The Texas Medical Board (Board) proposes the repeal of current Chapter 172, concerning Temporary and Limited Licenses. This includes Subchapter A, concerning General Provisions and Definitions, §§172.1 and 172.2; Subchapter B, concerning Temporary Licenses, §§172.3 – 172.11; Subchapter C, concerning Limited Licenses, §§172.12–172.13, 172.15-172.19; Subchapter D, concerning Disaster Emergency Rule, §172.20 and 172.21.

The Board also proposes new Chapter 172, concerning Pain Management Clinics, §§172.1 – 172.5.

Also the Board contemporaneously proposes the repeal of current Chapter 195, concerning Pain Management Clinics, §§195.1 – 195.5.

The Board has determined that due to the extensive reorganization of Chapters 160-200, repeal of Chapter 172 is more efficient than proposing multiple amendments to make the required changes.

The proposed new sections are as follows:

New §172.1, Definitions, defines the various forms of pain that implicates need of Pain Management Clinic Registration.

New §172.2, Gold Designated Practice, explains the eligibility criteria and application process for the Gold Practice designation.

New §172.3, Certification of a Pain Management Clinic, explains which clinics must register as a Pain Management Clinic and the procedures and information needed for processing certificate applications.

New §172.4, Minimum Operational Standards, explains minimum standards for any physician treating a pain patient.

New §172.5, Audits, Inspections, and Investigations, explains the board's regulatory actions of audits, inspections, and investigations. It details the information requested and the process followed by the board during these actions.

Scott Freshour, General Counsel for the Texas Medical Board, has determined that, for each year of the first five years the proposed repeals and new sections are in effect, the public benefit anticipated as a result of enforcing these proposed sections will be to remove redundant language from rules, simplify the rules, and make the rules easier to understand.

Mr. Freshour has also determined that for the first five-year period these proposed repeals and new sections are in effect, there will be no fiscal impact or effect on government growth as a result of enforcing the proposed sections.

Mr. Freshour has also determined that for the first five-year period these proposed repeals and new sections are in effect there will be no probable economic cost to individuals required to comply with these proposed sections.

Pursuant to Texas Government Code §2006.002, the agency provides the following economic impact statement for these proposed repeals and new sections and determined that for each year of the first five years these proposed repeals and new sections will be in effect there will be no effect on small businesses, micro businesses, or rural communities. The agency has considered alternative methods of achieving the

purpose of these proposed repeals and new sections and found none.

Pursuant to Texas Government Code §2001.024(a)(4), Mr. Freshour certifies that this proposal has been reviewed and the agency has determined that for each year of the first five years these proposed repeals and new sections are in effect:

(1) there is no additional estimated cost to the state or to local governments expected as a result of enforcing or administering these proposed repeals and new sections;

(2) there are no estimated reductions in costs to the state or to local governments as a result of enforcing or administering these proposed repeals and new sections;

(3) there is no estimated loss or increase in revenue to the state or to local governments as a result of enforcing or administering these proposed repeals and new sections; and

(4) there are no foreseeable implications relating to cost or revenues of the state or local governments with regard to enforcing or administering these proposed repeals and new sections.

Pursuant to Texas Government Code §2001.024(a)(6) and §2001.022, the agency has determined that for each year of the first five years these proposed repeals and new sections will be in effect, there will be no effect on local economy and local employment.

Pursuant to Government Code §2001.0221, the agency provides the following Government Growth Impact Statement for these proposed repeals and new sections. For each year of the first five years these proposed repeal and new sections will be in effect, Mr. Freshour has determined the following:

(1) These proposed repeals and new sections do not create or eliminate a government program.

(2) Implementation of these proposed repeals and new sections does not require the creation of new employee positions or the elimination of existing employee positions.

(3) Implementation of these proposed repeals and new sections does not require an increase or decrease in future legislative appropriations to the agency.

(4) These proposed sections do not require an increase or decrease in fees paid to the agency.

(5) These proposed repeals and new sections do not create new regulations.

