

SUNSET ADVISORY COMMISSION

STAFF REPORT WITH COMMISSION DECISIONS

Anatomical Board of the State of Texas

2022-23

88TH LEGISLATURE



SUNSET ADVISORY COMMISSION



Senator Charles Schwertner, M.D.
Chairman

Representative Justin Holland
Vice Chair

Senator Nathan Johnson

Representative Keith Bell

Senator Angela Paxton

Representative Terry Canales

Senator Charles Perry

Representative Travis Clardy

Senator Drew Springer, Jr.

Representative Craig Goldman

James “Jim” Lee, Public Member

Jeff Austin III, Public Member

Jennifer Jones
Executive Director

Cover photo: The Texas State Capitol was completed in 1888. With the Goddess of Liberty atop the dome, the Texas State Capitol Building is 19 feet taller than the U.S. Capitol Building in Washington, D.C. The photo shows the south facade of the Capitol. Photo Credit: Janet Wood

ANATOMICAL BOARD OF THE STATE OF TEXAS

SUNSET STAFF REPORT WITH COMMISSION DECISIONS
2022-23
88TH LEGISLATURE

HOW TO READ SUNSET REPORTS

For each agency that undergoes a Sunset review, the Sunset Advisory Commission publishes three versions of its staff report on the agency. These three versions of the staff report result from the three stages of the Sunset process, explained in more detail at [sunset.texas.gov/how-sunset-works](https://www.sunset.texas.gov/how-sunset-works). The current version of the Sunset staff report on this agency is noted below and can be found on the Sunset website at [sunset.texas.gov](https://www.sunset.texas.gov).

Sunset Staff Report

The first version of the report, the Sunset Staff Report, contains Sunset staff's recommendations to the Sunset Commission on the need for, performance of, and improvements to the agency under review.

CURRENT VERSION: Sunset Staff Report with Commission Decisions

The second version of the report, the Sunset Staff Report with Commission Decisions, contains the original staff report as well as the commission's decisions on which statutory recommendations to propose to the Legislature and which management recommendations the agency should implement.

Sunset Staff Report with Final Results

The third and final version of the report, the Sunset Staff Report with Final Results, contains the original staff report, the Sunset Commission's decisions, and the Legislature's final actions on the proposed statutory recommendations.

TABLE OF CONTENTS

| Page

Sunset Commission Decisions

..... A1

Summary of Sunset Staff Recommendations

..... 1

Board at a Glance

..... 5

Issue/Recommendations

1 The State Anatomical Board Cannot Continue to Effectively

Oversee Whole Body Donation in Texas 9

Appendixes

Appendix A — Anatomical Board Member Institutions 21

Appendix B — Regulatory Comparisons and Considerations Covering

Whole Body Donation 23

Appendix C — Staff Review Activities 27

SUNSET COMMISSION DECISIONS

Summary

Sunset reviewed the Anatomical Board of the State of Texas (SAB) during the 2020-21 biennium, but its Sunset bill did not pass during the 87th Legislative Session. Instead, the Legislature placed SAB under full Sunset review again in the 2022-23 biennium. In this second review of SAB, Sunset staff found many of the same previously identified problems and again determined while the state continues to have an interest in overseeing whole body donations, SAB cannot continue to perform this oversight effectively.

Instead of presenting definitive recommendations to the Sunset Commission, Sunset staff proposed a series of options to the commission and ultimately, the Legislature, to consider when determining the organizational and regulatory structure needed to best meet the needs of the state in overseeing whole body donation in Texas.

In January 2023, the Sunset Commission adopted a new recommendation raised during the commission meeting to transfer SAB's functions to the Texas Funeral Service Commission (TFSC) and clarify the regulation of whole body donation organizations unaffiliated with higher education institutions, known as non-transplant anatomical donation organizations (NADOs) in Texas. The following material summarizes the Sunset Commission's decision.

ADOPTED NEW RECOMMENDATION

Abolish the Anatomical Board of the State of Texas and transfer its functions to the Texas Funeral Service Commission.

- Establish a seven-member whole body donation advisory committee at TFSC, including two members from higher education institutions with willed body programs (WBPs), two members from NADOs, two members from anatomical facilities, and one public member.
- Require WBPs and NADOs to register with TFSC.
- Require registrants to obtain informed donor consent and require tracking and recordkeeping from intake to final disposition.
- Require NADOs to be accredited by the American Association of Tissue Banks and exempt NADOs from certain regulatory requirements, including inspections.
- Authorize TFSC to enforce Chapter 691 of the Texas Health and Safety Code and to establish fees for facility inspections.
- Prohibit TFSC members and licensees from owning more than a 10 percent interest in a NADO.
- Direct Sunset staff to work with the Texas Legislative Council, SAB, and TFSC to ensure these changes are accurately included in the Sunset legislation.

Fiscal Implication Summary

Overall, the Sunset Commission's recommendation is designed to clarify statute and increase the effectiveness of the regulation of whole body donation in Texas. However, the exact fiscal impact of the Sunset Commission's recommendation cannot be fully estimated at this time. While the recommendation would transfer SAB's fund balance to TFSC, the agency would incur costs to administer the regulation, which it should cover through fees in the future. The Legislature would determine the amount of funding for this regulation as part of the appropriations process in future years.

SUMMARY OF SUNSET STAFF REPORT

In Texas and many other states, adults can donate their deceased bodies to further medical research, education, and training. These donations serve as a primary resource of affordable cadavers and anatomical specimens for higher education institutions and other health professions. The Anatomical Board of the State of Texas (SAB) oversees the distribution of these donated bodies to the state's 13 Willd Body Programs (WBPs), forensic science institutions, and search and rescue training organizations. Currently, Texas statute also allows WBPs to transfer donated bodies and anatomical specimens to other board-inspected and approved facilities, including bioskills training facilities, medical device companies, search and rescue organizations, and other higher educational institutions that do not operate their own WBPs.

During the 2020-21 biennium, the Sunset Commission voted to abolish SAB as a stand-alone board, reconstitute it as an advisory committee, and transfer its functions to the Texas Funeral Service Commission (TFSC). However, House Bill 1565, the SAB Sunset bill, did not pass during the 87th Legislative Session. Instead, the Legislature passed Senate Bill 713, which continued SAB as a stand-alone board for two years and placed it under full Sunset review again in the 2022-23 biennium. As a result, SAB is currently subject to review and abolishment under the Sunset Act, so the Sunset Commission and 88th Legislature will need to take action to continue SAB and its functions.

This Sunset review again questioned the need for and effectiveness of the board's oversight and regulation, and considered alternative methods of performing needed functions. Sunset staff determined the state continues to have an interest in overseeing whole body donations, but SAB cannot continue to perform this oversight effectively or objectively for many reasons both within and outside the board's control. Internally, SAB is not statutorily authorized to hire staff and receives no appropriations, which results in the board going down inappropriate and unsustainable paths, such as board members performing facility inspections. Externally, as the previous review also noted, Texas statutes and regulations have not kept up with the changing nature of the whole body donation industry, creating regulatory gaps and uncertainty. Currently, Texas statutes do not clearly account for or regulate the donation of bodies and anatomical specimens to Non-Transplant Anatomical Donation Organizations (NADOs), including commercial, for-profit companies like Science Care. As a result of this statutory ambiguity, SAB had to request an attorney general opinion in 2019 to determine whether Science Care is authorized to operate in Texas and subject to SAB oversight.

