

BILL ANALYSIS

C.S.S.B. 2040
By: Springer
Public Health
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Willed body programs allow adults to donate their deceased bodies to further education and research. These programs serve as a primary resource for institutions of higher education and other health professions by ensuring affordable access to cadavers, which are essential for teaching and training. The Anatomical Board of the State of Texas oversees the distribution of these donated or unclaimed deceased bodies to approved institutions of higher education for use in medical or forensic science education and research. The anatomical board does not receive any state appropriations and does not have authority to hire staff. Following its first review of the anatomical board in more than 35 years during the 2020-2021 review cycle, the Sunset Advisory Commission found that the anatomical board cannot provide effective oversight or adhere to regulatory best practices in its current form. This is particularly true given the emergence of new participants in the whole body donation field that are commercial and sometimes for-profit in nature. These participants, known as non-transplant anatomical donation organizations (NADOs), are now doing the same or similar things in Texas as are the more traditional higher education body donation programs. However, outdated statutory language does not fully account for the existence of NADOs and as such the state cannot effectively oversee them.

C.S.S.B. 2040 seeks to abolish the anatomical board as a standalone state agency and transfer its functions to the Texas Funeral Service Commission (TFSC) with certain statutory modifications aimed at addressing the issues identified by the sunset commission, while reconstituting the anatomical board as an advisory committee to the TFSC.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the Texas Funeral Service Commission in SECTIONS 1.06, 1.08, 1.14, 1.17, and 1.20 of this bill.

ANALYSIS

Abolition of Anatomical Board; Transfer of Powers and Duties; Transition

C.S.S.B. 2040 abolishes the Anatomical Board of the State of Texas as a standalone state agency tasked with overseeing and regulating the distribution of donated or unclaimed deceased bodies and anatomical specimens to board-approved institutions of higher education for use in medical education, research, and training. The bill amends the Occupations Code to transfer this function instead to the Texas Funeral Service Commission (TFSC) and to provide also for the regulation by the TFSC of non-transplant anatomical donation organizations (NADOs) and anatomical

facilities. For these purposes, the bill adds definitions to the Health and Safety Code to specify that:

- a "non-transplant anatomical donation organization" is a person accredited to engage in the recovery, receipt, screening, testing, processing, storage, or distribution of tissue or human remains for any purpose other than transplantation into a living individual in Texas; and
- an "anatomical facility" is a facility in Texas inspected and approved by the TFSC to use bodies and anatomical specimens that does not otherwise operate as a willed body program (WBP) or a NADO.

Moreover, the bill codifies in the Health and Safety Code a definition of "willed body program" for use as a descriptor for the donation programs operated by institutions of higher education and updates references in statute accordingly. The codified definition for "willed body program" is a program operated at an institution of higher education in Texas that allows a living individual to donate the individual's body or anatomical specimen for educational or research purposes.

C.S.S.B. 2040 continues the anatomical board in existence until September 1, 2024, on which date the board members' terms expire, for the sole purpose of transferring obligations, property, rights, powers, and duties to the TFSC as they exist immediately before the bill's effective date. The bill sets out additional provisions relating to that transfer, among them provisions for the following:

- consultation with appropriate state entities regarding the transfer to ensure the transfer is completed not later than September 1, 2024;
- the continuation in effect of anatomical board rules adopted under the board's rulemaking authority as TFSC rules until superseded by the applicably adopted TFSC rules;
- the continuation in effect of an authorization issued by the anatomical board as provided by the law in effect immediately before the bill's effective date;
- the continuation of an authorization, complaint, investigation, or proceeding pending on the bill's effective date without change in status; and
- the transfer of all unexpended and unobligated funds under board management to the general revenue fund for the TFSC's administration of the transferred duties.

The bill clarifies that a reference to the anatomical board in a law or administrative rule means the TFSC. The bill requires the TFSC, for state fiscal year 2024, to quarterly prepare and submit to the lieutenant governor, the speaker of the house of representatives, the Sunset Advisory Commission, and each standing committee of the legislature with primary jurisdiction over the TFSC a report on the progress of the transfer. Not later than December 1, 2024, the TFSC must submit to the sunset commission and each standing committee of the legislature with primary jurisdiction over the TFSC any legislative recommendation necessary to improve the TFSC's administration of state law governing the donation of bodies and anatomical specimens.

State Anatomical Advisory Committee

C.S.S.B. 2040 amends the Health and Safety Code to create the State Anatomical Advisory Committee to advise and provide expertise to the TFSC on matters related to the regulation and operation of WBPs, NADOs, and anatomical facilities in Texas. The advisory committee is composed of seven members appointed by the TFSC as follows:

- two members who represent institutions of higher education that operate WBPs;
- two members who represent NADOs;
- two members who represent anatomical facilities; and
- one public member.