(6) These proposed repeals and new sections do repeal existing regulations as described above. These proposed new sections do not expand or limit an existing regulation.

(7) These proposed repeals and new sections do not increase the number of individuals subject to the sections' applicability.

(8) These proposed repeals and new sections do not positively or adversely affect this state's economy.

Comments on the proposal may be submitted using this link: https://forms.office.com/g/7RY3QA7SbK. A public hearing will be held at a later date. Comments on the proposal will be accepted for 30 days following publication.

The repeal of the rules is proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to recommend and adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine; and enforce this subtitle. The repeal of the rules is also proposed in accordance with the requirements of Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for readoption, readoption with amendments, or repeal every four years. No other statutes, articles or codes are affected by this proposal.

<rule>

172.1 Purpose
§172.2 Construction and definitions
§172.3 Distinguished Professors Temporary License
§172.4 State Health Agency Temporary License
§172.5 Visiting Physician Temporary Permit
§172.6 Visiting Professor Temporary License
§172.7 National Health Service Corps Temporary License
§172.8 Faculty Temporary License
§172.9 Postgraduate Research Temporary License
§172.10 Department of State Health Services Medically Underserved Area (DSHS-MUA) Temporary License
§172.11 Temporary Licensure—Regular
§172.12 Out-of-State Telemedicine License
§172.13 Conceded Eminence
§172.15 Public Health License
§172.16 Provisional Licenses for Medically Underserved Areas
§172.17 Limited License for Practice of Administrative Medicine
§172.18 Military Limited Volunteer License
§172.19 Sports Team Physician Limited License
§172.20 Physician Practice and Limited License for Disasters and Emergencies
§172.21 Other Health Care Providers Practice and Limited License for Disasters and Emergencies

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The new rules are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to recommend and adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine; and enforce this subtitle. The new rules are also proposed in accordance with the requirements of Chapter 168 of the Texas Occupations Code. The new rules are also proposed in accordance with the requirements of Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for readoption, readoption with amendments, or repeal every four years. No other statutes, articles or codes are affected by this proposal.

<rule>

§172.1. Definitions.

Pain management clinics at which a majority of patients are treated for chronic pain are subject to Chapter 168 of the Act, unless otherwise exempted. In determining if the clinic is treating a majority of patients

for chronic pain, one of the primary indicators is the prescribing of opioids. The board will utilize the following definitions in making that determination:

(1) Acute pain--the normal, predicted, physiological response to a stimulus such as trauma, disease, and operative procedures. Acute pain is time limited to no later than 30 days from the date of the initial prescription for opioids during a period of treatment related to the acute condition or injury. Acute pain does not include, chronic pain, pain being treated as part of cancer care; pain being treated as part of hospice or other end-of-life care; pain being treated as part of palliative care; or post-surgical, post-procedure, or persistent non-chronic pain.

(2) Chronic pain--pain that is not relieved with acute, post-surgical, post-procedure, or persistent non-chronic pain treatment. This type of pain is associated with a chronic pathological process that causes continuous or intermittent pain for no less than 91 days from the date of the initial prescription for opioids. Medical practices treating this type of pain patient may be subject to Chapter 168 of the Act.

(3) Post-surgical, post-procedure, persistent non-chronic pain--pain that occurs due to trauma caused by the surgery or procedure; or an underlying condition, disease, or injury causing persistent non-chronic pain. These types of pain last 90 days or less, but more than 30 days, from the date of initial prescriptions for opioids during a period of treatment.

§172.2. Gold Designated Practice.

