TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

October 13, 2017

VIA ELECTRONIC MAIL to Rita.Chapin@tmb.state.tx.us

Ms. Rita Chapin
333 Guadalupe Street No. 3
Austin, Texas 78701

Re: Comments on proposed new 22 Tex. Admin. Code §§174.1-174.8, §174.9, §178.3, and §190.8 as published in the Texas Register on September 15, 2017 (42 TexReg 4755-4766)

Dear Ms. Chapin,

On behalf of over 50,000 members, the Texas Medical Association (TMA) expresses its appreciation for the opportunity to provide comment on recently proposed rules by the Texas Medical Board (TMB). TMA is a private, voluntary, non-profit association of Texas physicians and medical students and was founded in 1853 to serve the people of Texas in matters of medical care, prevention and cure of disease, and improvement of public health. Today, its mission is to "Improve the health of all Texans."

TMA submits these comments on proposed rules concerning telemedicine, mental health services, information on complaints, and disciplinary guidelines (i.e., proposed 22 TAC §§174.1-174.8, §174.9, §178.3, and §190.8). TMA has previously submitted comments on drafts of these proposed rules, and the proposed rules published in the Texas Register appear to have no differences from the most recent drafts circulated among stakeholders. Accordingly, TMA reiterates its previous comments and encourages the TMB to follow the comments outlined in that letter in addition to the comments offered here. A copy of those comments is attached to this letter and incorporated by reference.

Once again, TMA notes that the Association was a major proponent of Senate Bill 1107. TMA believes this legislation will provide greater opportunities for physicians who want to provide patients with another option for accessing medical care. While TMA generally supports reducing the regulatory footprint on providing medical services through telemedicine (as appears to be a goal of the TMB's rule proposal), TMA still expresses concern, however, over some aspects of the proposed rules implementing Senate Bill 1107. As it expressed in its previous letter, TMA is concerned that the proposed rules may not be sufficient to implement Senate Bill 1107 and to ensure that patients using telemedicine medical services receive appropriate, quality care.

TMA also expresses general concern that the rules are not sufficiently reader-friendly. As interest in telemedicine continues to grow, many physicians may be turning to the TMB rules in order to understand what is required of physicians who provide services through telemedicine. Rather than adopting rules that could provide a comprehensive explanation of applicable laws and regulations and could thus aid in compliance, the TMB here proposes rules that do not fully implement and

interpret the law, and instead provide bits and pieces of applicable laws and regulations. TMA is concerned that this approach to rulemaking may actually hinder, rather than aid, compliance, forcing readers to flip between laws and rules in order to piece together what is expected. Indeed, TMA notes several proposed rules, as explained in greater detail below, that could cause confusion because of incompleteness, redundancy, or lack of clarity.

TMA offers the comments below, in order of the rules as published in the Texas Register, to explain in greater detail its support of and concerns with the proposed rules.

I. SUBCHAPTER A, CHAPTER 174: TELEMEDICINE (22 TAC §§174.1-174.8)

1. **Proposed §174.1. Purpose.**

a. The Stated Purpose of the Proposed Rules Should More Closely Track the Administrative Procedure Act's Definition of a "Rule."

The proposed rules in §174.1 establish a purpose for 22 Tex. Admin. Code Chapter 174 on telemedicine, which is that the rules "clarify the requirements in Chapter 111 of the Texas Occupations Code related to the provision of telemedicine medical services." TMA suggests that the purpose of these rules is not actually to *clarify* statute, but should be to *implement* or *interpret* Chapter 111 of the Texas Occupations Code.

In fact, Texas law defines an agency rule as a "statement of general applicability that: (i) *implements, interprets, or prescribes law or policy*; or (ii) describes the procedure or practice requirements of a state agency." §2001.003, Tex. Govt. Code (emphasis added). TMA suggests that if TMB recognized the rules' purpose to implement or interpret state law on telemedicine—rather than just to clarify what the TMB believes needs to be clarified—that the rules might provide a more comprehensive framework for telemedicine as S.B. 1107 seems to have envisioned. If the rules simply *clarify* the applicable law on telemedicine, it suggests that the statute is not clear itself and may yield a regulatory framework in which readers may be left piecing together provisions from the Texas Occupations Code and TMB rules in order to understand the applicable regulations for telemedicine.

TMA thus recommends that these rules more closely follow the statutory guidance for agency rules and amend the first sentence of proposed §174.1(b) as follows (with changes in bold font):

> (b) This chapter is promulgated to **implement and interpret** the requirements of Chapter 111 of the Texas Occupations Code related to the provision of telemedicine medical services.

b. The Proposed Rules Needlessly Exempt Certain Individuals from the Application of Telemedicine Regulations.

§174.1 also exempts from the application of Chapter 174 certain individuals and entities. TMA previously questioned the basis for the exclusion of FQHCs and health insurance help lines (see attached letter, p.9). TMA incorporates these comments by reference, and further suggests that out-of-state telemedicine licensees, which the proposed rule would also exempt, should be subject to these rules.

Out-of-state telemedicine licensees are authorized by TMB rule to provide "follow-up of patients where the majority of patient care was rendered in another state." 22 TAC §172.12(c). Follow-up care could hypothetically include the issuance of prescriptions, for example, and S.B.1107 and these

proposed rules both lay out important guidelines relating to issuing prescriptions remotely through telemedicine. Exempting out-of-state telemedicine licensees from the application of these regulations, at best, creates an inconsistent framework and at worst, means that out-of-state telemedicine licensees are not subject to important regulations that promote patient safety for telemedicine-based prescriptions.

Finally, out-of-state telemedicine licensees are *already* subject to all other statutes and laws, so exempting them here contradicts other TMB rules. In 22 TAC §172.12(c), TMB regulations provide that out-of-state telemedicine licensees "shall practice medicine in a manner so as to comply with all other statutes and laws governing the practice of medicine in the state of Texas," and that would certainly include recently enacted telemedicine laws.

Based on the comments here and in the previous comments in the attached letter, TMA thus recommends removing the applicability exemptions for clarity.

2. Proposed §174.2. Definitions.

a. *The Definition of "Prescription" Contains Regulations that Should Not be in a Definition and Only Partially Restates Applicable Law in a Way That Causes Confusion*.

