



Texas Medical Board

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December 14, 2016

The Honorable Larry Gonzales, Chair
Sunset Advisory Commission
P.O. Box 13066
Austin, TX 78711-3066

Delivered via e-mail to: Larry.Gonzales@house.state.tx.us and Sunset@sunset.texas.gov

Dear Chair Gonzales:

Thank you for the opportunity to present information at the public hearing on December 9, 2016. Below we are providing key clarifications about Texas Medical Board (TMB) processes and actions due to the wide variety of information provided in public testimony to the Commission. We are happy to provide additional information to any commission member about a specific case or board process discussed during the hearing.

DUE PROCESS (See Attachment A).

As required by statute and rule, TMB follows a thorough process to review all complaints received and, as appropriate, investigate them and determine if additional board action is warranted. The board has the authority to issue a non-disciplinary remedial plan as well as a disciplinary agreed order based on the results of an investigation and, if relevant, an informal disciplinary hearing.

- Currently, the Medical Practice Act provides physicians with extensive due process; the process includes approximately 15 steps.
- Physicians have at least 4-5 opportunities to present information in response to any complaint, depending on how far the complaint goes through the process, including presenting in-person to a two-member disciplinary panel of the Board.

SOAH PROCEEDINGS

Almost all cases filed at the State Office of Administrative Proceedings (SOAH) are because the physician has requested a trial or refused to settle the matter during the informal disciplinary process.

Unless a physician's license is suspended, that physician continues to practice medicine without any restriction or limitation during the entire SOAH process.

TEMPORARY SUSPENSIONS (See Attachment B).

TMB uses this process sparingly and only with the most egregious cases. To take this type of action TMB must prove a physician is a "continuing threat" to the public as defined in statute and rule. Multiple steps of due process are also provided to a physician in these proceedings.

COMPLEMENTARY AND ALTERNATIVE MEDICINE (See Attachments C, D, and E).

The practice of complementary and alternative medicine (CAM) is authorized by TMB rules (Chapter 200) which provide clear guidelines to practitioners and have been in place for almost 20 years. The rules address public protection by ensuring patients seeking and receiving CAM are fully informed of the treatment and go into it with "eyes wide open."

CAM practitioners are in no way targeted by TMB as the agency is complaint-driven with very limited proactive inspection authority. Over the past 5 years, approximately 20 practitioners have been disciplined but none have been restricted from practicing CAM. Most were disciplined for failure to provide adequate informed consent and disclosure related to treatment to their patients.

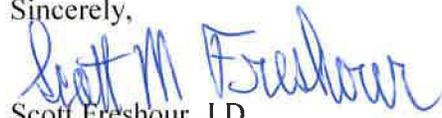
NON-JURISDICTIONAL COMPLAINTS

To clarify our testimony at the hearing, there are multiple reasons a complaint may be determined non-jurisdictional and this type of complaint can be related to a physician though many of these complaints concern a practitioner not under TMB authority, i.e., dentist, psychologist, podiatrist.

A complaint may be determined non-jurisdictional if the physician-related action is outside of TMB authority. This could include: a patient had to wait too long to see the physician, a patient is upset at the cancellation of an appointment, a doctor does not accept a certain type of insurance, a patient is concerned about the condition of facility, etc. These are potential concerns for the public, but are not violations of the Medical Practice Act.

We hope this information is helpful and are happy to provide any additional information.