Since this time, the whole body donation industry has continued to expand nationwide, and some other states have chosen to specifically regulate NADOs. While recommending regulation of NADOs is a policy decision Sunset staff

SAB cannot continue to effectively oversee whole body donation in Texas.

cannot make, this report provides a full picture of this rapidly changing and growing industry for the Sunset Commission and Legislature to have when considering how best to regulate this industry and its participants in Texas. Additionally, while Sunset staff would normally provide recommendations to help address SAB's internal challenges, staff cannot do this without the knowing what level of oversight and regulation the board should provide. As a result, this staff report takes a different approach from the prior review of SAB. Instead of recommendations, this staff report presents a series of options for the Sunset Commission and ultimately the Legislature to consider when determining whether SAB and its functions should be continued and if so, proposes different organizational and regulatory structures that could be considered to meet the needs of the state.

The following material summarizes Sunset staff's proposed options regarding the continuation of the Anatomical Board of the State of Texas.

Sunset Staff Issue and Proposed Options

ISSUE 1

The State Anatomical Board Cannot Continue to Effectively Oversee Whole Body Donation in Texas.

Because SAB is subject to abolishment under the Texas Sunset Act, if policymakers determine a continuing need for the board and its functions exists, both the Sunset Commission and Legislature will need to take action to reauthorize the board. However, the level of oversight and regulation of whole body donation needed in Texas and what the board's role should be in providing it is a policy decision. Therefore, Sunset staff provides, but takes no position on, the following options for the Sunset Commission's consideration. Regardless of whether the Sunset Commission chooses to adopt one of these options, it will need to determine whether or not the board should be continued and if so, recommend an appropriate Sunset review date.

Proposed Options

Option 1. Abolish SAB as a stand-alone board, reconstitute it as an advisory council to the Texas Higher Education Coordinating Board to coordinate and distribute whole body donations among higher education institutions, and remove the board's regulatory authority.

Option 2. Abolish SAB as a stand-alone board, reconstitute it as an advisory committee, and transfer its regulatory and administrative functions to the TFSC or another appropriate state agency.

Option 3. Restructure SAB as a fully resourced state agency, align its regulatory and administrative functions with best practices, and provide the resources necessary to administer its functions.

Option 4. Consider raising the policy question of if and how NADOs should be regulated in Texas for deliberation during the 88th Legislative Session.

Fiscal Implication Summary

Until the Sunset Commission adopts specific recommendations related to the continuation and functions of SAB, the fiscal implication cannot be estimated.

BOARD AT A GLANCE

Since 1907, the Anatomical Board of the State of Texas has facilitated the distribution of cadavers for the advancement of medical science.¹ Today, the board oversees the distribution of donated or unclaimed bodies and anatomical specimens to board-approved medical and forensic science institutions, and search and rescue training organizations for use in medical education, research, and training. The accompanying textbox provides several definitions relevant to the board and this review. To fulfill its mission, the board carries out the following key activities:

- Inspects and approves member institutions and facilities that request donated cadavers or anatomical specimens to ensure compliance with board standards.
- Collects fees for and records the receipt of whole body donations to willed body programs (WBPs) within the state, and approves transfers of donations to approved facilities both within and outside of Texas.
- Facilitates coordination among WBPs to ensure Texas colleges and universities have an adequate supply of cadavers to meet education, research, and training needs.
- Adopts rules regarding the donation to and use of whole bodies and anatomical specimens by WBPs and other facilities using these bodies and anatomical specimens in Texas.

Key Terms

Anatomical specimen: part of a human corpse

Approved facility: a facility approved by the board to hold and use bodies and anatomical specimens transferred from willed body programs for education, medical research, or healthcare-related skill training; includes graduate medical institutions, forensic science programs, search and rescue organizations, medical training facilities, and other anatomical facilities

Body or cadaver: human corpse

Final disposition: upon completion of use, the willed body program cremates or hydrolyzes the body and either returns the cremated remains to the donor's family if requested, or appropriately buries or scatters them

Member institution: a college or university with representation on the board

Willed body program (WBP): a program operated by a college or university that allows adults living in Texas to donate their bodies to the college or university for use in medical education and research. Appendix A lists member institutions and WBPs in Texas.

Key Facts

- **Governance.** The chief executive officer of each school or college of chiropractic, dentistry, medicine, or osteopathy incorporated in Texas appoints a professor of surgery or basic anatomical sciences to represent the institution on the board for a two-year term.² Members often serve multiple consecutive terms, as statute does not set term limits. The board members represent 16 Texas colleges and universities, referred to as “member institutions,” listed in Appendix A. The board meets at least once per year and members elect a chair, vice chair, and secretary-treasurer who serve two-year terms.³
- **Funding.** The board receives no state appropriations. Instead, the board collects fees from the registration of each body donated to WBPs and the transfer of those bodies and anatomical specimens to approved facilities, as described in the accompanying textbox.⁴ Statute authorizes the board to manage its funds through a local bank and any excess

Anatomical Board Fees

Registration Fee

- Identification Tag: \$16 per tag, per body, provided in sets of 100

Transfer Fees

- In-state: \$16 per transfer, per body
- Out-of-state: \$80 per transfer request

revenue accrues year to year.⁵ In 2021, the board collected \$79,456 from registration and transfer fees, and spent \$14,893 on its website, records storage fees, and reimbursement for board member travel to inspections and board meetings. The board's ending fund balance for 2021 was \$441,793.

- **Staffing.** The board has no staff. Instead, the board members conduct all of the board's activities with assistance from WBP staff.⁶ For example, one board member issues reimbursement checks and reconciles the board's financial reports while another coordinates inspections.
- **Willed body programs.** The board approves certain institutions to operate WBPs in Texas that allow an adult, upon death, to donate their whole body to help advance medical education, research, and training.⁷ Texas has 13 WBPs, 11 of which are operated by member institutions, as well as Texas State University's Forensic Anthropology Center and Sam Houston State University's Applied Forensic Science Facility. WBPs ensure Texas' colleges and universities have adequate access to sufficient numbers of legally acquired and affordable cadavers and anatomical specimens to train students across several health professions. WBPs also provide cadavers and anatomical specimens to other board-approved facilities conducting research and healthcare skill training courses. WBPs do not accept donations for living transplant recipients, including organs or tissue. The U.S. Food and Drug Administration regulates these donations and in Texas, the nonprofit organization Donate Life Texas manages the state's organ, tissue, and eye donor registry.⁸

The board establishes standards for WBPs and approved facilities to ensure donated bodies are treated respectfully, safely transported, and appropriately disposed of or returned to family members after cremation.⁹ In particular, the board establishes health, safety, and privacy standards for any entity requesting to use whole body donations or anatomical specimens.¹⁰ For example, the board requires cadaver dissection and preparation areas to have machinery to conduct at least seven full air exchanges per hour.¹¹ The board may investigate WBPs or approved facilities for improper use of a body or anatomical specimen, and can suspend or revoke authority to receive bodies or anatomical specimens if it determines an approved WBP or facility has improperly used a body or specimen.¹² Over the past three years, the board has not conducted any formal investigations or taken any formal enforcement action.

Each WBP sets its own specific requirements for donations, including various legal disclosures, as well as terms and fees associated with transporting cadavers to the WBP location and other approved anatomical facilities. When arranging for the final disposition of the donor's body upon completion of use, WBPs follow state regulatory requirements from the Texas Funeral Service Commission and either return the remains to the donor's family if requested or appropriately bury or scatter them. WBPs typically charge a fee to return cremated remains to cover costs. The textbox, *WBP Whole Body Donation Options*, explains two ways WBPs accept donations.