The definition of "Prescription" in proposed §174.2(1) states that if a prescription for a controlled substance is issued by a licensed physician, "the physician must have a current valid DEA registration number," and if issued by another practitioner acting under proper delegation, the "practitioner must have a current, valid DEA registration," and additionally, if the controlled substance is listed on Schedule II, the practitioner must "use the official prescription forms" with certain required information. TMA expresses two concerns regarding this section.

i. §174.2(1) Does Not Really *Define* What a "Prescription" Is.

The first concern is that the conditions and requirements in the proposed definition, including Paragraph (C) that states that e-scripts are allowed as permitted by state and federal law, do not really *define* or *describe* what a prescription is. Instead, these conditions establish *requirements for* prescriptions through telemedicine and how the TMB will regulate these prescriptions.

This creates two problems. First, when readers look for regulations relating to prescriptions through telemedicine, they might look to a section of rule with a heading that might be relevant (as opposed to a definition). In this subchapter, §174.5 "Issuance of Prescriptions" might seem to be the best place to go to understand regulations on prescriptions. A reader might not think to look for prescription *regulations* in the *definitions* section because it is already a commonly understood word or principle—so much so, that in statute and rule, "prescription" is often left undefined. *See e.g.*, §§164.053(a) and 168.002, Tex. Occ. Code; 22 TAC Ch. 169.[1] So to make these regulations more user-friendly, TMA recommends that any *regulations* relating to prescriptions through telemedicine reside somewhere besides a definition section, which is probably most fittingly in §174.5, where readers would most likely expect to find regulations on prescriptions.

The second problem with inserting conditions and regulations in a *definition* is that it changes the technical meaning of the word. For example, the proposed rules suggest that to be a "prescription" in

[1] TMA notes that when "prescription drug" *is* defined, it is just that: a definition. For example, 22 TAC §193.2 defines "prescription drug" by describing the meaning of "prescription drug" rather than inserting regulations on prescription drugs.

Chapter 174, it must be issued by a Texas licensed physician. Does that mean that if what is typically understood to be a prescription is not a "prescription" under the rules if it is issued by an out-of-state physician? Or if a physician does not have a current valid DEA registration number, as the proposed rules require, does that mean that a prescription for a controlled substance it is not a "prescription" under the rules? Technically, since the proposed rules define "prescription" to require these conditions, these examples would not be a "prescription" under the proposed rules and could leave gaps in enforcement. Thus, to ensure clarity in the rules, TMA again recommends keeping these conditions and regulations to §174.5, and if the TMB must provide a definition for "prescription" in §174.2, TMA recommends a definition like that found in 22 TAC §193.2.

ii. <u>The Partial Restatement of Applicable Law in Proposed §174.2(1) Could Create Confusion.</u>

TMA's second concern with the definition of "prescription" is that it contains partial restatements of applicable law that could cause confusion. The requirements to have a valid DEA registration number, to use official prescription forms, and others in the proposed definition are restatements of existing law. *See e.g.*, 21 USC §801 et seq., §§481.061, 481.074-076, Tex. Health & Safety Code. The trouble, though, is that they are *incomplete* restatements of law. By stating only, for example, that "if the prescription is for a controlled substance, the physician must have a current valid DEA registration number," without any reference to the additional applicable laws and requirements that apply to prescribing controlled substances, the rules erroneously suggest the law requires nothing else. TMA recognizes that partially restating law could be useful, though, if it is to highlight a particular legal requirement, as long as it is clear that what is highlighted does not represent the totality of applicable law. But that is not what the proposed rules do. Without a more clear guidance for readers, the regulations have limited utility as a resource for readers to understand the applicable regulatory framework. Instead, a restatements of applicable law in fragments arguably does more harm than good.

Also, if the TMB recognizes TMA's first concern with the proposed "prescription" definition and keeps these requirements in proposed §174.5, the TMB would note that §174.5(c) *already* has a general notice that a prescription issued through telemedicine must "meet all other applicable laws." Therefore, the partial restatements of law in the definition are redundant as well as potentially confusing when placed in the definition.

To conclude TMA's concern with the §174.2(1), TMA recommends eliminating substantive regulations from the definition of "prescription" and if a definition is required, defining the term in a way that is similar to other TMB regulations.

Further, TMA recommends avoiding partial restatements of law without further clarification. TMA recommends that the proposed rules include a general notice of applicability of other law as found in §174.5(c)(2), and if the rules mention any particular legal requirement to highlight the requirement, it could do so in a way that makes it clear that applicable rules *include* the mentioned or highlighted requirement, and the requirement does not represent all applicable law. For instance, if the proposed rules must reference a valid DEA registration number, the rule could state that a prescription issued through telemedicine must "meet all applicable state and federal laws and regulations, including that the physician use a current, valid DEA registration number."

Finally, TMA does note that the clarification in 174.2(1)(C) that e-scripts are allowable to the extent permitted by state and federal law is helpful, but recommends that clarification not be buried in a definition section.

b. *The Definition of "Prescription" Highlights the Need to Clarify Any Distinctions between "Practitioner," "Physician," and "Provider" in the Rule.*

In TMA's previous comments, TMA noted the inconsistent use of "practitioner," "physician," and "health professional." The importance of consistent use of these terms is highlighted in proposed §174.2(1), where the definition of "prescription" draws a distinction between a "licensed physician" in Paragraph (A) and "licensed practitioner" in Paragraph (B). This distinction may cause confusion for several reasons.

First, using a general term like "practitioner," a term that is not defined, does not clarify exactly which professionals are included in the application of the term. Rather than use a general term, the proposed rules would be clearer if they simply identified a physician assistant or an advanced practice registered nurse as being the appropriate "practitioners" because it would leave no question as to the professionals included in the application of the rules.

Further, this distinctive term used here causes problems elsewhere in the rules where "practitioner" may be intended to include "physician" as well. In proposed §174.5, for example, the proposed regulations apply only to "licensed practitioners." While in proposed §174.2, "practitioner" may not have included a physician, does the term include a physician in proposed §174.5? Because of the distinction made in this section, the rules could create more confusion later when the same distinction does not seem to be made.