Sincerely,



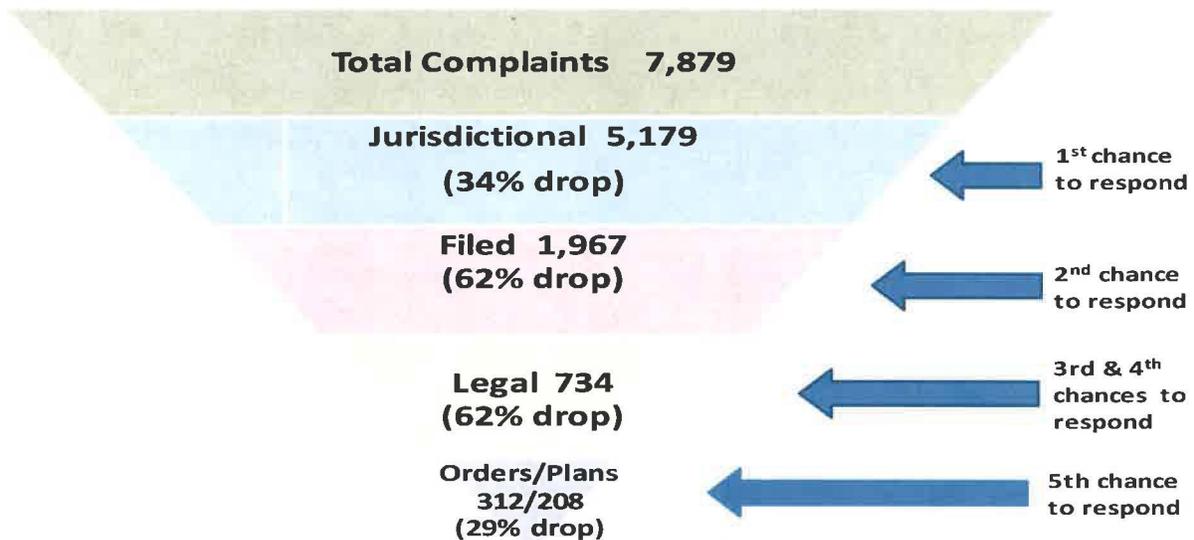
Scott Freshour, J.D.

Interim Executive Director

cc: Members, Texas Sunset Commission
Michael Arambula, M.D., Pharm.D, TMB President

ATTACHMENT A - Five Opportunities for Physician Response to Complaint

Complaints FY '16



- Almost 8,000 initial complaints received ultimately resulting in approx. 312 agreed orders and 208 remedial plans (non-disciplinary actions).
- Jurisdictional Review: Roughly 1/3 to 1/2 of all complaints are found to be non-jurisdictional.
- **Response #1 - Notice to Licensees.** Licensees have 28 days to respond to an initial complaint determined to be jurisdictional. Roughly one-half of all active complaints are dismissed based on the physician's response.
- **Response #2 - Formal Investigation ("filed" complaint).** The physician is notified that an investigation has begun and is given the opportunity to provide another response with additional information.
- **Response #3 - Investigation completed.** TMB staff completes the investigation, including obtaining all relevant medical records, witness statements, and any other related records. The physician has had multiple opportunities to respond at this point.
 - Many investigations do not demonstrate a potential violation. This determination reduces the active investigation count to approximately 700 investigations that are referred to the Litigation Department.
 - If there is a determination of a potential violation, an Informal Settlement Conference (ISC) is scheduled and the physician is given notice.
- **Response #4 - Notice of the ISC.** This notice is usually provided 60-70 days before the ISC and must be provided at least 45 days prior. TMB staff provides all evidence that will be presented at the ISC when notice is given. The physician can file a response to the agency's evidence including evidence the physician wants the ISC panel members (one physician and one public member) to consider. This must be submitted at least 15 days before the hearing.
- **Response #5 - ISC is held.** The ISC usually lasts 1-2 hours with the majority of the time for the physician to address the panel and answer questions. This proceeding is confidential so that the physician is protected from unwarranted public disclosure of potential violations that have not been determined or resolved. Out of approx. 700 ISCs held, about 500 resulted in either a non-disciplinary remedial plan or a disciplinary order.

ATTACHMENT B - DESCRIPTION OF TMB TEMPORARY SUSPENSION (TS) PROCESS

The Temporary Suspension process is the only instance where a physician may be restricted or limited from practice until a SOAH proceeding is concluded. TS hearings are considered public by statute and are posted in the *Texas Register*.

TS HEARING “WITHOUT NOTICE”

- TMB has the authority to conduct a public TS hearing without notice, if it is determined that immediate action is required. A high evidentiary threshold must be met as defined by statute.
- Potential outcomes of the proceeding include: 1) suspension of a license; 2) restriction of a license; or 3) no action taken.
- If the “without notice” process is used, TMB must notify the physician of the outcome and provide the opportunity for a hearing with notice as soon as practicable after at least 10-days’ notice.