(a) A clinic may apply to be designated as a "Gold Designated Practice." In order to be eligible for a "Gold Designated Practice" status, a clinic must:

(1) complete a board-approved application form;

(2) provide a Medical Home Agreement, written collaborative, coordinated care agreement or memorandum of understanding to provide management and treatments of pain, that describes measures that it provides and may be used for reduction of pain such as, but not limited to:

(A) multimodal treatment such as surgery, injections, pain pumps, osteopathic manipulation, epidurals, trigger point injections, dry needling, and topical creams or patches;

(B) multi-disciplinary practices such as medication assisted tapering and weaning, computer-based training pain coaching, acupuncture, chiropractic, physical therapy, massage, and exercise/movement; or

(C) collaborative care or other behavioral health integration services such as evidenced-based cognitive behavioral therapy interventions for mental health and pain reduction, medication management and opioid weaning, patient-centered education, regular monitoring and assessments of clinical status using validated tools, assessment of treatment adherence, motivational interviewing, and a structured approach to improving the biopsychosocial aspects of pain management; and

(3) In addition to providing a Medical Home Agreement, written collaborative, coordinated care agreement, or memorandum of understanding to provide management and treatments of pain described above, the clinic must either:

(A) meet the standards for exemption under §168.002(7) of the Act, including the clinic being operated by a majority of physicians who currently hold or previously held ABMS or AOA board-certification or

subspecialty certification in pain management; and

(i) have a majority of physicians performing or properly supervising delegates in providing other forms of treatment besides qualifying pain management prescriptions to a majority of the patients at the clinic;

(ii) utilization by the clinic's providers of a Medical Home Agreement signed by the primary prescriber and the patient; or

(iii) have a written collaborative, coordinated care agreement or a memorandum of understanding with the patient's primary physician for treating and managing the patient; or

(B) be a Certified Pain Management Clinic (PMC) that is operated by physicians who previously held an ABMS or AOA Board-certification or sub-specialty in pain management or hold a ABMS or AOA Board-certification in an area that is eligible for a pain management subspecialty; and

(i) have a Medical Home Agreement signed by the primary prescriber and the patient; or

(ii) have a written collaborative, coordinated care agreement or memorandum of understanding providing that each physician who prescribes qualifying prescriptions will consult with a pain specialist for the patient.

(b) The designation may be verified by an initial audit and is valid for five years.

(c) No further audits or inspections will be conducted during the five-year "Gold Designated Practice" period, unless:

(1) a complaint is received or initiated by the board concerning operation of the clinic or operators at the clinic;

(2) the clinic changes location; or

(3) the clinic's ownership structure changes to a majority of new owners.

(d) Practices that only treat pain patients as part of cancer care or that provide only palliative care, hospice, or other end-of-life care are exempt under the Act from certification requirements as a PMC, but do not qualify for the "Gold Designated Practice" status.

§172.3. Certification of Pain Management Clinics.

(a) Any clinic meeting the definition of a pain management clinic under §168.001 of the Act must be certified.

(b) Certification requires:

(1) a board-approved application filed by a physician owner of the clinic. If there are multiple physician owners, the application must be filed by one of the majority of owners, or if there are no majority owners, then each physician owner is responsible for designating one physician owner to file an application.

(2) submission of the following documentation:

(A) proof of ownership of the clinic, which may include filing with county clerks, the Comptroller and Secretary of State, as applicable;

(B) days and hours of operation;

(C) name of medical director;

(D) list of employees, including contract physicians and other healthcare providers, and their applicable education, qualifications, training and professional licenses;

(E) protocols and standing delegation orders issued by licensed physicians to healthcare providers; and

(F) proof of payment of the required filing fee.

(c) The Executive Director (ED) or the ED's designee reviews all applications. After reviewing the applications, the ED will send a notice of determination to the applicant which includes the ED's determination. If the application is denied, then the ED will provide the information regarding the right to appeal.

(d) Before 180 days after the expiration of the clinic's certificate, a clinic seeking renewal must submit:

(1) a board-approved application;

(2) documentation that establishes all providers at the clinic involved in any part of patient care have completed at least ten hours of continuing education related to pain management in the preceding two years; and

(3) the required renewal fees.

(e) If there is any investigation pending with the board against any owner or certificate holder at the time of renewal, a provisional renewal will be issued until the investigation is resolved.

(f) Initial applications are valid for one year from the date filed, unless expressly extended by board staff.

(g) All records relating to an application or renewal of certification are considered investigative information and are confidential under §164.007 of the Act.