TMA notes this distinction to emphasize the importance of using consistent terms throughout the rest of Chapter 174. TMA recommends clarifying exactly which professions are meant to be a "practitioner" in proposed §174.2, and recommends clarifying other uses of "practitioner" and other general terms as outlined below.

c. *The TMB Should Eliminate Unnecessary Definitions from the Proposed Rules.*

The rules in proposed §174.2(2) and (3) define the terms "store and forward technology" and "telehealth services"—terms that are defined in S.B. 1107 but do not appear elsewhere in 22 TAC Chapter 174. These definitions are unnecessary and TMA recommends deleting them.

3. Proposed §174.3. Prevention of Fraud and Abuse: TMB Needs to More Clearly Identify Applicable Standards

TMA previously raised concern with the provisions of proposed §174.3 relating to fraud and abuse standards. (See attachment, p. 9). TMA incorporates those previous comments by reference and reiterates that the TMB should clarify the "good faith effort" requirements stated in this provision. TMA further reiterates that the rules should also clarify exactly which standards a physician is required to follow, because the standards that proposed §174.3 cites either do not exist or, if they do exist, seem to be unfindable.

4. **Proposed §174.5. Issuance of Prescriptions**.

a. *The TMB Should Clarify the Meaning of the Provision that States the Rule Does Not Limit Professional Judgment.*

The first sentence of §174.5(b) states that the "rule does not limit the professional judgment, discretion or decision-making authority of a licensed practitioner." It is not clear what exactly is meant by this. Does this mean that anything in the rule will not limit the professional judgment of a physician—even the standard of care?

The next sentence in this proposed rule states that physicians are "expected to meet the standard of care," but is this not a limitation on professional judgment? While one would hope that one's professional judgment always meets the standard of care, it may not always be the case. Thus, it is not clear what the proposed rule means when it says that this rule will not limit professional judgment, discretion, or decision-making.

TMA understands that the TMB cannot spell out every specific circumstance when prescriptions are or are not appropriate to issue through telemedicine. And if the TMB is trying to say that—that it is not going to spell out concrete circumstances for appropriate telemedicine prescribing—then perhaps there is a clearer way to say it. But this provision of the proposed rules only adds confusion.

TMA recommends eliminating that sentence entirely. TMA believes the subsequent sentence—requiring physicians to comply with the standard of care—speaks for itself.

b. *The Applicable Standard of Care Should Be Clarified.*

Proposed §174.5(b) states that practitioners are "expected to meet the standard of care and demonstrate professional practice standards and judgment." This is the first of three *different* articulations of the standard of care that the TMB states in these rules—other articulations are in proposed §174.6(a)(1) (which actually properly recites that statutory clarification of the standard of care) and proposed §174.9(4) (which, as explained below, confusingly slightly changes the applicable standard of care).

Here, the proposed rules do not explain the standard of care. Generally, the standard of care is what a reasonable and prudent physician would do in the same or similar circumstances. Without clarifying here that the standard of care that applies is that which applies in an in-person setting, the proposed rules deviate from the standard articulated in S.B. 1107. Further, the proposed rules add the requirement to "demonstrate professional practice standards and judgment." What does this mean if it does not mean to comply with the standard of care?

TMA thus recommends amending proposed §174.5(b) to state that physicians "are subject to the same standard of care that would apply to the provision of the same health care service or procedures in an in-person setting and is subject to all applicable statutes and rules, when issuing, dispensing, delivering, or administering a prescription medication as a result of a telemedicine medical service."

c. *The Rules Should Refer to Physicians Instead of Practitioners*

In its comments above on proposed §174.2, TMA cited proposed §174.5 as an example that illustrates confusion that can result from what seems to be inconsistent use of terms to refer to a physician. In

§174.5(b) and (c), it is not clear whether the "practitioners" includes physicians because of the distinction made in §174.2(1) between "licensed practitioners" and "licensed physicians."

S.B. 1107 refers to a "practitioner-patient relationship" because it is a term of art and that particular relationship is, according to state law, a prerequisite to a valid prescription.[2] The scope of S.B. 1107 and of existing state law contemplates more than just physicians and the use of the broader "practitioner" is appropriate in that context. Here, however, physicians expect to turn to TMB rules to find regulations relating to *physicians*. Instead, the proposed rules contain regulations relating to "practitioners," "providers,"[3] and "health professionals,"[4] without defining any of these terms. Simply for the purpose of aiding physicians in understanding and complying with TMB rules, TMA recommends that the proposed rules make this clarification by changing "practitioner" to "physician" in this section.

d. *Proposed §174.5(c) and (d) Could be Simplified*

Proposed §174.5(c)(2) and (d) appear to say the same thing—that prescriptions issued through telemedicine are subject to all other applicable laws. Subsection (d) is more specific in that it mentions specific provisions of law, but TMA believes it ultimately conveys the same message as that conveyed in Subsection (c). TMA suggests consolidating these provisions to make the regulations simpler and to avoid the implication that the two provisions mean something different.

5. **The Repeal of Current §174.5 and the Possible Vagueness of Proposed §174.6.**

TMA previously noted that by repealing the text of current §174.5, the TMB eliminates guidelines that are especially helpful for circumstances that do not result in a prescription—a circumstance that S.B. 1107 only lightly touches.

As noted in TMA's previous comments, the TMB now proposes broad guidelines in proposed §174.6 that do not explain the minimum for establishing a physician-patient relationship and rely on the requirement to comply with an in-person standard of care. While this does allow flexibility for physicians, but, as TMA previously cautioned, it could also result in both under- and over-enforcement. The attached letter (p. 2-5) discusses this issue in greater detail and is incorporated here by reference.

6. **Proposed §174.6. Minimum Standards for the Provision of Telemedicine Medical Services: "health professional" should be replaced with "physician."**

TMA reiterates its previous comments about consistency with respect to terms referring to physicians. In proposed §174.6(a), the language uses "health professional" and "practitioner" rather than physician. The TMA against urges the TMB to consistently use terminology to avoid confusion in the rules.