WBP Whole Body Donation Options

- **Pre-registration.** A person can pre-register to donate their body to one of the 13 WBPs in Texas by completing a bequest form with witnesses, along with any other WBP-specific paperwork. WBPs encourage pre-registered donors to share the documents with their families, doctors, and funeral home so the donor's preference upon death is clear. Upon death, the family, doctor, or funeral home contacts the WBP and arranges for transport.
- **After-death.** A family member or otherwise designated person, within the hierarchy laid out in the state's Uniform Anatomical Gift Act, can elect to donate a decedent's body by contacting the board or one of the WBPs directly. The board will direct the person wishing to make the donation to the WBP geographically closest to the decedent to obtain the necessary paperwork and arrange for the transport of the body to the WBP.

- Inspection and approval of facilities.** The board must inspect and approve a member institution or other facility, including university WBPs, before the facility can receive and use bodies and anatomical specimens under the board's jurisdiction.¹³ Two board members perform the initial inspection within 60 days of the facility submitting a written request to receive and use a cadaver or anatomical specimen.¹⁴ If a facility meets all of the board's requirements, the board grants approval for the WBP to begin accepting whole body donations or to receive transferred bodies and anatomical specimens from another approved WBP. Approved facilities include research organizations, medical training facilities, medical device companies, and other graduate-level educational institutions without WBPs. The textbox, *Inspection Criteria Examples*, illustrates some of the board's considerations during inspections. The board's approval lasts not more than five years for all facilities except those operated by search and rescue organizations, which lasts not more than three years.¹⁵ Only one board member performs renewal inspections, and member institutions must provide the board an audit every five years, coinciding with the inspection.¹⁶ Currently, the board has approved 95 facilities, including the 16 member institutions and 79 other facilities. In 2021, the board conducted 23 inspections and approved all 23 facilities.

Inspection Criteria Examples

- Appropriate supervision of students by trained personnel
 - Security to ensure only authorized access to facility and bodies
 - Proper storage of hazardous chemicals
 - Minimum of seven air exchanges per hour, with actual measurements of air exchanges
- Registration and disbursement of bodies.** Upon receiving a donated body, the WBP registers the body with the board using a tag and a unique number that stays with the body or all anatomical specimens derived from the body until final disposition. Since WBPs can only transfer whole bodies and anatomical specimens to board-approved facilities, the registration number helps track their location until final disposition. Individual WBPs can charge fees to recoup the costs of storage, embalming, transport, and cremation, but cannot directly profit from donations.¹⁷ The board collects data from WBPs for its annual use and procurement report, which tracks the number of bodies donated to each WBP and how WBPs use or distribute the whole body donations. The board uses this information to help ensure each member institution has enough cadavers to meet the needs of its educational programs. In 2021, the WBPs registered 3,711 donated bodies.
- Related federal and state regulation.** In 1968, Congress approved the Uniform Anatomical Gift Act (UAGA) and recommended all states enact it to provide a consistent national framework governing and facilitating organ donations for transplantation.¹⁸ All 50 states have since adopted some form of UAGA, with more recent revisions building on the existing legal framework covering donations for transplantation to include whole body donation and clearly account for the use of all or part of a human body, known as an anatomical gift, for transplant, therapy, research, or education.¹⁹ While the U.S. federal government has jurisdiction over parts of human bodies donated for transplantation or other medical therapy, it does not regulate non-transplant anatomical donation, including whole body donation.²⁰ In Texas, the board has jurisdiction over whole bodies donated to WBPs and anatomical specimens derived from these bodies for education, research, and training, and violations of the board's statute are considered an offense punishable by a fine of between \$100 and \$500.²¹ Additionally, Texas laws generally prohibit the abuse of a corpse, classifying activities such as disturbing, damaging, dissecting, and trafficking deceased humans or cremated remains as felonies.²² However, statute recognizes legitimate purposes exist for the use of all or part of a deceased human body by authorizing the use and dissection of a whole body or anatomical specimen to further medical or forensic science.²³

-
- ¹ Section 1, Chapter 53, (HB 264), Acts of the 30th Texas Legislature, Regular Session, 1907.
 - ² All citations to Texas statutes are as they appear on <http://www.statutes.legis.texas.gov/>. Section 691.002, Texas Health and Safety Code.
 - ³ 25 Texas Administrative Code, Chapter 471.
 - ⁴ 25 T.A.C., Section 477.6.
 - ⁵ Section 691.008(b), Texas Health and Safety Code.
 - ⁶ 25 T.A.C., Section 473.1.
 - ⁷ Section 691.028, Texas Health and Safety Code.
 - ⁸ 21 Code of Federal Regulations, Parts 1270 and 1271.
 - ⁹ Section 691.022(b), Texas Health and Safety Code.
 - ¹⁰ 25 T.A.C., Section 479.3.
 - ¹¹ 25 T.A.C., Section 479.3(c)(1).
 - ¹² Section 691.034(b) and (c), Texas Health and Safety Code.
 - ¹³ Section 691.034(a), Texas Health and Safety Code.
 - ¹⁴ 25 T.A.C., Section 479.2(c)(1)(A).
 - ¹⁵ 25 T.A.C., Section 479.2(c)(1)(B). The board is in the process of moving to a three-year inspection cycle.
 - ¹⁶ 25 T.A.C., Sections 479.2(c)(1)(B) and 485.1.
 - ¹⁷ Section 692A.016, Texas Health and Safety Code.
 - ¹⁸ Annie Cheney, *Body Brokers: Inside America's Underground Trade in Human Remains*, Crown Publishing Group, New York City, 2007, p. 28.
 - ¹⁹ Denay L. Wilding Knope, "Over My Dead Body: How the Albrecht Decisions Complicate the Constitutional Dilemma of Due Process and the Dead," *University of Toledo Law Review* 41, No. 1 (2009): 169-211, <https://heinonline.org/HOL/P?h=hein.journals/utol41&i=186>; Section 692A.004, Texas Health and Safety Code.
 - ²⁰ "Tissue and Tissue Product Questions and Answers," U.S. Food and Drug Administration, last modified May 7, 2019, [https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-and-tissue-product-questions-and-answers#:~:text=Does%20FDA%20regulate%20Organ%20donation,hearts%2C%20kidneys%2C%20and%20livers](https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-and-tissue-product-questions-and-answers#:~:text=Does%20FDA%20regulate%20Organ%20donation,hearts%2C%20kidneys%2C%20and%20livers;); Section 692A.011, Texas Health and Safety Code.
 - ²¹ Section 691.035, Texas Health and Safety Code.
 - ²² Section 42.08, Texas Penal Code.
 - ²³ Section 691.033(a), Texas Health and Safety Code.

ISSUE 1

The State Anatomical Board Cannot Continue to Effectively Oversee Whole Body Donation in Texas.

Background

The donation of human organs, tissue, and other body parts used for human transplant or other medical therapy is regulated by the federal government.¹ However, the regulation of whole body donation — when an adult, upon death, donates their whole body to help advance medical education, research, and training — is left up to each state. In Texas, the Anatomical Board of the State of Texas (SAB) oversees whole body donation by registering and facilitating the distribution of cadavers donated to willed body programs (WBPs) operated by a college or university. SAB inspects and approves WBPs in Texas and other anatomical facilities authorized to receive cadavers from WBPs to ensure the bodies are treated respectfully and properly transported.²

SAB first underwent Sunset review in the 1984-85 biennium and the 69th Texas Legislature reauthorized it with several changes, including giving the board fee collection authority, reducing its size, and clarifying its authority to inspect and approve facilities.³ The Legislature did not place the board under Sunset review again until the 2020-21 biennium, at which time Sunset staff concluded Texas' higher education institutions could effectively operate and oversee their WBPs without the board, and recommended abolishing SAB. However, the Sunset Commission did not adopt this recommendation and instead voted to transfer SAB's functions to the Texas Funeral Service Commission (TFSC) and reconstitute the board as an advisory committee to TFSC. The board's Sunset bill did not pass during the 87th Legislative Session; instead, the Legislature continued SAB for two years and placed it under full Sunset review again in the 2022-23 biennium.⁴

As required by the Sunset Act, this re-review questioned the need for and effectiveness of the board's functions and considered alternative methods of performing them. Sunset staff again found Texas has a continuing need to oversee donations to WBPs. However, the board's outdated statute, limited resources, and minimal regulatory role prevent it from effectively and objectively overseeing whole body donation in Texas, including WBPs and new participants in the expanding field of whole body donation, such as commercial, for-profit body donation companies like Science Care.