The bill revises provisions applicable to the former anatomical board to reflect the transfer of regulatory authority to the TFSC and the creation of that new advisory committee.

C.S.S.B. 2040 does the following with respect to the advisory committee:

- establishes two-year terms of office for advisory committee members, with an authorization for members to be reappointed;
- requires the TFSC to appoint advisory committee members not later than the 60th day after the bill's effective date and provides for the holdover of members of the former anatomical board until a majority of the advisory committee's members are appointed;
- clarifies that anatomical board members may be appointed to the advisory committee if they are otherwise eligible; and
- exempts the advisory committee from Government Code provisions relating to the composition and duration of state agency advisory committees.

Regulation of Donation and Use of Bodies and Anatomical Specimens

C.S.S.B. 2040 includes NADOs among the entities to which an adult living in Texas who is of sound mind may donate their body by will or other written instrument for use in advancing medical or forensic science.

C.S.S.B. 2040 establishes an informed consent requirement for a will or other instrument conveying a donor's intent to donate to be considered effective. The bill requires the will or other instrument to also clearly convey the donor's acknowledgment that the donor was informed about the following:

- the consequences of the donation before providing consent;
- the use the donee plans for the donated body parts; and
- if applicable, any body part and the condition in which the body part will be returned to the person designated by the donor.

The donor must be informed in writing about such information in a clear manner on a single piece of paper that is 8-1/2 by 11 inches with 14-point type. The bill requires the TFSC by rule to design and adopt a form that complies with those specifications that WBPs and NADOs must use.

C.S.S.B. 2040 authorizes the TFSC to receive, distribute, and transfer a body or anatomical specimen from inside or outside of Texas. The bill includes anatomical facilities among the entities to which the TFSC or its representative may distribute donated bodies and specifies that a body or anatomical specimen donated to a registered NADO is not subject to redistribution.

C.S.S.B. 2040 includes NADOs and anatomical facilities among the entities authorized to use, dissect, operate on, examine, and experiment on a body or anatomical specimen that has been distributed by the TFSC. The bill subjects NADOs to the recordkeeping requirements for WBPs and other persons that receive a body or anatomical specimen and expands the scope of the recordkeeping requirement to provide that the records must track the body or specimen from intake to final disposition.

Regulation and Registration of Applicable Persons and Entities

C.S.S.B. 2040 requires a WBP and a NADO to register with the TFSC in the form and manner prescribed by the TFSC in order to legally operate in Texas.

C.S.S.B. 2040 establishes that, to be eligible for registration, a NADO must be accredited by the American Association of Tissue Banks (AATB) under its Standards for Non-Transplant Anatomical Donation. The bill authorizes the TFSC to issue conditional registration to a NADO that is not yet accredited and requires a registered NADO to inform the TFSC within the time prescribed by TFSC rule if the NADO loses its AATB accreditation. The bill requires the TFSC to establish a process to periodically verify a NADO's compliance with the AATB Standards for Non-Transplant Anatomical Donation. The process may authorize the TFSC to inspect a NADO but may not be duplicative of the accreditation process or occur more frequently than once every five years.

C.S.S.B. 2040 prohibits a TFSC member or the holder of any license issued by the TFSC from holding an ownership interest in a registered NADO.

C.S.S.B. 2040 subjects anatomical facilities to inspection by the TFSC along with WBPs, which is a prerequisite to being approved to receive and use bodies and anatomical specimens, and removes the language subjecting other persons to inspection. The bill provides for the investigation and discipline of NADOs and anatomical facilities on the same basis as WBPs and other persons authorized to receive and use or dissect bodies or anatomical specimens. While NADOs are not subject to mandatory inspections, the bill authorizes the TFSC to inspect a NADO as part of such an investigation.

C.S.S.B. 2040 requires the TFSC to adopt rules and procedures necessary to administer the provisions relating to the regulation and registration of persons and institutions using bodies and anatomical specimens.

Fees

C.S.S.B. 2040 replaces the authorization for the anatomical board to set and collect reasonable and necessary fees for receiving and distributing bodies and anatomical specimens with an authorization for the TFSC by rule to set and collect fees in amounts reasonable and necessary to cover the cost of administering state law governing the donation of bodies and anatomical specimens, including fees for the following:

- receiving and distributing bodies and anatomical specimens;
- conducting inspections and other verification activities; and
- registering WBPs and NADOs.

