

Anatomical Board of the State of Texas

John Hubbard, PhD, PT Chairman PO Box 195895 Dallas, TX 75219

November 30, 2022

Austin, TX 78768

The Honorable Charles Schwertner, M.D., Chair Texas Sunset Advisory Commission PO Box 12068 Capitol Station

The Honorable Justin Holland, Vice-Chair Texas Sunset Advisory Commission PO Box 2910 Capitol Station Austin, TX 78711

Re: Anatomical Board of the State of Texas Response to Sunset Staff Report

Dear Chairman Schwertner and Vice-Chair Holland:

Thank you for the opportunity to provide comments on the Texas Sunset Advisory Commission Staff Report regarding the Anatomical Board of the State of Texas (SAB). I wish to express our collective appreciation for the courtesies and professionalism the staff assigned to review our agency extended to us during their review of our agency. We appreciate the hard work the staff invested in understanding the operations and responsibilities of the SAB. We agree in principle with the published report and look forward to partnering with the Texas Sunset Advisory Commission to implement optimal solutions for the State of Texas.

The Anatomical Board of the State of Texas was established in 1907 to serve the common need amongst our health professions schools to oversee a dignified, legal, and ethical means of acquiring and distributing deceased bodies for anatomical study, training, and research. For the past 115 years, the SAB has served the State of Texas as an autonomous state agency without legislative funding, a central office, or paid staff. The overall mission of the Anatomical Board of the State of Texas to regulate the legal acquisition and distribution of donated human bodies for education and research remains paramount and should be of key interest to the State Legislature. We cannot overstate the importance of maintaining the dignity and respectful treatment of these donor individuals and their families. Maintaining the public confidence that these donor bodies will be properly acquired, distributed, and utilized is our ultimate concern.

The principles contained in THSC 691 and 692A are common to all entities, whether they be educational institutions or private entities. The stance of the Anatomical Board of the State of Texas is that all Willed/Whole Body Donation Programs (WBPs) operating within the State of Texas (educational or private) adhere to a single set of rules and regulations administered by a single authoritative state agency. Questions of legal policy and moral authority are as valid now as they were in 1907 when the SAB was first created. Citizens of the State of Texas should have

the assurance that whatever entity their bodies are donated to will operate under appropriate rules and regulations. *The SAB's primary objective is that whole-body donation and use in Texas be regulated consistently across all entities.*

The SAB continues to regulate the receipt and distribution of deceased human bodies, approve facilities, and maintain records related to the use of these bodies in the State of Texas as it has since 1907. Due to the rather static nature of the institutions and their body donation programs, the statutory legislation authorizing schools to receive and distribute donated human bodies remained relatively unchanged until 1985. The 1985 reform changed the makeup of the board, gave the SAB the authority to charge fees, and established the SAB as an approved human body recipient. This statutory revision also clarified the board's authority to inspect and approve institutions and facilities for the receipt and use of cadavers, as well as to revoke those same privileges if warranted. Since those 1985 legislative revisions, the prevailing statutes have gone unchanged other than a 2017 amendment (SB 1214) allowing WBP's to transfer cadavers or anatomical specimens to authorized forensic science or law enforcement search and rescue training organizations.

Despite the absence of recent statutory changes, the SAB has recognized the need to be more efficient. While the SAB made recent improvements to its structure and operations, there continues to be a need to update the organizational structure and regulatory statutes related to whole-body receipt, distribution, and use in Texas. The SAB is prepared to partner with its public/private counterparts to develop and present proposed statutory and organizational changes in concert with this Commission to be presented to the legislative bodies in the upcoming session. We believe that an inclusive and collaborative effort will lead to a sustainable path for all entities involved while remaining true to the initial mission to provide ethical and dignified procedures for body use in Texas.

Many things have changed since the last updates to THSC 691 and 692A. While the number of health-related educational institutions with operating WBPs has remained relatively consistent, there has been a significant increase in non-educational-based WBPs operating as Non-transplant Anatomical Donation Organizations (NADOs). Several of these NADOs have expressed their desire to operate within the State of Texas. There has also been a significant increase in the use of donor bodies for medical research and healthcare professional skill training programs. These groups did not exist to any significant extent in 1985, and the language of the current statute is extremely vague on how the SAB is to regulate and guide their activities. The SAB feels that these entities should be equitably regulated as well as have representation on any newly restructured State Anatomical Board.