Findings

The state has a continuing interest in overseeing whole body donations to WBPs in Texas and ensuring higher education institutions have an adequate supply of cadavers for education and research.

Whole body donations are essential for the education of future and current healthcare professionals at schools and colleges of chiropractic, dentistry, medicine, and osteopathy in Texas, and for forensic science programs and search and rescue organizations. Whole body donations and the partitioning of bodies into anatomical specimens allow students, medical professionals, and researchers to study, train, and further understand the complex nature of the

WBPs may only redistribute cadavers after higher education needs have been met.

human body in a way that no other method can replicate. Without donated cadavers as a primary, affordable resource, Texas higher education institutions would not be able to adequately teach and train students. Together, SAB and WBPs help ensure Texas higher education institutions and other programs and organizations maintain access to affordable cadavers and anatomical specimens. Because Texas is unique with more higher education institutions than most other states, it is especially important to ensure some sort of coordination and equitable distribution of donated cadavers among all these entities exists. When distributing bodies, statute requires SAB to give priority to schools and colleges that need cadavers for lectures and demonstrations.⁵ WBPs may only redistribute cadavers to other authorized recipients after higher education needs have been met, and SAB may only approve transporting a cadaver to an authorized recipient in another state if Texas' supply exceeds needs.⁶ This collegial approach to acquiring a needed but limited resource requires coordination among the WBPs, which the board helps facilitate. As shown in the accompanying table, the supply of cadavers donated to WBPs and registered with SAB has exceeded higher education needs over the last five years. As a result, WBPs have routinely made cadavers available to other authorized recipients, including higher education institutions without a WBP and other SAB-inspected and approved anatomical facilities, such as a bioskills training facility where medical professionals learn or improve upon techniques and procedures.

Texas WBP Donations and Transfers, FYs 2017-21*

Fiscal Year	Donated Cadavers Registered with SAB	Cadavers Cremated, Hydrolyzed, or Reclaimed Prior to Use	Cadavers Transferred to Other Authorized Recipients in Texas	Out-of-State Transfer Requests for Cadavers or Anatomical Specimens**	Total Cadavers Cremated or Hydrolyzed
2017	2,497	168	1,462	154	2,447
2018	2,716	164	1,469	189	2,645
2019	3,319	176	1,655	450	2,576
2020	3,553	364	731	246	2,705
2021	3,711	475	1,273	739	3,323

* Total donated cadaver numbers do not match up with cremated, hydrolyzed, reclaimed, and transferred numbers because cadavers are used and transferred across multiple years. A cadaver's final disposition year is not necessarily the same as the year it was donated.

** Many requests are for specific body parts and not just whole bodies, so these numbers represent a combined total covering all out-of-state transfer requests.

As currently structured, SAB cannot effectively or objectively oversee the expanding field of whole body donation in Texas.

SAB is not properly structured or equipped to oversee the growing number of WBPs and anatomical facilities currently subject to state oversight, raising questions as to the board's intended and appropriate ongoing role in overseeing

WBPs at higher education institutions. Despite the tremendous efforts of its dedicated board members who are employees of the educational institutions they represent, numerous deficiencies limit SAB's ability to effectively administer its current duties.

- **Improper and imbalanced board composition.** To establish clear accountability, the governor typically appoints the members of a state board and designates the presiding officer, with confirmation by the Senate. Additionally, under the Texas Constitution, state boards must be composed of an odd number of three or more members.⁷ The board's current structure does not meet these standards. By statute, the board is made up of a representative from each school or college of chiropractic, dentistry, medicine, or osteopathy in the state, appointed by the chief executive officer of the institution.⁸ As the number of these schools and colleges has increased, so has the board's size, growing from 11 members in 1984 to 16 members currently, which is unconstitutional. An even number of board members can result in split votes and hinder decision making, particularly as SAB's rules require a majority of institution representatives be present for a quorum, a majority vote for final approval of facilities to accept donated or transferred bodies, and a majority vote for denial or withdrawal of approval of facilities.⁹

The current makeup of the board does not comply with the Texas Constitution.

Furthermore, the statutory composition of the board is outdated and no longer sensibly represents the whole body donation field in Texas, resulting in missing representation on the policymaking body. In 2015, the Legislature clearly authorized forensic science programs to operate WBPs and receive transferred cadavers, but did not add positions on the board for these programs.¹⁰ As a result, Sam Houston State University and Texas State University operate WBPs for their forensic science programs but lack board representation. Additionally, operating a WBP is not a statutory requirement for board membership. Currently, five of the 16 institutions represented on the board do not have an active WBP yet retain rulemaking and inspection authority over those that do. Appendix A lists the board-represented institutions and shows which do and do not currently operate WBPs.

Operating a WBP is not a requirement for board membership.

Finally, the structure of the board also does not fully account for the advent of health science centers, which can include multiple component institutions that meet board membership eligibility requirements. Statute requires the board representative from each member institution to be a professor of surgery or basic anatomical sciences associated with the institution.¹¹ However, in some cases, board members represent an entire health science center, some of which have component institutions that also meet board membership eligibility. For example, the Texas A&M Dental School, which is part of the university's health science center, has a representative on the board, but the University of Texas Health Science Center at Houston has one board member representing the entire institution, despite having several facilities subject to board inspection, including a dental school.

Board members
inspecting
other members'
facilities can
create the
appearance
of potential
conflicts of
interest.

- **Lack of resources leads to inappropriate but unavoidable actions.** The board is not statutorily authorized to hire staff and receives no state appropriations, which results in the board going down improper and unsustainable paths.

Board member involvement in inspections. Without staff, board members carry out SAB's primary regulatory duty of inspecting WBPs and other facilities that use donated bodies or anatomical specimens from WBPs. Having board members perform inspections places the board at risk of making potentially anticompetitive and unfair decisions, as board members inspect facilities and make regulatory decisions that could directly benefit or harm WBPs at member institutions fellow board members represent, or entire medical schools and other anatomical facilities. The board has taken steps to mitigate potential problems and Sunset staff found no evidence of unfair decisions. However, having board members performing inspections inherently carries risk and can create the appearance of potential conflicts of interest.

University staff assisting with board duties. The board is currently using WBP staff employed by member institutions to perform administrative duties. While this helps the board's busy members accomplish necessary tasks, having these staff perform administrative tasks for the state is unusual and improper. Also, much like the board members, WBP staff must balance their day-to-day duties with SAB tasks, which is not a sustainable path with an increasing workload. Additionally, to help address the limited number of board members available to inspect an increasing number of programs and facilities, the board has considered using WBP staff to assist with inspections. While the board has few alternative options and must seek assistance where it can, having WBP staff conducting inspections would not support best practices for objective regulatory decision making.

The board still
needs to clearly
establish and
communicate
objective
inspection
criteria.