TS HEARING “WITH NOTICE” (required after a TS without Notice)

- At the public TS hearing with notice, the physician receives all the evidence which TMB is going to rely on in the TS hearing at least 10 days prior.
- Physicians have the right to file documentary information and evidence up to 24 hours before the TS hearing. The physician is allowed to bring witnesses to testify on their behalf at the hearing. They also have the right to cross exam all the board’s witnesses and file objections to the Board’s evidence.
- It is a full trial-type hearing that lasts on average 8-14 hours, and includes presentation of sworn testimony, cross-examination, and due process under the Texas Rules of Evidence.

POST-TS ISC

- After a TS with notice, the physician has the right to an Informal Settlement Conference (ISC) which is a confidential disciplinary hearing. The ISC follows a standard process as laid out in statute and rule. A physician can waive the ISC and go straight to SOAH after the TS with notice.

APPLICABLE TS CASELAW

Wiseman v. TMB (3rd Court of Appeals-Austin): An appeal from any disciplinary action, including a temporary order, may not be taken until the Texas Medical Board issues a final decision in the overall dispute following an informal show compliance hearing and contested case at the State Office of Administrative Hearings pursuant to the procedures set out in the Medical Practice Act.

Until the Board makes a final decision in the dispute, a physician has not exhausted their administrative remedies so as to give the state courts jurisdiction to review the administrative action;

The doctor at issue in this case received adequate due process protection, and the Act continued to provide due process protections in the remainder of the process by requiring he be given notice, an opportunity to participate and defend himself, and the opportunity to appeal once the Board came to a final decision.

ATTACHMENT C

SNAPSHOT OF PUBLIC BOARD ACTIONS RELATED TO COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

- TMB issued approximately 17 public agreed orders (disciplinary actions) from 2008 to 2016, which is approx. two orders per year. (PDF copies of all orders are available on the TMB website).
- Most CAM orders are related to inadequate informed consent and/or advertising.
- Chapter 200 rules have been in effect for almost 20 years and provide clear guidance for CAM providers.

Rea, William James, M.D., Lic. No. D2294, Dallas

Order: August 27, 2010, based on Dr. Rea treating patients with injections for chemical/environmental sensitivity where the injections contained only the “electromagnetic imprint” of the agents. The Order required Dr. Rea to provide an informed consent document stating that: 1) injections for chemical/environmental sensitivity contain only the “electromagnetic imprint” of the agents in question; 2) the therapy is “not FDA approved;” and 3) the therapeutic value of the injections is disputed. In addition, Dr. Rea is prohibited from using any formulations that contain any amounts of substances classified as hazardous or carcinogenic by the EPA. The Order contained no limitations on his CAM practice.

Rao, Shehagiri, M.D., Lic # G0803

Order: August 31, 2012, based upon Dr. Rao’s failure to obtain informed consent for five minor autistic patients who were treated with chelation therapies, suppositories, supplements and prescribed medications, including Namenda. The Order required Dr. Rao to have his charts monitored, and complete certain CMEs. The Order contained no limitations on his CAM practice.

Tan, Ricardo Barrera, M.D., Lic. No. E7515, Arlington

Order: February 13, 2015, based on the prescribing thyroid supplements to one minor patient with normal thyroid levels and inadequate medical records, including failure to obtain appropriate informed consent. On August 26, 2016, the Board modified Dr. Tan’s February 2015 Order when Dr. Tan failed to document that he discussed conventional medical treatment options with a patient prior to treating a patient with complementary and alternative medicine. The Order required Dr. Tan to have his charts monitored and complete certain CMEs. The Order contained no limitations on his CAM practice.

Gonino, V. John, D.O., Lic. No. J2032, Rockwall

Order: April 12, 2013, based on a failure to supervise those acting under his supervision, and the violation of Board rules related to the practice of alternative and complementary medicine. Order required Dr. Gonino to have his charts monitored, complete certain CMEs, and to provide a revised informed consent form. The Order contained no limitations on his CAM practice.

ATTACHMENT D

SNAPSHOT OF PUBLIC BOARD ACTIONS RELATED TO COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) ADVERTISING

- Approximately seven public orders related to CAM advertising were issued from 2008 to 2016. (PDF copies of all orders are available on the TMB Website).