As the sole state agency responsible for regulating the donation and distribution of these donor bodies since 1907, the SAB recognizes the need for change in its structure and operational abilities. The submitted Sunset Report offers a few options to provide more effective oversight of Whole-Body Donation programs within our state.

Option #1 is to abolish the SAB as a stand-alone board and reconstitute it as an advisory council to the Texas Higher Education Coordinating Board (THECB). Placing the SAB as an advisory council under the THECB does not appear to fit into the mission or vision of the THECB. While they may have an interest in regulating the WBP's within institutions of higher education, they would most probably be disinterested in regulating the business practices of private entities operating WBP's in Texas. This option leads to two possible scenarios: 1) deregulating body use for private entities such as NADOs or 2) creating a separate state agency to regulate the business of these private WBPs. Both options create a double standard and variable rules and regulations for WBPs, leading to confusion for the citizens of the state.

Option #2 is to abolish the SAB, transfer its functions to another state regulatory agency and establish an advisory committee within that agency. This option would allow the state to continue to regulate both educational and private WBPs with a single set of rules and regulations under the oversight of a single state agency. However, this option would be dependent on the existing state agency's ability to utilize its licensing, inspection, investigation, and enforcement arms to support the SAB's mission of oversight of all WBPs and all entities to which these bodies or anatomical specimens may be distributed. This option carries with it the enormous transition of regulatory authority to an organization that may not be equipped financially or with appropriate personnel to quickly and efficiently carry out the legislative responsibilities that the SAB currently manages. This option would most probably result in a gap in the regulation of body donation and use in Texas to the detriment of the citizens of the State.

Option #3 is to continue the SAB as an autonomous agency, but restructure it as a traditional state agency with appropriate funding, a central office, and dedicated personnel trained to perform the duties the legislature authorizes the SAB to carry out. This option provides a more seamless and efficient transition incorporating the existing expertise of the SAB, to implement the regulatory authority of the newly restructured agency quickly and effectively. Despite the reported agency challenges, the SAB has continued to efficiently regulate all WBPs along with the facilities these bodies are distributed to within the State of Texas. While the increased demand for body donations has now exceeded the current structural and legislative authority of the SAB, the need to regulate the ethical acquisition and dignified use of these body donations effectively and equitably remains. A restructured SAB with a clear regulatory statute is best positioned to protect the altruistic gift of body donors and their families while advancing health sciences-related anatomical education, training, and research.

If given the opportunity, the SAB is ready to contribute to innovative, inclusive, and equitable solutions for body donation and use in Texas. There are public/private partnerships ready for development, and the SAB, if allowed to continue as the single regulatory agency, is committed to partnering with all entities to ensure that all human body donors in this state are treated with the utmost respect, distributed only to appropriate facilities, utilized appropriately, and returned back to their donor families.

Regardless of which option is implemented by the Commission, the primary question at hand is: Should body donation and use in Texas continue to be regulated? If yes, then the next question is: Should regulation of body donation and use be equitable across all entities?

The Sunset Report raised policy considerations regarding the regulation of Non-transplant Anatomical Donation Organizations (NADOs). While the State of Texas currently has arbitrary language in THSC 692A authorizing NADOs to operate in this state under the oversight of the SAB (reinforced by the OAG ruling KP-0279), questions remain as to how these entities can or should be regulated. Of the nine states who have addressed this issue in statute, only two have chosen to not regulate the activities of NADOs. All seven of the other states require some type of license or registration for NADOs and submit them to oversight authority by the responsible agency, including investigation and enforcement procedures, and periodic inspections of their facilities.