- **Unclear inspection criteria and facility approval process.** To use a donated cadaver, WBPs and other anatomical facilities must request and pass a board inspection.¹² However, the board's approval process is not clearly defined in rule or elsewhere, and is not available on the board's website. When a request is received, the board schedules an inspection for which the potential outcomes are failure, conditional approval, and approval. The criteria the board uses to determine these outcomes is also not clearly defined or publicly available. In a conditional approval scenario, inspectors make recommendations to address their concerns, which the program or facility must implement within a specific timeframe. In response to the 2020 Sunset staff report, the board recently took steps to establish an application form and inspection manual, but still needs to clearly establish and communicate objective inspection criteria to the programs and facilities. Clearly defining the application requirements and process for gaining approval after inspection in rule and posting them online would provide the information applicants need to submit complete applications and fully understand the board's requirements and inspection process.

- **Deficient regulatory and enforcement authority.** Since its creation in 1907, the Legislature has adjusted the board's statutory authority and responsibilities in a piecemeal fashion without full consideration of the growth and modernization of whole body donation and the subsequent changes needed to effectively oversee and regulate WBPs in Texas. Despite SAB having some regulatory elements in its statute, such as required facility inspections, the Legislature did not structure or intend the board to operate like other, more typical state regulatory boards and agencies.

The board's statute is missing common regulatory elements, such as requiring registration or licensure of WBPs, establishing clear qualifications for facility approval and inspection requirements, and authorization to use a full range of enforcement tools such as administrative penalties to hold WBPs accountable. Currently, the board's seemingly strongest regulatory authority is the requirement for the board to inspect facilities before authorizing them to use WBP cadavers and anatomical specimens. While statute authorizes the board to perform some other regulatory activities, including investigations, suspensions, and revocations, in practice, the board rarely, if ever, receives complaints that would necessitate these actions.¹³

SAB was not structured or intended to be a typical state regulatory board.

- **Unauthorized and outdated rules.** Unlike most state agencies, SAB does not have general rulemaking authority to administer its statute. Instead, statute only authorizes the board to adopt rules for certain activities, listed in the accompanying textbox.¹⁴ Statute also does not clearly authorize or require the board to adopt rules for facility inspections, although the board has done so. Additionally, statute requires state agencies to review their rules every four years and determine whether the reasons for initially adopting each rule continue to exist.¹⁵ However, the board has not conducted a review of its rules since 2000. The board's failure to comply with this requirement could result in stakeholders and members of the public having to comply with rules that may not accurately reflect current law and board practice. In addition, neglecting to review rules allows for the continuation of regulation that may not be meaningful or needed.

SAB's Limited Rulemaking Authority

- Authorized to adopt rules for administration (minutes; records)
- Required to establish rules for complaint intake
- Required to adopt rules to ensure bodies and specimens are treated with respect
- Required to adopt rules for safe cadaver transport and adequate recordkeeping
- Required to adopt rules surrounding authorized use and dissection

- **Lack of transparency and responsiveness.** While the board has improved its website since the 2020 staff review, common elements that would be useful to the public and stakeholders are still missing. The board does not post information commonly found on state agency websites, such as information about public meetings including agendas, minutes, and notice of the next scheduled board meeting. The board also does not publish information relevant to applicants and the public, such as how to apply for board inspection and approval or how to file a complaint against a board-approved facility. In both the 2020 and current review, Sunset staff received complaints from the public and stakeholders about the lack of a phone number on the board website and difficulty getting in touch with

someone representing the board. According to the board, this results from the lack of staff and the workload of the board members who have other full-time jobs as professors at higher education institutions and many other responsibilities.

Texas statute
has not kept up
with emerging
actors in the
whole body
donation field.

The emergence of new participants in the whole body donation field raises fundamental policy questions about if and how Texas should regulate them.

Currently, Texas statute does not clearly account for participants in the whole body donation field unaffiliated with higher education institutions. These participants, often known as Non-Transplant Anatomical Donation Organizations (NADOs), include commercial, for-profit companies like Science Care. Texas does not currently license or register NADOs, but as outlined in Appendix B, other states have begun to clearly account for and regulate these entities. The level of regulation in other states varies and some states, such as Illinois and Florida, have exempted NADOs from being regulated in the same way as WBPs if the NADO is accredited by the American Association of Tissue Banks (AATB).

The accompanying textbox lists several *Ways NADOs Can Differ From WBPs*. Much like WBPs in Texas, NADOs accept and supply whole body donations

and anatomical specimens for research, training, and education, but Texas law does not specify if or how NADOs should be regulated. The lack of clear statutory direction regarding oversight of NADOs in Texas has caused confusion and resulted in several legal questions and concerns, detailed in the textbox on the following page. The policy question of whether to regulate NADOs in Texas was not addressed in the previous Sunset staff review of SAB and resulting staff report, but it was discussed and considered as part of SAB's Sunset bill in the 87th Legislature, which did not pass. As a result, fundamental policy questions about the regulation of all whole body donation activity in Texas, including SAB's role, remain unaddressed.

Ways NADOs Can Differ From WBPs

- Can be for-profit companies
- Often operate across state lines and internationally
- Sometimes receive and distribute far more cadavers and specimens than WBPs
- Sometimes use different preservation and final disposition methods of cadavers and specimens
- More likely to provide anatomical specimens than whole bodies to clients
- Often guided by national accreditation rather than state regulation
- Often willing to cover costs of transport of a cadaver across a longer distance than WBPs

Legal Concerns Regarding the Regulation of Whole Body Donations in Texas¹⁶

In 2019, SAB requested an opinion from the Office of the Attorney General (OAG) asking if statute permits a commercial entity known as Science Care to operate a WBP in Texas. Science Care's current operation in Texas is limited to providing bodies and anatomical specimens already in its possession to clients, such as surgeons or medical device manufacturers, for training and research. The OAG opinion issued in response asserted Science Care can operate under existing Texas statute based on its licensure as a tissue bank in New York. The opinion concluded Science Care is subject to SAB oversight if it receives whole body donations within the state and that any use or transfer of whole body donations must be coordinated through the board.

At this time, Science Care has chosen not to accept whole body donations at its Texas facility in Coppell, Texas and does not operate as a WBP in this state. However, Science Care does accept whole body donations from people in Texas. Instead of receiving the bodies at its Texas facilities, the bodies are shipped directly to one of the company's intake facilities in another state. The bodies and resulting specimens can then be shipped to clients, including back into Texas. In fact, Science Care provides anatomical specimens to some of the same facilities and organizations in Texas that also receive bodies and specimens from SAB-approved WBPs. NADOs such as Science Care also ship bodies and specimens to clients outside of the United States, which SAB does not permit Texas WBPs to do based on a 1987 OAG opinion.

Despite the OAG opinions, the lack of statutory clarity and specificity regarding SAB's jurisdiction over whole body donation activity in Texas has created an impasse between the board and NADOs like Science Care. In SAB's *Self-Evaluation Report* submitted to the Sunset Commission in 2021, the board suggested the regulation of whole body donation in Texas needs to be clarified in statute, including who can solicit donations; the processing, storage, and transport of donations among facilities; and the board's authority to inspect and approve appropriate facilities. In 2022, SAB received a letter from attorneys representing Science Care asserting the board was exceeding its statutory authority by enacting certain regulations, including fees and inspection requirements, that went beyond legislative intent, suggesting the board was seeking to prevent the company from operating in Texas. The resulting stalemate has raised expectations that some of these issues can be addressed in the 88th Legislative Session.

