Message From the TMB President:
Key Clarifications Regarding Opioid Prescribing

2016 CDC Guidelines

As the opioid epidemic continues to be addressed at the federal, state and local levels, a developing concern is how previously issued prescribing guidelines are impacting patients and the care they receive in light of increased awareness and enforcement.

In 2016, the Centers for Disease Control (CDC) issued guidelines for prescribing opioids for chronic pain. Overall the federal guidelines, which are evidence based, follow closely in line with best prescribing practices; however, there are concerns in the patient and medical communities that the guidelines are being misapplied in such a way that can adversely affect patient care and create unnecessary barriers for chronic pain patients.

The first important clarification to make on the CDC guidelines is that they are directed at primary care clinicians treating chronic pain patients in outpatient settings. They are not intended for specialists who should already be appropriately managing their patients for pain, nor are they intended for cancer patients or those in hospice, palliative or end-of-life care.

The other misconception is that there is a specific morphine milligram equivalent (MME) that physicians are bound by in their prescribing of opioids. This is not the case. What the guidelines state—again directed at those in primary care settings—is that clinicians should use extra caution when prescribing opioids at any dosage, especially above 90 MME/day and should at that point strongly consider referring the patient to a pain specialist for ongoing chronic pain treatment.

A third issue is the misinterpretation that the federal guidelines require tapering of opioids. There is no such requirement. The CDC states that the benefits versus potential harms of ongoing opioid therapy should be evaluated frequently, and if benefits do not outweigh the harms of continued opioid therapy, clinicians should utilize other therapies and work with patients to lower dosages, taper or discontinue opioids. Risk versus benefits should always be foremost in a physician’s mind. However, if the benefits outweigh the risks, there is no need to discontinue the therapy. In fact, immediately tapering or abruptly cutting off therapy altogether poses even greater risks to the patient. Again, a primary care physician should consider referral to a chronic pain specialist.

It’s important to remember that there is no “one size fits all” approach to treating pain and each patient is unique. When it comes to the Medical Board’s enforcement of proper prescribing practices, the standard of care, along

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with applicable Board rules (Chapter 170 and 195) and laws are going to supersede suggested guidelines.

The Board’s rules reiterate the overarching responsibility of physicians which is that whenever they are treating patients for chronic pain, they must ensure drugs are used in a therapeutic manner and that the treatment is monitored and evaluated on an ongoing basis.

**TMB’s Use of Prescription Monitoring Program (PMP)**

As required by legislation (House Bill 2561) passed in 2017, TMB works with the Texas State Board of Pharmacy to identify prescribing practices that may be potentially harmful and patient prescription patterns that may suggest drug diversion or drug abuse. There are four primary ways in which TMB accesses PMP data.

First, TMB investigators are authorized to access either a prescriber’s or a patient’s prescribing history in the PMP when reviewing relevant complaints related to pain prescribing and treatment issues. The PMP data is used in conjunction with risk-based criteria adopted in Rule 195 - Pain Management Clinics related to potential unregistered clinics. As with any TMB investigation, all information is considered confidential by state law and a practitioner has several steps of due process and opportunities to respond to TMB during the course of an investigation.

Secondly, TMB compiles a list of the Top 50 hydrocodone prescribers in the state every quarter. To clarify, no automatic enforcement action occurs simply from appearing on the list since there are several legitimate reasons why a provider may be a top prescriber. For example, a practitioner who provides care in a hospice or facility-based setting, would typically be prescribing more hydrocodone than most other types of practitioners, and is also automatically exempt from pain management clinic registration based on state law.

When reviewing the Top 50 list, TMB investigators will consider several criteria including practice settings, prescribing patterns, relevant prior complaint history, and whether there is overlap with pain management clinic registration requirements and exemptions before making a determination to request more information from the practitioner. Only if the totality of the information received, in conjunction with the PMP data, indicates that there may be a possible violation of state law or Board rule, will the Board file a complaint to gather more information.

Thirdly, state law requires the Pharmacy Board to notify TMB of PMP automatic push notifications sent to practitioners. TMB receives a monthly list of prescribers who have been notified that at least one of their patients met the “5-5-5” criteria – a patient received five or more prescriptions, the medications were prescribed by five or more prescribers, and the medications were dispensed by five or more pharmacies in the preceding month.

TMB investigators review these monthly reports to determine if a practitioner has received three or more consecutive 5-5-5 email alerts. If so, then the practitioner would be subject to an investigation. If a practitioner has received several nonconsecutive alerts then TMB investigators will identify this as a potential trend for closer monitoring.

Lastly, TMB monitors prescribing history in the PMP for those physicians who have cases related to inappropriate prescribing of controlled substances pending at the State Office of Administrative Hearings (SOAH). This way, TMB is able to assess if the physician poses a continuing threat to public health and safety that may warrant more immediate action.

**Filling Opioid Prescriptions**

Another increasing area of concern stems from corporate retail pharmacies enacting dispensing limits on certain opioid pain medications. While physicians and pharmacists share a responsibility in helping to curb the opi-
oid epidemic, there seem to be resulting unintended consequences of these blanket policies.

Physicians and pharmacists both have a shared obligation to the health and safety of the patient under federal law:

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. 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.” See 21 CFR §1306.04(a).

Similarly, under state law, Texas Occupations Code, Section 562.056, states that “a prescription must be issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner’s professional practice. The responsibility for the proper prescribing and dispensing of prescription drugs is on the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Section 551.006 provides for the exclusive authority of pharmacists to decide whether or not to dispense a prescription for any reason.

The provisions of the recently enacted federal law entitled, “SUPPORT for Patients and Communities Act,” are also instructive in that they require the federal Department of Health and Human Services to develop materials related to Medicaid and Medicare prescriptions in order to provide pharmacists, health care providers, and patients guidance on refusal to fill a prescription when a prescription is fraudulent, forged or of doubtful, questionable or suspicious origin, and when a pharmacist can dispense a partial quantity.

Under Texas Health and Safety Code, Sec. 481.074(e), partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or electronic prescription or emergency oral prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription, on the written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

As previously indicated, if prescriptions are modified, state law requires that the physician be notified of the change. The TMB has concerns with pharmacy policies being cited as a reason to modify or partially dispense certain prescriptions rather than following what state laws mandate.

When there are questions regarding the treatment, prescribed medications and quantities dispensed, physicians and pharmacists need to work on communicating those concerns with one another in order to not adversely affect the patient’s health and welfare. If a pharmacy has strict dispensing policies that do not allow certain medications to be filled as written, those policies should be communicated upfront to patients so they may decide whether they would like their prescriptions filled elsewhere.

The TMB is working with appropriate authorities to address these issues and will work with the Texas State Board of Pharmacy to bring consistency to enforcing the statute and ensuring patients have access to medications that they legitimately need.

Dr. Sherif Zaafaran, M.D., FASA
Texas Medical Board President

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