Arguments against legal regulation of NADOs are based on exempting them from regulation due to being accredited by a voluntary private entity, the American Association of Tissue Banks (AATB). However, voluntary accreditation is not equivalent to regulation by state statute and rules. Ignoring or exempting entities from following state laws on the basis of voluntary accreditation places the responsibility for the well-being of the citizens of Texas outside the control of the State of Texas. No entity accepting donated human bodies should be exempt from following rules and regulations set forth in the statute. By comparison, all institutions of higher education, as well as all hospitals and healthcare facilities, are accredited, but they still have state-level rules and regulations that govern their function. In fact, the AATB itself states that only a small number of NADOs operating in the United States are actually accredited, and those that are accredited are also to be regulated by prevailing state law (www.aatb.org/nados).

It is the opinion of the SAB that any deregulation or decrease in oversight of body donation and use within this state may lead to the following adverse results:

- Unethical and undignified use of donor bodies.
- 2. Disenfranchised citizens creating an unwillingness to consider body donation.
- 3. Alteration in the availability or costs of donor bodies for health-sciences-related education, training, or research.

The Sunset Review Report states (page 9) that the state has a continuing interest in overseeing whole body donations to WBPs in Texas. The SAB is currently the only state agency performing this continuing need for the State of Texas. With the establishment of a formal agency office, hiring of a competent executive director and staff, the SAB is prepared to establish equitable licensing regulations and fees, register all donor bodies, track all transfers of bodies or body parts, ensure appropriate preservation and final disposition of all bodies, inspect and approve all facilities deemed appropriate to receive donor bodies or anatomical specimens, and effectively see that the medical education, research needs, and clinical training activities in this state requiring the use of human bodies are met.

The State of Texas is a leader in many fields. Unfortunately, our state has not kept up with the changing world of Whole-Body Donation programs. While we can look to other states and how they have chosen to regulate these WBPs, we need to be proactive and update our statutes to not only reflect the current state of these entities but look at future developments and regulations of these entities. It is the stance of the SAB that the State of Texas should not cede any authority over activities occurring within our state involving our citizens to any external group, individual or private entity. The State of Texas should recognize that the conduct of all activity related to the donation of human bodies for educational and/or research activities needs to be governed by a modern, efficient statute and enforced by a single reorganized state agency.

It is the opinion of the SAB that if granted the continued authority to oversee all WBPs and NADOs (which are also WBPs) in this state, all programs, educational or commercial will have the same set of operating rules and regulations, be required to register and obtain a license, have consistent donor forms and information for the public to review, maintain appropriate records detailing the usage of all bodies or body parts, and ensure that the needs of the State of Texas are met prior to authorizing any bodies or body parts being transferred to another state.

The SAB has a long record of serving public needs without state appropriations or formal staff. Despite these limitations, the SAB has effectively registered all willed body donations and tracked cadaver and anatomical specimen transfers within the State of Texas for the past 115 years. With appropriate statutory and structural changes, the SAB will continue to ensure that body donation and use in Texas is conducted in an ethical and dignified manner that is supportive of the anatomical education, research, and training needs of our great state.

The SAB is prepared to work with the Texas Sunset Advisory Commission through the legislative process to *ensure that whole-body donation and use in Texas is regulated consistently across all entities for the protection of the citizens of our great state.*

With sincere regards,

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Chair, Anatomical Board of the State of Texas

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Anatomical Board of the State of Texas Members

Hubbard

Anatomical Board of the State of Texas

The members of the Anatomical Board of the State of Texas (SAB) appreciate the diligence and professionalism of the Sunset Staff during the Sunset Review process. Their comprehensive Sunset Staff Report highlights issues surrounding the current structure and function of the SAB and we thank them for their collaborative work during this review with the Board.

The Anatomical Board of the State of Texas (SAB) was established in 1907 to provide an ethical and sustainable method for the provision of bodies for dissection in medical school. The SAB structure and the statute governing whole-body donation and use of these bodies in Texas have not kept up with the times. While the landscape of whole-body donation and use has changed significantly over the past 115 years, the importance of ethical and dignified treatment of the deceased has not.

The SAB's primary objective in the Sunset process is that whole-body donation and use in Texas be regulated consistently across all entities.

The essential questions that need to be answered are:

- 1. Should body donation and use be regulated in Texas?
- 2. Should all entities involved in body donation and use be held to the same set of equitable standards?
- 3. Which agency is best suited to manage the regulation of body donation and use in Texas?