Sunset Staff Proposed Options

The Anatomical Board of the State of Texas is subject to review and abolishment on September 1, 2023, under the Texas Sunset Act.¹⁷ Normally, Sunset staff conducts a review of an agency and presents its findings and makes recommendations regarding the ongoing need for the agency and ways to improve the efficiency and effectiveness of its structure, operations, and performance. Given the considerable uncertainty of SAB's purpose and authority, and growing regulatory gaps regarding whole body donation in Texas, a recommendation to continue, transfer, or abolish the board, or to restructure it and improve its operations and performance cannot be made without wading into policy issues beyond Sunset staff's authority. Conversely, making such recommendations without considering the policy issues and implications would be irresponsible.

The role of the Sunset Commission, however, is to make recommendations to the full Legislature for consideration of the ongoing need for an agency, including its structure, operations, and performance.¹⁸ The Sunset review of SAB provides the Legislature an opportunity to holistically look at the current field of whole body donation in Texas and consider the level of oversight and regulation needed for university WBPs as well as the growing number of NADOs in this expanding industry.

This report does not include definitive recommendations from Sunset staff, but instead provides the following options for consideration. These options are based on the Sunset review of the board in 2020 and this more thorough review in 2022, as well as an in-depth review and analysis of whole body donation

and regulation nationwide. This is certainly not an exhaustive list of options the Sunset Commission and Legislature can consider, but offers a starting point for consideration and deliberation about state regulation of whole body donation in Texas.

Change in Statute

Option 1 Abolish SAB and establish the State Anatomical Advisory Council at the Texas Higher Education Coordinating Board (THECB).

This option would abolish SAB and reconstitute it as an advisory council at THECB. The council and THECB would not perform regulatory elements currently conducted by SAB, and oversight would be limited to higher education institutions. Together, the council and THECB would ensure Texas higher education institutions maintain access to affordable cadavers and anatomical specimens for education and research. Since Texas has more higher education institutions than most other states, the council's primary function would be to help coordinate and facilitate the equitable distribution of cadavers donated to WBPs among Texas colleges and universities, forensic science programs, and search and rescue organizations.

The advisory council would be composed of one representative from each Texas higher education institution eligible to operate a WBP appointed by the chief executive officer of each institution. Members of the advisory council would serve two-year terms. The members of the advisory council would elect a presiding officer among the membership and would be required to meet at least annually.

THECB, with the assistance of the advisory council, would:

- coordinate the distribution of donated bodies and anatomical specimens to eligible institutions;
- ensure each body and anatomical specimen in the custody of an institution is treated with respect;
- keep identification records of each body and anatomical specimen donated to and distributed by the eligible institutions through final disposition;
- set and collect reasonable and necessary fees for coordinating and distributing bodies and anatomical specimens; and
- be required to provide an annual report to the governor, Legislature, and THECB, on the advisory council's activities and any proposed rule changes necessary. The annual report shall include WBP data including but not limited to the total number of donations received by each program, the total number received from another WBP, method of final disposition, type of use, number transferred in or out of state, and location or type of facility transferred to.

Administration. THECB would provide administrative support to the council, but would be authorized to delegate the management of the council and its functions to one of the WBPs in Texas. SAB's fund balance would be transferred to THECB for the purpose of administering these duties.

Statute and rules. An adult would still be able to donate their body directly to a college or university with a medical school, dental school, or forensic science program, as currently authorized in law. Political subdivisions would continue to be authorized to work with WBPs to account for a body not claimed for burial or a body required to be buried at public expense, as is current practice.

THECB would have general rulemaking authority for the administration of the council and its functions, and to administer and oversee Chapter 691 of the Health and Safety Code using the expertise and

advice of the council, but regulatory provisions would be eliminated from this statute as discussed below. Violations of Chapter 691 of the Health and Safety Code would exclusively be criminal violations. This option would include the following statutory changes:

- Repeal regulatory provisions in the board's statute, including its inspection, investigation, and suspension or revocation authority. Criminal penalties associated with abuse of a corpse or an offense under Chapter 691 of the Texas Health and Safety Code would not be repealed.¹⁹
- Update Chapter 691 of the Texas Health and Safety Code to include requirements for entities eligible to receive bodies to maintain chain of custody, treat any body or specimen in its custody with respect, require proper labeling, and require the body is not kept or transported in a manner visible to the public. Additionally, WBPs would maintain responsibility for ensuring the final disposition of all WBP donations meets applicable regulations and requirements.
- Authorize THECB to charge fees to cover its costs related to recordkeeping, registering, and tagging donations, and authorize THECB to delegate this activity to a WBP, as is already current practice by SAB.
- Require each active WBP to conduct or contract for an audit at least once every five years covering its recordkeeping, procedures, and methods for the intake, storage, use, and transport of bodies and specimens. The WBP would also be required to provide the audit to the institution's board of regents or trustees.
- Authorize individual WBPs to determine which anatomical facilities they choose to transfer cadavers and specimens to if WBP supplies in Texas exceed needs. WBPs would have authority to cover costs of transfers by charging fees to cadaver and specimen recipients, as is current practice.

Chapters 691 and 692A, Texas Health and Safety Code would be updated to reflect these changes, and Sunset staff would work with staff from the Texas Legislative Council in drafting bill language to accurately account for them. Additionally, all existing SAB rules would continue upon transfer to THECB, which would be responsible for updating and adopting rules by September 1, 2024 to reflect changes in rulemaking authority.

Option 2 Abolish SAB and transfer its functions to the Texas Funeral Service Commission or another appropriate state regulatory agency, and establish a WBP advisory committee at the agency.

This option is based on the recommendation the Sunset Commission adopted during the 2020 review, but allows the Legislature to transfer SAB's functions to a state agency other than TFSC. This option would abolish SAB as a stand-alone board, reconstitute it as an advisory committee, and transfer its regulatory and administrative functions to one of the following state agencies: TFSC, the Texas Department of Licensing and Regulation (TDLR), or the Texas Department of State Health Services. This recommendation would allow for the state to continue its oversight of WBPs and other approved anatomical facilities, but would allow for the administering agency to mitigate the problems and workload challenges resulting from the board's current structure. This option would include the following statutory changes:

- Amend the policymaking body by abolishing SAB as a stand-alone board and require policymaking body members from the administering agency to appoint an advisory committee composed of one representative from each higher education institution eligible to operate a WBP to provide expert advice to the agency.

- Amend SAB's statute to replace its administrative and enforcement provisions with those of the administering agency's, including a full range of enforcement authority and authorizing fees for anatomical facility inspections at an amount covering the cost of administering the program.
- Transfer SAB's fund balance to the administering agency for the purpose of administering duties under Chapter 691 of the Texas Health and Safety Code.

Chapters 691 and 692A, Texas Health and Safety Code would be updated to reflect these changes, and Sunset staff would work with staff from the Texas Legislative Council in drafting bill language to accurately account for them.

Option 3 Continue SAB, but restructure it as a traditional state agency with funding and staff to regulate whole body donations in Texas.

This option would continue the board and restructure it as a fully resourced state agency and subject it to the state appropriations process. Additionally, the Sunset Commission and 88th Legislature could determine whether SAB should or should not regulate all WBPs and NADOs in Texas. The agency's statute and operations would be aligned with regulatory best practices, much like those of other licensing and regulatory agencies such as TDLR. This option would include the following statutory changes:

- Amend the policymaking body to comply with the state constitution by structuring it as a nine-member body. The board would consist of three public members, five members from higher education institutions that operate willed body programs, and one member from a bioskills training or research facility eligible to use cadavers or anatomical specimens.
- Align the board's statute with best practices for policymaking bodies, including requiring the governor to appoint the board members and presiding officer, requiring the advice and consent of the Senate on appointments, and establishing staggered, six-year terms for board members.
- Apply and update all standard Sunset across-the-board recommendations.
- Authorize the board to hire an executive director and to delegate its statutory authority to the executive director and other staff hired by that individual.
- Authorize the board to charge fees for applications and inspections, and require the board to recover its costs through those fees.
- Authorize the board to investigate and enforce the provisions in its statute, and to adopt rules to guide that activity.
- Authorize the board to use a full range of enforcement tools, including reprimands, cease and desist authority, and administrative penalties.
- Transfer SAB's existing fund balance to the General Revenue Fund, which should be appropriated to the board for startup costs. SAB would be part of the standard state appropriations process thereafter.

