

Rule Changes Effective July 19, 2018

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RULE CHANGES ADOPTED

CHAPTER 185. PHYSICIAN ASSISTANT

The amendments to **§185.4**, concerning Procedural Rules for Licensure Applicants, eliminates the requirement for applicants to have good moral character and adds language requiring applicants to submit to a criminal background check. These changes are based on the passage of SB 1625 (85th Regular Session), which amended §204.153 and §204.1525 of the Physician Assistant Licensing Act. The amendment also eliminates obsolete language referring to "surgeon assistants."

The amendment to **§185.6**, concerning Annual Renewal of License, changes registration of physician assistants to biennial instead of annual. The change also adds language to require applicants to submit to a criminal background check and includes new language providing that the Board may refuse to renew a license if the licensee is not in compliance with a Board Order. These changes are based on the passage of SB 1625 (85th Regular Session), which amended §§204.1525, 204.156 and 204.158 of the Physician Assistant Licensing Act.

The amendment to **§185.8**, concerning Inactive License, changes the reference to "annual" registration to "biennial" registration. This change is based on the passage of SB 1625(85th Regular Session), which amended §204.156 of the Physician Assistant Licensing Act.

The amendment to **§185.14**, concerning Physician Supervision, changes the reference to "annual" registration to "biennial" registration. This change is based on the passage of SB 1625 (85th Regular Session), which amended §204.156 of the Physician Assistant Licensing Act.

The amendment to **§185.17**, concerning Grounds for Denial of Licensure and for Disciplinary Action, adds language that provides the Board may refuse to renew a license if the licensee is not in compliance with a Board Order. This change is based on the passage of SB 1625 (85th Regular Session), which amended §204.158 of the Physician Assistant Licensing Act.

The amendment to **§185.31**, concerning Prescriptive Authority Agreements: Minimum Requirements, deletes language requiring face to face meetings as part of quality assurance and improvement plans. These changes are based on the passage of SB 1625 (85th Regular Session), which amended §157.0512 of the Medical Practice Act.

CHAPTER 198. STANDARDS FOR USE OF INVESTIGATIONAL AGENTS

The adoption of amendments to **§§198.1 - 198.4** and new **§198.5** and **§198.6**, concerning Standards for Use of Investigational Agents, amends Chapter 198 by dividing Chapter 198 into two separate subchapters, and adding Subchapter A, "Standards for Use of Investigational Drugs, Biological Products, or Devices" in an effort to distinguish the applicability of the provisions contained in Subchapter A and those provisions contained in new Subchapter B. Subchapter A contains amendments to §§198.1 - 198.4.

The amendment to **§198.1**, concerning Purpose, removes the word "agents" and replaces it with the terms "drugs, biological products, or devices" in order to align with statutory language contained in Health and Safety Code Chapter 489. It also includes new language to distinguish the applicability of Subchapter A and to differentiate Subchapter B.

The amendment to **§198.2**, concerning Definitions, removes the definition of "investigational agent" and defines the terms "drugs, biological products, or devices" and "terminal illness." These changes are consistent with the definitions and terms used in the Texas Health and Safety Code Chapter 489. The changes also include limiting language to clarify that such definitions are not applicable to Subchapter B.

The amendments to **§198.3**, concerning Practice Guidelines for the Use of Investigational Agents, removes the term "agent" throughout the section and includes the terms "drugs, biological products, or devices" in line with statutory language contained in Health and Safety Code, Chapter 489.

The amendments to **§198.4**, concerning Use of Investigational Agents for Patients with Terminal Illnesses, changes the title of this section by removing the term "agent" and replacing it with the terms "drugs, biological products, or devices" in order to correspond with statutory terms in Chapter 489 of the Texas Health and Safety Code. The remainder of this section is deleted, as it is contained in Chapter 489 of the Health and Safety Code.

New **Subchapter B**, "**Investigational Stem Cell Treatments for Patients With Certain Severe Chronic Diseases or Terminal Illnesses**" to distinguish the provisions contained therein with those provisions contained in Subchapter A. Subchapter B, contains new §198.5 and §198.6.

New **§198.5**, concerning Use of Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases or Terminal Illnesses, implements the requirements of House Bill 810, 85th Leg. R.S. (2017) which establishes the regulation of investigational stem cell treatments in Texas as set forth in Chapter 1003 of the Texas Health and Safety Code.

New **§198.6**, concerning Process and Procedures for IRBs Engaged in the Use of Investigational Stem Cell Treatments for Patients with Certain Severe Chronic Diseases or Terminal Illnesses, implements the requirements of House Bill 810, 85th Leg. R.S. (2017) which establishes the regulation of investigational stem cell treatments in Texas through statutory changes in Chapter 1003 of the Texas Health and Safety Code.