The bill exempts a NADO from a fee for receiving and distributing bodies and anatomical specimens.

Administration and Enforcement Authority

C.S.S.B. 2040 provides the following with respect to the TFSC's general duties relating to the donation of bodies and anatomical specimens:

- the requirement for the TFSC to distribute bodies and anatomical specimens to persons authorized to receive a body or specimen under the law does not apply to a body or specimen donated to a NADO;
- the TFSC must adopt rules, establish procedures, and prescribe forms necessary to administer and enforce provisions governing the donation of bodies and anatomical specimens, including rules establishing registration and inspection requirements and procedures; and
- the TFSC may issue a reprimand, assess an administrative penalty, impose other penalties, or revoke, suspend, or probate a registration or other authorization for a violation of provisions governing the donation of bodies and anatomical specimens or a TFSC rule adopted under those provisions, including a violation related to an inspection conducted in the applicable manner provided under state law regarding crematory services, funeral directing, and embalming.

The bill replaces the requirement for the anatomical board to adopt rules ensuring that each body and anatomical specimen in the custody of the board or an institution represented on the board is treated with respect with a requirement for the TFSC to adopt rules to ensure that each body and anatomical specimen is treated with respect while in the custody of the TFSC or the person authorized to receive the body or specimen.

Complaint Status Notifications

C.S.S.B. 2040 changes the frequency with which the parties to a complaint relating to the donation of bodies or anatomical specimens must be notified of the complaint status from at least quarterly to periodically.

Informational Documents

C.S.S.B. 2040 replaces the requirement for the anatomical board to develop and post online a document to inform a person making a gift of a decedent's body or anatomical specimen for purposes of education, including forensic science education, or research of the risks and benefits associated with donation with a requirement for the TFSC to develop and post online a document to inform a person making a gift of a decedent's body or anatomical specimen about the options for donation authorized under applicable state law.

Transportation of Bodies and Anatomical Specimens

C.S.S.B. 2040 replaces the requirement for the anatomical board to adopt rules ensuring that each body or anatomical specimen received or distributed by the board is properly transported with a requirement for the TFSC to adopt rules to ensure that each body or anatomical specimen received or distributed under applicable state law is properly transported. Additionally, the bill replaces the requirement to adopt rules ensuring that a label that contains the specific statement "CONTENTS DERIVED FROM DONATED HUMAN TISSUE" is affixed to the container in which a body or anatomical specimen is transported with a requirement to adopt rules ensuring that a label with a statement that the container's contents are derived from human tissue is affixed to the container.

Conforming Changes; Repealed Provisions

C.S.S.B. 2040 amends the Code of Criminal Procedure and Government Code to make conforming changes.

C.S.S.B. 2040 repeals the following provisions of the Health and Safety Code:

- Section 691.003;
- Section 691.004;
- Section 691.005;
- Section 691.006;
- Sections 691.007(a), (b), and (d);
- Sections 691.008(b) and (d);
- the headings to Sections 691.007 and 691.008; and
- Section 691.009.

EFFECTIVE DATE

September 1, 2023.

COMPARISON OF SENATE ENGROSSED AND SUBSTITUTE

While C.S.S.B. 2040 may differ from the engrossed in minor or nonsubstantive ways, the following summarizes the substantial differences between the engrossed and committee substitute versions of the bill.

With respect to the TFSC's fee-setting authority, the substitute revises the provisions of the engrossed as follows:

- whereas the engrossed authorized the fees set and collected by the TFSC to include fees for conducting inspections of WBPs and anatomical facilities, the substitute authorizes the fees set and collected to include fees for conducting any inspections and any other verification activities as authorized under applicable state law; and
- whereas the engrossed provided only for the fees established for the registration of WBPs and NADOs to be set through the rulemaking process, the substitute provides for any

fees established by the TFSC relating to the donation of bodies and anatomical specimens to be set and collected through the rulemaking process.

Whereas the engrossed provided for mandatory inspections by the TFSC of WBPs, anatomical facilities, and other persons before approval to receive and use bodies and anatomical specimens, the substitute provides only for the mandatory inspection of WBPs and anatomical facilities. Moreover, whereas the engrossed exempted a registered NADO from inspection, the substitute does not. Instead, the substitute includes provisions requiring the TFSC to establish a process to periodically verify a NADO's compliance with the AATB's Standards for Non-Transplant Anatomical Donation and providing that the process:

- may authorize the TFSC to inspect a NADO; and
- may not be duplicative of the accreditation process or occur more frequently than once every five years.