The rules also state that a "health professional" must establish a "practitioner-patient relationship." TMA again reiterates the importance of describing what is required to actually "establish" the relationship if it is required for providing a telemedicine medical service. S.B. 1107 provided some guidance on establishing that relationship for the purposes of identifying a valid prescription, but in

[2] *See* §562.056, Tex. Occ. Code.
[3] *See* Proposed 22 TAC §174.9.
[4] *See* Proposed 22 TAC §174.6.

proposed §174.6, the rule is not specific to prescriptions. There is thus no guidance on the requirements for the establishment of a "practitioner-patient" relationship.

7. **Proposed §174.7. Enforcement Authority: A Typo and Reiteration for Consistent Terminology.**

In the last sentence of §174.7, in the phrase "authority of the practitioner proving telemedicine medical services," "proving" should be changed to "providing."

Also, TMA again notes the use of the term "practitioner" in this section and encourages the TMB to ensure the meaning of these terms and the applicability of the rule are clear by being consistent.

8. **Proposed §174.8. State Licensure.**

TMA reiterates its previously submitted comments on proposed §174.8, in which it pointed out that the communications technology used should not have to be "advanced," and that the regulations should apply not to "residents of Texas" but to "patients who are physically present in Texas at the time of the treatment."(See attachment, p. 6-7).

TMA further points out that this proposed rule authorizes an "out-of-state physician" to provide "episodic consultations." The proposed rule does not clarify that the episodic consultations must be "through telemedicine." TMA recommends adding this clarification because "out-of-state physician" could be ambiguous, meaning both a physician who is physically out of the state and a physician who is licensed by another state (but could be physically in Texas). Clarifying that "episodic consultations" must be "through telemedicine" prevents physicians who have out-of-state licenses but are physically in Texas from practicing medicine in a manner not intended by the legislature and the TMB.

Finally, in the publication of these proposed rules, what is currently §174.8(a) has brackets around at the beginning and end of the subsection, but the text is not struck. TMA wishes to confirm that this text will indeed be struck.

The subject of current §174.8(a) is actually guidelines regarding the minimum requirements for establishing a physician-patient relationship. TMA previously commented on the need to articulate guidelines like these in order to fully implement S.B. 1107 (see attachment, p. 2). TMA reasserts the need for guidelines like those in current §174.8 not only because it would implement S.B. 1107 but also because it provides guidelines for circumstances when a physician does not issue a prescription as a result of a telemedicine encounter—a circumstance for which S.B. 1107 provides only minimal guidance. The attached letter (p.2) discusses this issue in greater detail and is incorporated here by reference.

II. SUBCHAPTER B, CHAPTER 174. MENTAL HEALTH SERVICES

1. **The Subchapter B Heading and the Rest of Subchapter B Should be Changed to Reflect its Application to Mental Health Services Provided through Telemedicine or Telehealth.**

TMA notes that the heading for Subchapter B is "Mental Health Services." TMA recommends that the heading be amended to add "through Telemedicine Medical Services and Telehealth Services." This makes the rules more user-friendly by clearly suggesting to the reader that the subchapter does

not regulate all mental health services but addresses those mental health services provided through telemedicine and telehealth.

The TMB should also add this clarification throughout the subchapter, including in the heading of §174.9.

2. Proposed §174.9. Provision of Mental Health Services.

a. *The Intended Application of the Proposed Rules Is Not Clear.*

As a threshold issue, it is not clear whether proposed §174.9 is intended to regulate physicians or *all providers of mental health services*. TMA notes that the TMB is the primary means of regulating physicians (§151.003, Tex. Occ. Code) and that the TMB may adopt rules to "regulate the practice of medicine in this state." §153.001, Tex. Occ. Code.

Proposed §174.9 does state that mental health services "are the practice of medicine." TMA recognizes that mental health services are within the statutory definition of "practicing medicine" but also that state law exempts certain professions from the applicability of the Medical Practice Act when those professions are engaged strictly in the practice of that profession as defined by law. Thus, it does not seem proper that the TMB has authorization to regulate any profession that provides mental health services.

Yet that is exactly what it seems these proposed rules do. The proposed rules require, for example, individuals providing mental health services to be properly licensed or certified and requires them to comply with the standards of care and keep proper medical records. TMA is concerned that to extent the applicability of these proposed rules is unclear, it makes the rules more difficult for physicians to understand and follow.

TMA recommends amending the opening paragraph of proposed §174.9 to make the application of this section more clear, and also recommends making changes throughout the section to specify the application to physicians. Further, TMA recommends amending the language to state that mental health services "fall within" the practice of medicine (rather than stating that mental health services simply "are" the practice of medicine), to avoid the implication that allied health professionals are actually practicing medicine rather than practicing their respective profession.

b. *Proposed §174.9(1): The Proposed Rules Should Clarify Language Regarding Delegation and Scope of Practice*.

The language in proposed §174.9(1) appears to be copied from existing rules that define a "patient site presenter." *See* 22 TAC §174.2(7)(B). In that context, a physician could delegate tasks to the patient site presenter, so the rules regulate the circumstances in which that delegation was permissible and to whom delegation was allowed. Specifically, the current definition states that the patient site presenter is one "to whom the distant site physician may *delegate* tasks and activities" (emphasis added).

The context of this language in the proposed rules is different: the proposed rules seem to discuss mental health services generally, which is provided by an "individual" who could be a physician, the physician's delegate, or another allied health professional.

The proposed rules have carried current regulations that dealt with a particular circumstance over into circumstances where this is not necessarily any need to have a patient site presenter or delegated duties. But the rules do not account for that. As a result, the proposed rules appear to inappropriately regulate *any* individual who performs mental health services and discuss delegation in a way that may cause confusion.

TMA recommends that the rule regulate only physicians rather than "any individual providing mental health services."

Finally, as TMA recommended for proposed §174.8, TMA recommends making the licensure requirement more specific to Texas by clarifying that physicians must be licensed in Texas when treating patients physically in Texas.

TMA thus recommends amending proposed §174.9(1) to read as follows:

> (1) Licensure Required—A **physician** providing mental health services **through telemedicine** must be properly licensed in this state to perform health care services **when treating patients who are physically present in Texas at the time of the treatment**.

c. *Proposed §174.9(2) and (3): The Proposed Rules Should Again Add Clarity with Respect to "Provider" and the "Provider-Patient Relationship."*

TMA again reiterates the need to use consistent terminology or add clarifying language to more clearly identify the subject of regulations. In §174.9(2) and (3), the proposed rules now refer to a "provider" and discuss a "provider-patient" relationship. "Provider" is not defined, so it is not clear what professionals are included in the application of this regulation. TMA asserts this should be limited to physicians and recommends that the TMB clarify this as it has suggested for other sections of the proposed rules.