Sunset staff would work with staff from the Texas Legislative Council in drafting bill language to accurately reflect these provisions and work with Legislative Budget Board staff on estimates for the necessary appropriations for the board to hire and support sufficient staff.

Finally, as a management action, the board and its staff would be directed to develop an administrative improvement plan, including the planned steps and timeline to establish and adopt all rules mentioned

above. The plan would also establish administrative processes including but not limited to the application process, rule review, and website and communications. The plan should also include an anticipated timeline for hiring staff after the effective date of the bill should the bill pass. The board should submit this plan to the Sunset Commission by January 1, 2024.

Additional Policy Considerations Regarding Regulation of NADOs

As discussed previously, the Sunset review of SAB presents the opportunity to look at the whole body donation industry holistically. The number of participants in the whole body donation industry in Texas and the rest of the nation is growing, particularly NADOs. While Texas does not currently regulate NADOs, several other states have begun to do so. When looking at any industry, a key question is what level of state oversight and regulation is needed to best protect the public and this is true for the whole body donation industry.

The Sunset Commission could choose to raise the policy question of if and how to regulate NADOs in Texas for deliberation during the 88th Legislative Session. The following considerations are offered to help with any discussions or deliberations about how to regulate NADOs in Texas should they occur.

- What, if any, level of oversight or regulation is appropriate for NADOs in Texas?
 - Should WBPs and NADOs have the same requirements or be regulated in the same way?
 - Should the state require a registration or license for NADOs?
 - Would accreditation by the AATB provide enough oversight and protection?
 - Should requirements for donor consent forms be prescribed in statute?
- What, if any, general standards should apply to NADOs?
 - Should statute require NADOs to treat donated bodies with respect?
 - Should statute require NADOs to maintain records and chain of custody for donated bodies and specimens?
- If the state regulates NADOs, which agency or entity should be responsible for oversight and regulation?
- Should NADOs be authorized to transfer bodies from Texas to outside the U.S.?

Fiscal Implication

Until the Sunset Commission considers and adopts specific recommendations related to the continuation and functions of SAB, the fiscal implication cannot be estimated. Currently, SAB has a fund balance of about \$442,000, which would be used for the continuation of any of the board's functions.

¹ “Tissue and Tissue Product Questions and Answers,” U.S. Food and Drug Administration, last modified May 7, 2019, <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-and-tissue-product-questions-and-answers#:~:text=Does%20FDA%20regulate%20Organ%20donation,hearts%2C%20kidneys%2C%20and%20livers.>

² All citations to Texas statutes are as they appear on <http://www.statutes.legis.texas.gov/>. Sections 691.022(b) and 691.034(a), Texas Health and Safety Code.

³ Chapter 485 (SB 201), Acts of the 69th Texas Legislature, Regular Session, 1985.

⁴ HB 1565, 87th Texas Legislature, Regular Session, 2021; Chapter 850 (SB 713), Acts of the 87th Texas Legislature, Regular Session, 2021.

⁵ Section 691.030(b), Texas Health and Safety Code.

⁶ Section 691.030(c-d), Texas Health and Safety Code.

⁷ Section 30a, Article XVI, Texas Constitution.

⁸ Section 691.002(a), Texas Health and Safety Code.

⁹ 25 Texas Administrative Code, Sections 475.4(b) and 479.2.

¹⁰ SB 1214, 84th Texas Legislature, Regular Session, 2015.

¹¹ Section 691.002(a), Texas Health and Safety Code.

¹² Section 691.034(a), Texas Health and Safety Code.

¹³ Section 691.034(b-c), Texas Health and Safety Code.

¹⁴ Sections 691.007, 691.010(b), 691.022(b), 691.031(a), and 691.033(d), Texas Health and Safety Code.

¹⁵ Section 2001.039, Texas Government Code.

¹⁶ Anatomical Board of the State of Texas, *Self-Evaluation Report*, 2021, p. 43

¹⁷ Section 691.003, Texas Health and Safety Code.

¹⁸ Section 325.012, Texas Government Code.

¹⁹ Section 42.08, Texas Penal Code.

APPENDIX A

Anatomical Board Member Institutions

The following institutions are members of the Anatomical Board of the State of Texas. Most of the member institutions operate willful body programs (WBPs), meaning they may accept donations of whole bodies. Institutions marked with an asterisk have chosen not to operate a WBP. Statute also authorizes Texas State University's Forensic Anthropology Center and Sam Houston State University's Applied Anatomical Research Center to operate WBPs, even though they are not member institutions.

Dental Schools	Medical Schools	Osteopathic Schools	Chiropractic Schools
Texas A&M College of Dentistry	Baylor College of Medicine Texas A&M College of Medicine Texas Tech University Health Sciences Center (TTUHSC) TTUHSC Paul Foster School of Medicine University of Houston College of Medicine* University of Texas (UT) Austin Dell School of Medicine* UT Health – San Antonio School of Medicine UT Health Science Center – Houston UT Medical Branch School of Medicine UT Southwestern School of Medicine	Sam Houston State University College of Osteopathic Medicine* University of North Texas Health Science Center College of Osteopathic Medicine University of the Incarnate Word School of Osteopathic Medicine*	Parker University Texas Chiropractic College*

APPENDIX B

Regulatory Comparisons and Considerations Covering Whole Body Donation

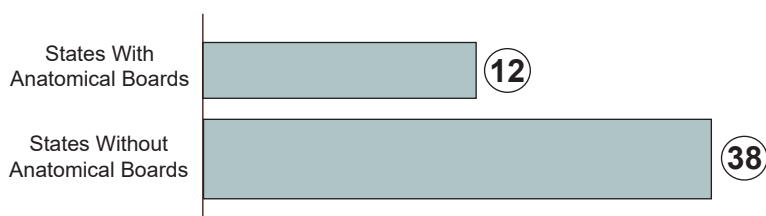
Regulation of the Donation and Use of Organs, Tissue, Whole Bodies, and Anatomical Specimens

- **Federal regulation.** The U.S. federal government regulates parts of human bodies used for transplant or other medical therapy.¹ Federal law and regulation plays a key role protecting potential organ and tissue donation recipients by screening donations to ensure donors do not transmit potentially dangerous infections and diseases. Unlike donation for transplant, whole body donation for education and research is not regulated by the federal government.
- **Uniform Anatomical Gift Act (UAGA).** In 1968, Congress recommended all states enact UAGA to provide a consistent national framework governing and facilitating the maximum number of procurement opportunities of organ donations for transplantation.² All 50 states have since enacted some form of UAGA. More recently, some states have chosen to build on this existing legal framework to include whole body donation and clearly account for the use of all or part of a human body for education, research, therapy, or transplantation.³ Because UAGA generally only governs how a body may be donated, some states have chosen to amend their state-specific UAGA to include provisions guiding or regulating whole body donation further than outlined in the uniform language. For example, Maryland's version of UAGA defines and permits donations of anatomical specimens to non-transplant tissue banks, but does not require further licensing or registration under that definition.⁴
- **Texas regulation.** Texas' UAGA requires the gift of a whole body to be coordinated through the Anatomical Board of the State of Texas (SAB).⁵ In addition, Texas' statute recognizes legitimate purposes exist for the use of all or part of a donated deceased human body by authorizing the use and dissection of a whole body or anatomical specimen to further medical or forensic science.⁶ Texas laws otherwise generally prohibit the abuse of a corpse independent of SAB, classifying activities such as disturbing, damaging, dissecting, and trafficking deceased humans or cremated remains as felonies.⁷ Violations of SAB's statute otherwise are considered an offense punishable by a fine of between \$100 and \$500.⁸

