above, to mitigate the risks of these negative effects.

Should you have any questions regarding these comments, please contact the representatives of the Medical Associations as respectively listed:

TMA (by phone: 800-880-1300)

Rocky Wilcox, Vice President and General Counsel, rocky.wilcox@texmed.org

Kelly Walla, Associate Vice President and Deputy General Counsel, kelly.walla@texmed.org

Jared Livingston, Assistant General Counsel, jared.livingston@texmed.org

TOA

Bobby Hillert, Executive Director, bhillert@toa.org, 214-728-7672

TPS

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Krista DuRapau, Executive Director, kdurapau@texaspain.org, 512-535-0010

Thank you for your prompt attention to this matter.

Sincerely,



Douglas W. Curran, MD  
President, Texas Medical Association



Andrew J. Palafox, MD  
President, Texas Orthopaedic Association



Richard Hurley, MD  
President, Texas Pain Society



C.M. Schade MD, PhD  
Past President, Texas Pain Society