Additionally, §174.9(3) states that the provider-patient relationship "can be established through use of telecommunications or information technology." TMA points out that it is not the *use of technology* that establishes the provider-patient relationship, but rather *providing mental health services through the use of technology* that should be available as an option to establish the requisite relationship. Simply using technology with the patient should not establish the required physician-patient relationship. TMA thus recommends that the proposed rule be amended to state that the required relationship "can be established **by providing mental health services to the patient** through use of telecommunications or information technology."

d. Proposed §174.9(4): Clarify the Use of Telemedicine or Telehealth, the In-Person Standard of Care, and Proper Medical Records.

As TMA recommended for the subchapter and section headings, TMA recommends clarifying in §174.9(4) that the rule is regulating providing mental health services *through telemedicine or telehealth*, and not just, as the rule states, "when providing mental health services."

Proposed §174.9(4) goes on to say that "such services must be conducted in the same manner as those in a traditional in-person setting." TMA notes that the articulation of the standard of the care requirement here differs from that which was stated in proposed §174.6, and also notes that the standard articulated in proposed §174.9 may be stricter. The standard here implies that a physician must conduct a visit with a patient through telemedicine *in the exact same way* as the physician would

were the patient seeing the physician in person. The difference in standards may create confusion and may limit the options of some physicians wishing to provide mental health services to patients through telemedicine.

TMA thus recommends copying the standard articulated in proposed §174.6, which provided that a physician "is subject to the same standard of care that would apply to the provision of the same health care service or procedures in an in person setting." Stating the requirement in this way ensures that the TMB is not imposing a higher standard of care and that physicians have the flexibility to provide services remotely while meeting the standard of care.

Finally, TMA notes the different standards for medical records imposed for mental health services provided through telemedicine. Proposed §174.9(4) requires the keeping of "proper medical records." This requirement could be confusing as it could lead to subjective interpretation of what a "proper" medical record is. In proposed §174.6, on the other hand, the proposed rules provide more clarification regarding the medical record requirements, citing the standards set out in 22 TAC §165.1. TMA recommends striking "proper medical records" and replacing it with what is in proposed §174.6(a)(3): "complete and accurate medical records as set out in §165.1 of this title."

e. Proposed §174.6(6): Clarify Any Differences in Permission for the Prescription of Acute Pain.

TMA notes that proposed Subchapter B states in proposed §174.9(6) treating chronic pain with scheduled drugs through use of telecommunications or information technology is prohibited unless otherwise allowed under federal or state law. Proposed §174.5(e)(2), in proposed Subchapter A, also provides the same requirement. But §174.5(e)(2) also provides that treating *acute* pain with scheduled drugs through telemedicine is *allowed*, unless otherwise prohibited. TMA suggests that if this provision appears Subchapter A, it should also appear in Subchapter B. Without including both provisions in Subchapter B, the discrepancy suggests that there is some reason for not including it, such as treating acute pain is actually not permitted as it would be under Subchapter A.

III. CHAPTER 178. COMPLAINTS: TMA REITERATES ITS PREVIOUS COMMENTS CALLING FOR ADDITIONAL CLARITY REGARDING NOTICE PROVISIONS.

TMA has previously submitted concerns regarding the proposed rules in §178.3, stating that the proposed rules impose greater restrictions on posting required notices. TMA reiterates the need for the TMB to address these concerns by amending the proposed rule to include text that TMA submitted with its previous comment letter and that are incorporated here by reference. (See attachment, p. 7-9).

IV. CHAPTER 190. DISCIPLINARY GUIDELINES. SUBCHAPTER B. VIOLATION GUIDELINES: TMA REITERATES ITS PREVIOUS COMMENTS ASSERTING THE NEED FOR GUIDELINES IN PROPOSED §190.8 FOR AT LEAST NON-TELEMEDICINE SETTINGS.

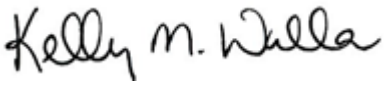
TMA explained in its previous comments on proposed §190.8 that the changes will have a more significant-than-intended impact on non-telemedicine prescription guidelines because that section provides guidelines for both telemedicine and non-telemedicine settings. TMA reasserts its position, incorporated here by reference, that the TMB should more carefully tailor the amendments to proposed §190.8 to ensure there are no unintended consequences. (See attachment, p. 3-4).

I. CONCLUSION

Again, TMA thanks the TMB for this opportunity to comment on proposed telemedicine rules. TMA asserts that the issues raised in this letter are important to successful implementation of S.B. 1107 and to responsible proliferation of telemedicine in Texas. If you have any questions, please do not hesitate to contact Jared Livingston at jared.livingston@texmed.org or at 512-370-1345.

Sincerely,

Donald P. "Rocky" Wilcox



Kelly M. Walla

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Attachment

TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

August 21, 2017

VIA ELECTRONIC MAIL to Rita.Chapin@tmb.state.tx.us

Ms. Rita Chapin
333 Guadalupe Street No. 3
Austin, Texas 78701

Re: Proposed Changes to Title 22, Texas Administrative Code, Chapters 174 and 198 (relating to Telemedicine)

Dear Ms. Chapin,

Thank you for the opportunity to be involved in the stakeholder meeting on July 17, 2017 regarding needed amendments to the Texas Medical Board's (TMB) telemedicine rules in Title 22, Texas Administrative Code, Chapters 174 and 198 in light of the recent enactment of Senate Bill 1107. The Texas Medical Association (TMA) has also received TMB draft revisions to Rule 174 and Rule 178.3 that were prepared subsequent to initial stakeholder input.

TMA wishes to address several additional issues that were not discussed at the stakeholder meeting, as well as to provide comments on the most recent revisions. Generally, TMA supports the direction in which the TMB is taking its rules relating telemedicine. TMA is concerned, however, that the TMB's proposed changes eliminate some regulations that are needed in order to properly effectuate S.B. 1107 and/or to ensure that patients using telemedicine medical services receive appropriate, quality care.