(h) A request to cancel a certificate must be accompanied by proof that the clinic no longer meets the definition of a pain management clinic under §168.001 of the Act.

§172.4. Minimum Operational Standards for the Treatment of Pain Patients.

(a) Physicians treating a pain patient must:

(1) operate in compliance with provisions of all applicable federal and state laws;

(2) follow the standard of care; and

(3) maintain complete, contemporaneous, and legible medical records, in the same manner as a non-pain patient, and include documentation of:

(A) monitoring efficacy, daily functionality, description of pain relief;

(B) mandatory PMP checks;

(C) pain contracts, if applicable;

(D) support for billing; and

(E) drug testing results and other forms of monitoring for patient compliance with treatment recommendations.

(b) For pain patients transferring their care to a new treating physician at a Gold Designated Practice, the following applies:

(1) The new treating physician must:

(A) document an initial problem focused exam;

(B) document a PMP check; and

(C) request medical records from the prior treating physician(s) within 15 business days of seeing the patient.

(2) The new physician may provide only a one-time 30-day maximum non-refillable prescription of pain medication at the initial visit.

(3) If the requested medical records are not received within 15 business days after the initial request, the physician must perform the following before issuing any other prescriptions for pain treatment to the patient:

(A) a complete history and physical, including assessment of abuse or diversion potential;

(B) diagnostic testing and obtain the results to verify pain sources or etiology, if applicable;

(C) drug testing; and

(D) a PMP check.

§172.5. Audits, Inspections, and Investigations.

(a) Audits.

(1) Audits are non-disciplinary reviews:

(A) conducted as an off-site document review; and

(B) initiated by a board subpoena request for documents as necessary to determine or verify:

(i) exemption from application of Chapter 168 of the Act;

(ii) need to certify as a PMC; or

(iii) no certification requirement.

(2) A total of 30 patients' records will be reviewed during an audit. The relevant portions of the 30 records to be reviewed are the initial visit; last two office visits; referrals; procedures notes/logs; consultation requests; consult notes, and prior authorization records, if any. These records will be a combination of new patients seen in one of the last two calendar months and established patients seen in the previous six calendar months with a minimum of 10 records for each type.

(3) Documents requested may also include those used to verify personnel training, qualifications, and general compliance with Chapter 168 of the Act and related rules.

(4) Upon completion of the audit, the board will issue a notice of determination to the audited clinic owner. The notice of determination will specify:

(A) Deficiencies, if any; and

(B) If necessary, any corrective actions the clinic must take, including a requirement to apply for certification.

(b) Inspections.

(1) Inspections are non-disciplinary reviews:

(A) done on both certified and non-certified clinics in accordance with §168.052 of the Act; and

(B) usually conducted on-site but may also be off-site, as determined by board staff.

(2) The following patient records will be reviewed during an inspection, as determined by board staff: patients seen during two calendar months out of the previous eight months from the date of the inspection.

(3) For certified pain management clinics, inspections are conducted to verify compliance with Chapter 168 of the Act and the applicable laws and rules.

(4) For non-certified clinics, inspections are conducted to determine if the clinic is subject to be certified under Chapter 168 of the Act.

(5) In accordance with §168.052(b) of the Act, to initiate an inspection the board has determined the following grounds can be utilized, but are not limited to:

(A) PMP reports;

(B) patient population analysis, including review of patients coming from outside the immediate

geographic location of the clinic;

(C) common addresses for multiple patients;

(D) notices to providers from the Pharmacy Board regarding a patient having multiple prescribing providers;

(E) complaints about the clinic and its operation; and

(F) law enforcement reports regarding providers or patients.

(6) Notice of intent to inspect will be provided at least five days in advance unless such timing would compromise the inspection.

(7) Notice of inspection results will be provided in writing to the clinic.

(8) If the inspection determines instances of non-compliance, the board will determine appropriate action to obtain compliance.

(c) Investigations may be conducted due to a complaint received or initiated by the board. An investigation will be conducted in accordance with the provisions of this Title and all applicable board rules.