The SAB recognizes that the criticisms listed within the Sunset Staff Report are warranted and legislative action is required to remedy them. The members of the SAB agree, in principle, with the issues raised in the Sunset Staff report and wish to work with the Sunset Commission to resolve these issues.

Establishing an inclusive and equitable set of regulations and standards for all entities within the body donation arena is of paramount importance. A regulatory framework with different tiers or with some entities not being regulated would create an imbalance. The citizens of this state should not have to wonder how their bodies are going to be treated, or what type of facility their bodies are going to be utilized in. *All entities who receive human bodies or specimens must be regulated, inspected, and approved to ensure proper settings and treatment of human remains. A single central agency is best suited to perform this task.*

Legislation resulting from the Sunset review of the Anatomical Board of the State of Texas should emphasize proper usage of human bodies for educational and research purposes and ensure donors and their families are treated with dignity and respect. The Board is ready and willing to partner with the Sunset Commission to develop solutions that maintain and protect the dignity of body donors and their families.

Table 1. Total SAB Inspected Facilities in Texas - Educational, Clinical Skills, Research, Search and Rescue

	Location	Houston/Galveston		Dallas, Fort Worth, East Texas, Texarkana		Austin, San Antonio, San Angelo, Edinburg, Lubbock, El Paso, Midland Amarillo, Wichita Falls			
Type of Facility									
								Subtotal	Total
Educational		9		6		23			38
SAB		5	3 WBP	4	4 WBP	7	4 WBP	16 SAB 11 WBP	
non-SAB		4	0 WBP	2	0 WBP	16	0 WBP	22 non-SAB 0 WBP	
Clinical Skills		14		21		10			45
Research		9		2		0			11
Search/Rescue		0		1		2			3
Total		32		30		35			97

Educational: 38 total: 15 medical, 7 PT, 5 PA, 3 mortuary sciences, 2 chiropractic, 2 forensic, 1 optometry, 1 dental, 1 anthropology, and 1 athletic training.

- <u>Example: UNT Health Science Center programs</u>: DO, PA, PT, Graduate (MS, PhD); TCU MD, CRNA, NP, plus CRNA program from Texas Wesleyan Univ. students train in our bioskills facility at UNT Health Science Center (900 students total).
- Texas Tech Health Science Center programs: MD, PA, PT, OT, and graduate, plus Bioskills

Clinical Skills (not shown) — UNT and Texas Tech Health Science Centers both have bioskills facilities that are not included in this total; and facilities such as Orthofix Institute in Lewisville was counted as Research (primary), but also have significant Clinical Skills training (secondary).

Examples of Bioskills Training activities:

- Anesthesiologists and CRNAs ultrasound guided pain management
- Cardiovascular beating heart surgery, endoscopic vein harvesting
- EMT/firefighter training airway techniques, trauma, chest tubes
- Medical/Residents/PA students suture clinics, trauma/EM training; interventional radiology
- Ob/Gyn hysterectomy and other laparoscopic procedures, ultrasound
- Orthopedics spine, hip/knee/shoulder replacement, tendon repair
- Podiatrists bone repair/implants, nerve repair
- Robotic surgery simulation with Da Vinci robot

Major Bioskills Facilities in Texas:

- BioSkills of North Texas Fort Worth
- Houston Methodist Institute for Technology, Innovation, and Education (MITIE) Houston
- Med to Market Austin
- National Bioskills Lab Farmers Branch
- Orthofix Institute Lewisville
- Science Care Medical Training and Bioskills Coppell
- UT Southwester Da Vinci Robotic Center Dallas

Benefits of BioSkills Facilities and SAB Donor Specimens to the state of Texas

- Better trained residents, clinicians, and healthcare professionals within the state
- Safer medical practice and better quality of life for all Texans
- Positions Texas to be "the state-of-the-art medical training center" for the entire U.S.
- Revenue from air transportation, hotels, restaurants, car rental from out-of-state participants
- Service to the state's numerous military facilities for trauma/field training
 - o Brooke Army Medical Strategic Trauma Readiness
 - Fort Hood Medical Simulation Center live combat/field training
 - Fort Sam Houston Joint Forces Combat Trauma Unit