More specifically, S.B. 1107 relies on the TMB to articulate the requirements for a "practitioner-patient relationship," yet the TMB is proposing to repeal all rules that do such. Also, S.B. 1107's scope is mostly limited to telemedicine encounters that result in the issuance of a prescription, but the TMB's proposed changes will affect more than just this type of encounter.

Aside from eliminating certain basic regulations, the revised rules are in need of clarification in other areas, including the inconsistent use of certain terminology and clarification on notice requirements. TMA raises these questions and concerns as outlined in greater detail below.

I. THE REVISED RULES UNNECESSARILY REMOVE CERTAIN REGULATIONS.

1. The TMB Needs Regulations Articulating the Requirements for the Establishment of a Physician-Patient Relationship for Prescribing Purposes.

Section 111.005(a)(1), Tex. Occ. Code, as added by S.B. 1107, provides that one of the ways that a physician may establish a valid practitioner-patient relationship for purposes of Section 562.056, Tex. Occ. Code, is to have a "preexisting practitioner-patient relationship with the patient *established in accordance with rules adopted under Section 111.006*."

This language clearly contemplates that adopted rules will articulate requirements in accordance with which a physician-patient relationship must be established. But the proposed changes to TMB rules eliminate any such guidelines from both §190.8 and §174.8, leaving only the mere requirement for a "practitioner-patient relationship" without explaining how that is established.

It is true that among the proposed struck provisions in TMB's proposed changes are regulations that are now preempted by S.B. 1107. For example, blanket requirements that face-to-face or in-person visits are necessary (in current §174.7(a) and §174.8(a)) and that online interaction with a patient is insufficient to establish a required practitioner-patient relationship (in current §174.6(d) and §174.8(c)) would conflict with the provisions of S.B. 1107. TMA has no objection to eliminating the portion of the rules conflicting with the new statute.

But a conflict with *part* of the rule should not require that *all* of the rules be struck. Existing rules list important prerequisites for a physician-patient relationship prior to prescribing—including patient identity authentication, patient history, mental status examination, and a discussion of any diagnosis and appropriate follow-up care—that remain applicable after the passage of S.B. 1107. More importantly, these requirements apply in situations other than the situation contemplated by S.B. 1107. Eliminating these regulations and relying only on S.B. 1107 to provide guidance on telemedicine encounters means that situations that are *not* addressed by the bill are left with virtually no clarity. This is discussed in the next section.

2. The TMB's Proposed Changes Remove Regulations That Are Needed for Patient Encounters That Are Not Addressed by S.B. 1107.

S.B. 1107 generally addresses: (1) issuing a prescription (2) in a telemedicine setting.[1] The bill's focus is not on either (a) issuing a prescription in a non-telemedicine setting, or (b)

[1] Sec. 111.005(a), Tex. Occ. Code, as added by S.B. 1107, provides for a valid practitioner-patient relationship if the conditions in that section are met, *for purposes of* Sec. 562.056, Tex. Occ. Code, which addresses the requirement for a valid practitioner-patient relationship for a valid prescription.

providing care or treatment other than by a prescription in a telemedicine setting.[2] Currently, TMB's rules address each of these circumstances and promote patient safety and clarity with respect to the standard of care in all circumstances. So to avoid unintended consequences, the rules should be amended only to the extent they are preempted by S.B. 1107; that is, because only the first circumstance—issuing a prescription in a telemedicine setting—was significantly altered by the bill, amended rules should be tailored to the bill's impact on this circumstance. Despite what should thus be a limited scope of rule amendments, the TMB's proposed changes have significant impact on the two circumstances that were largely not impacted by S.B. 1107 (as mentioned above). The net effect of these proposed changes could result in threats to patient safety and a lack of clarity with respect to applicable standards of care.

TMA thus encourages the TMB, in consideration of unintended consequences, to scale back some of its proposed changes and more carefully tailor its rule modifications to only that circumstance that S.B. 1107 addresses. Specifically, the TMB should review its proposed changes to:

1. §190.8, which would affect issuing a prescription in a non-telemedicine setting; and
2. §§174.5 and 174.8, which would affect providing care or treatment other than a prescription in a telemedicine setting.

a. <u>The TMB's Proposed Changes Remove Important Regulations in §190.8 That Apply to Non-Telemedicine Settings</u>

TMB proposes to delete almost all of §190.8(L), which would leave only the requirement to first establish a "valid practitioner-patient relationship" before prescribing dangerous drugs or controlled substances, without defining "practitioner-patient relationship" or describing the necessary requirements to establish that relationship. As explained above, TMA has concerns about removing the articulation of the required elements of this relationship as S.B. 1107 relies on the regulatory detail. But the change here is more troubling because 190.8 applies also to non-telemedicine settings, so the removal of these rules means there is no clarity for establishing a required physician-patient relationship *any time a physician issues a prescription.*

To be sure, §190.8 describes certain actions that would constitute "failure to practice in an acceptable professional manner consistent with public health and welfare within the meaning of the [Medical Practice] Act." The actions listed in the rule do not apply only to telemedicine settings, but apply to the practice of medicine generally. Thus, the prohibition in §190.8 that describes the standard for establishing a physician-patient relationship for

[2] The bill does provide that the same standard of care applies in all telemedicine encounters as that which applies in an in-person setting, and it does remove the board's authorization to require a face-to-face consultation following a telemedicine encounter, but beyond that, the bill is silent on other aspects of a telemedicine encounter that does not involve a prescription. *See* Sec. 111.007(a), Tex. Occ. Code.

prescribing purposes is important for physicians in every setting—not just telemedicine. Deleting the guidance in §190.8(L) as proposed will subject physicians to an unclear standard as to the requirements for a "practitioner-patient" relationship that must exist before issuing prescriptions.