Sebring, Lane, M.D., Lic. No. J7661

Order: February 7, 2014, based on Dr. Sebring's false or misleading advertising statements in a local publication. Specifically Dr. Sebring stated that breast cancer is caused by women wearing bras, and that vitamin C is more effective at treating cancer than chemotherapy. The Order required CME and contained no limitations on CAM.

De Wet, Pieter Juan, M.D., Lic. No. J0470

Order: April 10, 2015, based on Dr. De Wet's website which contained statements regarding ZYTO device, Laser Energetic Detoxification, and Ozone therapy that were false and/or misleading. The Order included reprimand, CME and administrative penalty and contained no limitations on CAM.

Jones, Andrew P., M.D., Lic. No. H1972

Order: August 28, 2015, the Order was based on the findings of an administrative law judge at SOAH, that Dr. Jones advertises products over the internet that he claimed will treat and cure diseases such as depression, Alzheimer's, cancer, and fibromyalgia. His license was revoked due to several prior similar violations.

Mays, Steven C., D.O., Lic. No. G4169

Order: August 21, 2009, based on Dr. Mays' false and misleading advertising related to the clinic's treatments and therapies for weight loss, thyroid, HGH, and other hormone replacement therapies; the informed consent lacked a description of side effects of HGH, and included a statement that the hormone replacement therapy was "elective and not medically necessary." The Order required a chart monitor, CME, JP exam and an administrative penalty and provided no limitations on CAM.

ATTACHMENT E

SNAPSHOT OF PUBLIC BOARD ACTION RELATED TO LYME DISEASE

- Example of one public order related to treatment of Lyme Disease from 2010. TMB estimates less than five board actions have been taken in the past eight to ten years. (PDF copy of this order is available on the TMB Website).

Wilson, Ronald Thomas, M.D., Lic. No. F6173,

Order: August 27, 2010, based upon Dr. Wilson's failure to meet the standard of care in the diagnosis and treatment of Lyme disease for one patient; nontherapeutic prescribing to the patient; and his unprofessional conduct of receiving a percentage of profits for a vitamin supplement that he recommended the patient purchase during their treatment. The Order required CME and an administrative penalty and provided no limitations on Dr. Wilson treating Lyme disease.



Texas Medical Board

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November 15, 2016

Ken Levine, Director
Sunset Advisory Commission
P.O. Box 13066
Austin, TX 78711-3066

Dear Mr. Levine:

Thank you for the opportunity to respond to the Sunset Staff Report on the Texas Medical Board (Board).

The Board is in agreement with all the report's issues and recommendations and is in agreement with, and appreciative of, the assessment that the agency generally is a solid model for licensure and enforcement. Implementation of the two management actions will begin by the end of the calendar year and the Board looks forward to working with the Texas Physician Health Program (TXPHP) in developing a memorandum of understanding detailing the administrative support of the program.

I would like to take this opportunity to comment on the implementation of SB 202 enacted in 2015, relating to the Sunset review of the Department of State Health Services (DSHS) and the transfer of four occupational licensing programs (approximately 43,000 licensees) from DSHS to TMB. The legislation required that the transfer occur by August 31, 2017. The Board began the transition in October 2015 and all licensing and enforcement functions were transferred by December 31, 2015.

The transfer was challenging and it became apparent by the late spring of 2016 that additional process improvements were needed to reduce the length of time to issue these new licenses. These changes were completed by August 2016 and both license processing times and the level of customer service provided to licensees have improved. The Board has also requested additional resources in the FY 18-19 Legislative Appropriations Request to continue to improve customer service levels to licensees and the public.

On behalf of the Board members and staff, I would like to thank you and your staff for a thorough and detailed review resulting in recommendations that would improve the agency's regulatory efficiency and effectiveness while maintaining the mission of public protection.

We look forward to working with you in the upcoming legislative session.

Sincerely,

A handwritten signature in blue ink that reads "Scott M. Freshour".

Scott Freshour, J.D.

Interim Executive Director

cc: Michael Arambula, M.D., Pharm.D., TMB President
Members, Texas Medical Board
Allison Jones, M.D., Presiding Officer, Texas Physician Health Program