The Texas Medical Board (Board) proposes the repeal of current Chapter 170, concerning Prescription of Controlled Substances. This includes Subchapter A, concerning Pain Management, §§170.1 – 170.3; Subchapter B, concerning Utilization of Opioid Antagonists, §§170.4 – 170.8; Subchapter C, concerning Prescription Monitoring Program Check, §170.9; and Subchapter D, concerning Electronic Prescribing of Controlled Substances, §170.10.

The Board also proposes new Chapter 170, concerning Standards for Use of Investigational Agents. This includes new Subchapter A, concerning Standards for Use of Investigational Drugs, Biological Products, or Devices, §170.1, and Subchapter B, concerning Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases or Terminal Illnesses, §170.5 and §170.6.

Also, the Board contemporaneously proposes the repeal of current Chapter 198, concerning Standards For Use of Investigational Agents. This includes Subchapter A, concerning Standards For Use of Investigational Drugs, Biological Products, Or Devices, §§198.1 – 198.4; and Subchapter B, concerning Investigational Stem Cell Treatments For Patients With Certain Severe Chronic Diseases Or Terminal Illnesses, §198.5 and §198.6.

The Board has determined that due to the extensive reorganization of Chapters 160-200, repeal of Chapter 170 is more efficient than proposing multiple amendments to make the required changes.

The proposed new subchapters and sections are as follows:

SUBCHAPTER A. STANDARDS FOR USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.
New §170.1, General Standards for Use of Investigational Agents, explains the standards required of a physician who administers or provides for the use of investigational agents, drugs, biological products, or devices.

SUBCHAPTER B. INVESTIGATIONAL STEM CELL TREATMENTS FOR PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES.
New §170.5, General Standards for the Use of Investigational Stem Cell Treatments for Patients with Severe Chronic Diseases or Terminal Illnesses, explains the standard required of a physician who administers or provides for the use of Investigational Stem Cell treatments in patients.
New §170.6, Annual Reporting of Clinical Trial of Investigational Stem Cell Treatments, outlines reports required to be submitted to the board by IRBs overseeing clinical trials of investigational stem cell treatments.

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 repeals 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/dN5CVcxeKm. 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>

§170.1. Purpose.

§170.2. Definitions.
§170.3. Minimum Requirements for the Treatment of Chronic Pain.

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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>

§170.4. Purpose.
§170.5. Definitions.
§170.6. Opioid Antagonist Prescription Guidelines.
§170.7. Liability for Act or Omission with Respect to Prescribing an Opioid Antagonist.
§170.8. Documentation.

*n

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>

§170.9. Prescription Monitoring Program Check.

*n

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>

§170.10. Electronic Prescribing of Controlled Substances.

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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 the 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>

SUBCHAPTER A. STANDARDS FOR USE OF INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, OR DEVICES.

§170.1. General Standards for Use of Investigational Agents.

(a) Pursuant to Chapter 489 of the Texas Health and Safety Code, a physician who administers or provides for the use of investigational drugs, biological products, or devices must:

(1) comply with all applicable state and federal laws and rules;

(2) meet the standard of care;

(3) comply with ethical standards including Declaration of Helsinki and the Belmont Report;

(4) maintain adequate medical records; and

(5) document the proposed investigational agent to be used:

(A) is included in an FDA/NIH approved protocol or study; or

(B) is approved by an Institutional Review Board (IRB) meeting standards under subsection (b) of this section.

(b) The approving IRB must be:

(1) affiliated with an academic setting or a Texas-licensed hospital;

(2) accredited by the Association for the Accreditation of Human Research Protection Programs, Inc.

(3) registered by the U.S. Department of Health and Human Services Office for Human Research Protection, pursuant to 21 CFR Part 56; or

(4) accredited by a national accrediting organization recognized by the board.

*n

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 the 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>

SUBCHAPTER B. INVESTIGATIONAL STEM CELL TREATMENTS FOR PATIENTS WITH CERTAIN SEVERE CHRONIC DISEASES OR TERMINAL ILLNESSES.

§170.5. General Standards for the Use of Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases or Terminal Illnesses.

In accordance with Chapter 1003 of the Texas Health and Safety Code, physicians who administer or provide for the use of investigational stem cell treatments must:

(1) comply with all applicable state and federal laws and rules;

(2) be certified to administer stem cell in accordance with §1003.055 of the Texas Health and Safety Code;

(3) ensure the patient is enrolled in a clinical trial investigating the use of adult stem cells in humans;

(4) maintain adequate medical records including documentation of the patient's qualifying severe chronic disease or terminal illness;

(5) obtain a signed written informed consent including the patient eligibility determination found in §1003.053(2)(a) of the Texas Health and Safety Code; and

(6) provide stem cells in a qualifying facility.

§170.6. Annual Reporting of Clinical Trial of Investigational Stem Cell Treatments.

(a) In accordance with Chapter 1003 of the Texas Health and Safety Code, each IRB overseeing clinical trials of investigational stem cell treatments must submit an annual report to the board that:

(1) sets forth the study's current findings;

(2) specifies the number of patients participating in the trial(s);

(3) documents the treatment results for patients, as applicable;

(4) generally describes the effects of the treatments including all adverse events;

(5) outlines the study's findings to date;

(6) identifies the medical school or hospital the IRB is affiliated with;

(7) provides the location where the patients' treatments were provided in accordance with §1003.055 of the Texas Health and Safety Code; and

(8) includes the names of all physicians certified by the IRB or the affiliated entity and the time-period of that certification.

(b) The annual report shall not include any patient identifying information.

(c) The annual report shall cover the time period beginning September 1 and ending on August 31.

(d) The report must be submitted to the board before the end of the calendar year in which the reporting time period ends.