To be clear, there may be *some* parts of the rule that relate only to telemedicine. TMA does not object to, for example, the TMB's removal of requirements in this section that blanketly require a face-to-face visit or in-person evaluation and prohibit establishing a required relationship through electronic communications. But TMA still asserts that the rule changes should be more carefully tailored in consideration of the fact that this rule may still be needed to describe required elements of the physician-patient relationship for prescribing purposes in both telemedicine and in-person settings.

b. <u>The TMB's Proposed Changes to §§174.5 and 174.8 Disregard the Need for Regulations of Telemedicine When a Prescription is Not Issued</u>

The TMB's proposed changes will have an unintended consequence in a second circumstance: using telemedicine to see patients in an encounter that does not result in the issuance of a prescription.

The only non-insurance-related requirement that S.B. 1107 imposes that applies to all telemedicine encounters—both those that involve a prescription and those that do not—is the standard that a physician "providing a health care service or procedure as a telemedicine medical service or a telehealth service is subject to the same standard of care that would apply to the provision of the same health care service or procedure in an in-person setting." §111.007, Tex. Occ. Code.[3]

Since the rest of the bill requirements on telemedicine relate only to providing a prescription through telemedicine, there is still a need for regulations that clarify telemedicine standards when a physician does not issue a prescription. Existing TMB rules in §§174.5 and 174.8 do just that. Those regulations provide physicians instruction on the need for patient authentication, patient history, a discussion of the diagnosis and risks and benefits of various treatment options, and instructions for follow-up care.

But in proposing rule changes in response to S.B. 1107, the TMB proposes to eliminate all of this important instruction. Patients and physicians alike may be able to rely on S.B 1107's guidance for telemedicine encounters that involve a prescription, but if the TMB effectuates its proposed changes to §§174.5 and 174.8, there will be no guidance on telemedicine standards when there is not a prescription, leaving patients without necessary protections and physicians without guidance on what is required to comply with TMB expectations when a physician sees a patient through telemedicine and does not issue a prescription.

[3] While it is not a "requirement" of telemedicine encounters imposed by the bill, the bill does remove the authorization for the board to require a face-to-face consultation with a patient following an initial telemedicine encounter.

Some amendment may be needed to conform current regulations to S.B. 1107, but it should be limited to the extent that the current regulations conflict with S.B. 1107's direction.

c. The TMB Should Not Rely on the Standard of Care Alone for the Regulation of Telemedicine.

Perhaps instead of relying on the current rules that are more prescriptive in order to regulate telemedicine, the TMB is relying simply on its requirement in the proposed changes to §174.6(a)(1) that physicians should comply with "the same standard of care that would apply to the provision of the same health care service or procedures in an in-person setting." If this is the case, TMA shares concerns expressed at the stakeholder meeting: that TMB's regulations may be too open. Relying on such broad regulations can result in both under- and over-enforcement: not enforcing regulations against some bad actors while at the same time enforcing regulations against others who were in good faith attempting to comply with unclear guidance.

TMA reminds the TMB that even though S.B. 1107 provided clear guidance for telemedicine encounters involving a prescription, the TMB is still authorized to adopt rules that "ensure that patients using telemedicine medical services receive appropriate, quality care." §111.004(1), Tex. Occ. Code. TMB should thus carefully reexamine its rules and its proposed changes to determine whether the rules can further appropriate and quality telemedicine care.

II. CERTAIN RULE REVISIONS REQUIRE FURTHER CLARIFICATION

1. The Privacy Notice Requirements Need Further Clarity.

The revised §174.4(a)(1) provides, "Physicians that communicate with patients by electronic communications other than telephone or facsimile must provide patients with written or electronic notification" of privacy practices "prior to evaluation or treatment via a telemedicine medical service." TMA asserts that this provision could be clearer in several ways. First, this rule seems to assume that physicians using telemedicine have not already provided the required notice to patients. In fact, a physician may use telemedicine to see his or her own existing patient, in which case an additional privacy practices notice would be duplicative. The rule should be further amended to accommodate the instance in which a physician has already provided the privacy practices notice, whether in person or electronically.

Second, this revised rule exempts physicians who communicate with patients through telephone or facsimile, though it is not clear why those methods are exempted. Some telemedicine models have physicians communicating with patients through telephone after the patient's medical history is compiled. Though the physician is communicating with the

patient through the phone, it is nevertheless important that the patient receive applicable privacy practices in this encounter.

Finally, TMA appreciates the clarification that electronic notification may satisfy the rule's requirements. But TMA is concerned that the way the rule expresses this—"written or electronic notification"—could imply that electronic notifications are not in writing, or that written notifications required elsewhere do not include electronic notifications.

To address each of these concerns, TMA proposes amending the revised rule as follows:

> (1) Physicians that communicate with patients by electronic communications ~~other than telephone or facsimile~~ must provide patients with written ~~or electronic~~ notification, which may be provided in electronic form, of the physician's privacy practices prior to evaluation or treatment via a telemedicine medical service, if the physician has not previously provided the patient with such notification of privacy practices. In addition, a good faith effort must be made to obtain the patient's written ~~or electronic~~ acknowledgment of the notice. Such written acknowledgement may be in electronic form, including by e-mail~~, of the notice~~.

2. The Rules Inconsistently Use "Practitioner," "Physician," and "Health Professional."

S.B. 1107 refers to a "practitioner-patient relationship" because it provides clarification as to the legal threshold of a "practitioner-patient relationship" under Section 562.056, Occupations Code, when a prescription is issued through telemedicine. Though the bill uses "practitioner-patient relationship," the term may not be preferred in rules effectuating the statute. TMA is concerned that the rules' inconsistent use of "practitioner," "physician," and "health professional," may cause confusion to physicians and others as to which profession is actually being regulated. For instance, is there an intended distinction where, in some rules, requirements are imposed on a "physician," (see e.g., §174.4) while elsewhere, requirements are imposed on a "health professional" (see e.g., §174.6) or "practitioner" (see e.g., §174.5(1)(a))?

Because physicians expect to be able to read TMB rules to understand what is required of physicians, TMA encourages the TMB to more consistently clarify that the rules apply to physicians, and if necessary to include other professions, specifically state that that is the case.