State Anatomical Boards

Currently, 38 states do not have anatomical boards, as listed in the *Anatomical Boards in the United States* chart, and rely on guidance from their state-specific versions of UAGA.⁹ In these states, medical schools often set policies and standards for their own will ed body programs (WBPs) in the absence of a state board, and set standards for any school or private company they provide donations to. Medical schools in some larger states have formed formal and informal consortia to help facilitate distribution of whole body donations and anatomical specimens. In the 12 states that have boards, including Texas, the degree

Anatomical Boards in the United States



Appendix B

of regulation and actual oversight — including regular inspections or audit requirements — varies, with boards sometimes simply providing a tracking system for a donor’s body and anatomical specimens. A very small number of states do not have a medical school, reducing the need for an anatomical board.

Appendix B

Regulation of Non-Transplant Anatomical Donation Organizations (NADOs) in the United States

Several states have also chosen to clearly account for and regulate NADOs through a variety of approaches, ranging from definitional considerations to actual licensing requirements. Terminology used to account for this activity varies but generally encompasses recovering, screening, procuring, storing, and transporting whole or parts of deceased human bodies for education, research, or training.

State	Responsible Agency	Statutory Terminology	Type of Regulation	Term	Rulemaking by Responsible Agency	Investigation and Enforcement	Licensing or Registration Fees	Inspections
AZ ¹⁰	Department of Health Services	Procurement organization	License required ¹¹	2 years	✓	✓	✓	✓
CO ¹²	Department of Regulatory Agencies	Non-transplant tissue bank	Registration required	1 year		✓	✓	✓
FL ¹³	n/a	Non-transplant anatomical donation organization	Accreditation required through American Association of Tissue Banks	n/a				
IL ¹⁴	n/a	Non-transplant anatomic bank	Accreditation required through American Association of Tissue Banks	n/a				
NJ ¹⁵	Department of Health	Anatomical research recovery organization (nonprofit status required)	Registration required	1 year	✓	✓	✓	✓
NV ¹⁶	Department of Health and Human Services	Non-transplant anatomical donation organization	Certification required	n/a	✓	✓	✓	
NY ¹⁷	Department of Health	Non-transplant anatomic bank	License required	2 years	✓	✓		✓
OK ¹⁸	State Anatomical Board	Non-transplant tissue bank (nonprofit status required)	Registration required	n/a	✓	✓		✓
OR ¹⁹	Oregon Health Authority	Non-transplant anatomical research recovery organization	License required	2 years	✓	✓	✓	✓

Appendix B

¹ “Tissue and Tissue Product Questions and Answers,” U.S. Food and Drug Administration, last modified May 7, 2019, <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-and-tissue-product-questions-and-answers#:~:text=Does%20FDA%20regulate%20Organ%20donation,hearts%2C%20kidneys%2C%20and%20livers.>

² Annie Cheney, *Body Brokers: Inside America's Underground Trade in Human Remains*, Crown Publishing Group, New York City, 2007, p. 28.

³ Denay L. Wilding Knope, “Over My Dead Body: How the Albrecht Decisions Complicate the Constitutional Dilemma of Due Process and the Dead,” *University of Toledo Law Review* 41, No. 1 (2009): 169–211, <https://heinonline.org/HOL/P?h=hein.journals/utol41&i=186>; All citations to Texas statutes are as they appear on <http://www.statutes.legis.texas.gov/>. Section 692A.004, Texas Health and Safety Code.

⁴ Title 4 (Wills), Subtitle 5 (Maryland Revised Uniform Anatomical Gift Act), Sections 501-522, Maryland Code.

⁵ Section 692A.011, Texas Health and Safety Code.

⁶ Section 691.033(a), Texas Health and Safety Code.

⁷ Section 42.08, Texas Penal Code.

⁸ Section 691.035, Texas Health and Safety Code.

⁹ While North Carolina does have a statutorily established Commission of Anatomy, the commission's website indicates it is not a state office nor a part of a larger state agency. “Commission of Anatomy of North Carolina,” Division of Public Health Website, last modified May 1, 2020, <https://coa.dph.ncdhhs.gov/>.

¹⁰ Title 36 (Public Health and Safety), Chapter 7, Article 3, Arizona Revised Statutes.

¹¹ Defines procurement organization to include a non-transplant anatomical donation organization.

¹² Title 12 (Professions and Occupations), Article 140, Sections 101-108, Colorado Revised Statutes.

¹³ Title 29 (Public Health), Chapter 406, Part II, Sections 406.49-406.61, Florida Statutes.

¹⁴ Chapter 755 (Estates), Section 50, Articles 1 and 5, Illinois Compiled Statutes.

¹⁵ Title 26 (Health and Vital Statistics), Chapter 6, Sections 68-76, New Jersey Statutes.

¹⁶ Title 40 (Public Health and Safety), Chapter 451, Sections 500-598, Nevada Revised Statutes.

¹⁷ Article 43-b, Organ, Tissue and Body Parts Procurement and Storage, New York Laws, Public Health; Title 10, Chapter 2, Part 52, Sections 1-11, New York Codes, Rules and Regulations.

¹⁸ Title 63 (Public Health and Safety), Section 109, Oklahoma Statutes.

¹⁹ Volume 12 (Public Health), Chapter 438, Sections 705-994, Oregon Revised Statutes.

APPENDIX C | Staff Review Activities

During the review of Anatomical Board of the State of Texas, Sunset staff engaged in the following activities that are standard to all Sunset reviews. Sunset staff worked extensively with board members; attended the annual board meeting; met with staff from legislative offices; conducted interviews and solicited written comments from the public, stakeholders, and trade associations; reviewed board documents and reports, state statutes, previous legislation, and literature; researched the organization and functions of similar agencies in other states; and performed background and comparative research.

In addition, Sunset staff also performed the following activities unique to this board:

- Toured willd body programs (WBPs) and interviewed WBP staff at higher education institutions in Texas.
- Observed board member inspections of several WBPs and other approved facilities in Texas.
- Toured and interviewed staff at a Texas bioskills training facility.
- Reviewed national accreditation standards for whole body donation published by the American Association of Tissue Banks.
- Interviewed staff from various government agencies, including the Texas Department of Licensing and Regulation, Texas Department of State Health Services, Texas Funeral Service Commission, Texas Higher Education Coordinating Board, and Department of Information Resources.

Sunset Staff Review of the *Anatomical Board of the State of Texas*

REPORT PREPARED BY

Darren McDivitt, *Project Manager*

Trisha Linebarger

Jennifer Jones, *Project Supervisor*

Jennifer Jones
Executive Director

Sunset Advisory Commission

Location

Robert E. Johnson Bldg., 6th Floor
1501 North Congress Avenue
Austin, TX 78701

Mail

PO Box 13066
Austin, TX 78711

Website

www.sunset.texas.gov

Email

sunset@sunset.texas.gov

Phone

(512) 463-1300