3. The TMB Needs to Clarify the Rule Relating to Licensure.

In revised §174.8, the rules mention communication through "advanced communications technology" when treating "residents of Texas." TMA asserts that "advanced" is not

necessary—the word was struck from previous law in the enactment of S.B. 1107 because "advanced" is not defined and, further, unduly limits the purview of what telemedicine has become. Also, the rule does not specify that this rule is applicable when treating individuals who are present in Texas *at the time of treatment*. It is a patient's location—not the patient's residency—that determines the applicable law. TMA thus recommends the board amend this rule as follows:

> Physicians who treat and prescribe through ~~advanced~~ communications technology are practicing medicine and must possess a full Texas medical license when treating <u>patients who are physically present in Texas at the time of the treatment</u> ~~residents of Texas~~.

4. The Revised §178.3 Should Clarify Details Regarding Different Methods of Notification.

TMA also supports the TMB's amendment to rules relating to methods of notification under §178.3 to accommodate different circumstances of patient encounters. At the same time, TMA requests amendments to this language to clarify details regarding each of the methods of notification listed in the revised text.

TMB has replaced §178.3(a)(1)(B) with a list of possible notification methods, but because these methods appear in a list following the clause "if providing telemedicine medical services," it is not clear whether the notification methods are possible means of satisfying the notice *only if* the encounter is through telemedicine. For instance, the previous rule allowed physicians to satisfy the notice requirement by providing notice "in a bill for services." Under the revised rule, "in a bill for services" appears after the condition "if providing telemedicine medical services," which could suggest that a physician can provide the requisite notice in a bill for services *only* when the physician provides telemedicine medical services. Further, the board eliminates the option of satisfying the notice requirement by providing notice on a "registration form, application, or written contract for services of a licensee." If this is no longer a viable option for fulfilling this notice requirement, the change seems to be outside the scope of rule changes relating to telemedicine.

Next, the structure of the revised rule may cause confusion relating to what is required to comply with the rule. In §178.3(a)(1), before the colon, the rule states that licensees can satisfy the rule requirement "by one or more of the following methods." The revised rule then lists two options: one under (A), which describes a required sign in the licensee's place of business, and a second alternative applicable "if providing telemedicine medical services." Because these two are framed as alternatives, and that one or the other can satisfy the requirements, the rule suggests that if a licensee provides telemedicine, he or she need only choose one of the listed methods under that alternative, which could be something as simple as a "recording."

Additionally, the revised rule states "in a bill for services, the approved notification statement in subsection (b) and (c) below." It is not clear whether the "approved notification statement" must appear only in a bill for services, and not in any of the other methods listed as being related to telemedicine (e.g. on a provider's website).

Finally, at the end of the new Paragraph (B), the rule explains certain details about the notice, including that it must be in at least 10-point font and easily readable. At the same time, the revised rule allows for notices that would not be in writing (e.g., "by recording"). In that case, are there no requirements as to content if the notice is not in writing?

TMA encourages TMB to address these concerns to make the rule clearer. TMA recommends amending the revised rule as follows:

(1) Complaints against licensees. Pursuant to the Act, for the purpose of directing complaints to the board, the board and its licensees shall provide notification to the public of the name, mailing address, [~~and~~] telephone number, and website address of the board as follows:

(A) by one or more of the following methods:

(i) ~~(A)~~ displaying in a prominent location at a licensee's place of business, signs in English and Spanish of no less than 8 1/2 inches by 11 inches in size with the board-approved notification statement printed alone and in its entirety in black on white background in type no smaller than standard 24-point Times Roman print with no alterations, deletions, or additions to the language of the board-approved statement; [or]

(ii) ~~(B)~~ placing the board-approved notification statement printed in English and Spanish in black type no smaller than standard 10-point 12-pitch typewriter print on each bill for services by a licensee with no alterations, deletions, or additions to the language of the board-approved statement; or

(iii) ~~(C)~~ placing the board-approved notification statement printed in English and Spanish in black type no smaller than standard 10-point, 12-pitch typewriter print on each registration form, application, or written contract for services of a licensee with no alterations, deletions, or additions to the language of the board-approved statement; and

(B) if providing telemedicine medical services, by at least one of the following methods:

(i) one of the methods described under Paragraphs (B) or (C);

(ii) a prominently displayed link on the licensee's website that directs a user to the board-approved notification statement;

(iii) in an app the licensee uses to communicate with a patient, by containing the board-approved notification statement; or

(iv) by a recording that contains the board-approved notification statement.

III. TMA REQUESTS CLARIFICATION REGARDING THE INTENT OF CERTAIN RULE REVISIONS

TMA seeks clarification on the TMB's intent in still other parts of the revised rules:

1. Why is the scope of the rules still limited?

In revised §174.1, the rule states that the chapter does not apply to certain out-of-state telemedicine licenses, federally qualified health centers (FQHC), or to consultations provided by health insurance help lines. Prior to the enactment of S.B. 1107, there may have been a reason to allow greater latitude for FQHCs and help lines. But because S.B. 1107 and these revised rules reduce the regulatory footprint on telemedicine and allow for a greater variety of models, are these exceptions are still necessary?

2. What are the standards with which fraud and abuse protocols must be consistent?

The TMB has revised §174.3 to state, "In order to establish that a physician has made a good faith effort, these protocols ~~standards~~ must be consistent with ~~those~~ standards established by the Health and Human Services Commission pursuant to §531.02161 of the Government Code." First, TMA is unaware of a "good faith" requirement that a physician must meet that this revised rule addresses. To state that a physician may establish good faith without a specific requirement to establish good faith causes confusion.

Additionally, the rule refers to standards established by HHSC rule under §531.02161, Government Code. These HHSC standards cannot be located. If these standards actually do exist, TMA asks that the rules provide a more direct citation to them. If these standards do not exist, TMA asks that the TMB use some other, more descriptive standard for the benchmark for a physician's fraud and abuse protocols.

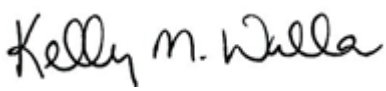
IV. CONCLUSION

Again, TMA commends the TMB for its transparency and its efforts to involve stakeholders in this stage of rule formulation. TMA asserts that the issues raised in this bill are important to successful implementation of S.B. 1107 and to the continued proliferation of telemedicine in Texas. TMA appreciates that the TMB will be attentive to addressing these issues. If you

have any questions, please do not hesitate to contact Jared Livingston at jared.livingston@texmed.org or at 512-370-1345.

Sincerely,

Donald P. "Rocky" Wilcox



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