

November 29, 2022

The Honorable Charles Schwertner, M.D., Chairman
Texas Sunset Advisory Commission
PO Box 13066
Austin TX 78711

The Honorable Justin Holland, Vice Chair
Texas Sunset Advisory Commission
PO Box 13066
Austin TX 78711

Dear Senator Schwertner, Representative Holland, and Committee Members:

Science Care is humbled by and sincerely appreciates the opportunity to respond and provide comment on the November 2022 Staff Report generated by the Sunset Advisory Commission concerning the Anatomical Board of the State of Texas.

No entity, regardless of industry, tax status, or the esteem in which it is held should be allowed to operate in a vacuum or conduct its business without proper oversight. Whether arising out of negligence or predatory acts, it is the obligation of the State to ensure its residents are protected from harm which can be perpetrated by entities of any industry or sector. In keeping with these sentiments, Science Care wishes to reiterate that our organization is not advocating a change to Texas law or the structure of its agencies which would see Non-Transplant Anatomical Donation Organizations (NADOs) go unregulated in Texas. Equally as important, Science Care does not wish to see the residents of the State of Texas go unprotected by the State with respect to their End-of-Life decisions. Rather, it is specifically because of our commitment to ensuring that all who choose to further scientific and medical advancements through body donation to science are afforded the reverence, dignity, and respect they deserve that we believe the best path forward is through the adoption of proper and efficient regulation and oversight which is specific to NADOs by the State of Texas.

With the most recent updates to Texas statutes relating to body donation having taken place more than 35 years ago (roughly 15 years prior to the advent of NADOs), the current structure of oversight, rules, and regulations relating to body donation within the State of Texas is in dire need of update to eliminate ambiguity, inapplicability, and the opportunity for ineffective or arbitrary enforcement.

This, in conjunction with the lack of resources available to the State Anatomical Board identified within the Commission's Staff Report, is what prompts Science Care to strongly endorse that the Commission recommend the State adopt a hybrid approach to resolution, which acts on the suggestions outlined in Option 1 and Option 4 of the November 2022 Staff Report.

Below is additional feedback and comment pertaining to each of the Options suggested within the Commission's Staff Report:

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.

Science Care is in favor of the Commission recommending adoption of Option 1 in conjunction with recommending adoption of Option 4;

- The SAB was established in 1907. With the advent of NADOs not occurring until much later in the 20th century, it is clear that those who had a hand in the creation and establishment of the SAB could not have contemplated the existence of entities which operate outside of higher education institutions to facilitate body donation.
 - It logically follows, that the SAB was never intended to provide oversight or regulation to entities which operate outside of the State university system. By attempting to provide oversight of NADOs in its current form, the SAB is operating beyond its statutory authority, without the support of legislative intent or enabling statutes.
- The current structure of the State Anatomical Board and the statutes, rules, and regulations under which the SAB operates are well suited for willied body programs (WBPs) operated by universities within the State of Texas. However, various regulatory barriers which arise out of the inherent differences between university-operated WBPs and NADOs exist. As such, it makes sense that the SAB be reconstituted as an advisory council to the Texas Higher Education Coordinating Board (THECB), with its regulatory authority limited expressly to university-operated WBPs.
- The members of the SAB are each university affiliates, with vast knowledge and experience in the oversight of university-operated WBPs making them uniquely qualified to oversee those particular WBPs. However, the differences between university-operated WBPs and NADOs are many. The SAB is not equipped with the resources or manpower to adapt quickly and efficiently in order effectively oversee the operations of NADOs. Ineffective oversight is akin to no oversight at all, putting the residents of Texas at risk to potential 'bad actors'.
- Option 1 affords the SAB the opportunity to focus solely on, and improve its effectiveness in the oversight of university-operated WBPs, the purpose for which it was originally created. Focus solely on WBPs eliminates the distraction of being tasked with learning how NADOs operate and developing or enacting revised SOPs and practices in order to regulate them, which would be a process that would diminish the effectiveness of the SAB at carrying out its primary responsibility and statutorily required obligations to the citizens of Texas.

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

Science Care is opposed to the Commission recommending adoption of Option 2.

- While the TFSC may seem like a more appropriate State entity to task with the regulation and oversight of NADOs than the SAB, Science Care's experiences with State entities and commissions that oversee functions pertaining to death/aftercare nationwide over the past 20 years are testament to why the TFSC would not be an optimal resolution.
 - Invariably, these commissions are comprised (either in whole or in part) of active members and owners of funeral establishments and crematories. This leads to a conflict of interest where NADOs are concerned, as funeral establishments and crematories tend to view NADOs (or any form of body donation) as direct competition to their business.
 - In some instances, funeral homes and crematories have engaged in the unethical practice of not only operating traditional death/after care entities, but concurrently establishing and operating secondary entities under their control which engage in the activities of a traditional NADO. Various publicly available news stories catalog the negative impacts to decedents and their families which can arise out of this practice, which stem from a lack of protections and oversight. However, more

applicable to the topic at hand would be the conflict of interest arising in event such entities were to exist within the State of Texas. Electing to have the TFSC regulate NADOs could effectively allow certain NADOs to set the rules and regulations by which all NADOs operating within the State of Texas must abide. To foster transparent, robust, and effective regulation and oversight, Science Care would caution against granting the TFSC the authority to regulate and oversee NADOs.

- Upon the Commission's request, Science Care can provide more specific details and accounts of the situations described above.

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.

Science Care is opposed to the Commission recommending adoption of Option 3.

- While a fully resourced state agency which oversees NADOs may seem like a logical resolution, pursuing this course of action would be costly to the residents of Texas while being concurrently unnecessary. The creation of a fully resourced state agency can be an arduous and costly process. When looking at the way other states have ensured the regulation of NADOs while protecting their citizenry, allocating an unknown amount of State resources to effectuate creation and maintenance of a new state regulatory agency would likely not yield more effective results than other states which have chosen to pursue alternative, less costly regulatory paths.
 - To protect their citizens from the increased costs associated with oversight and regulation of NADOs, many states have opted to enact legislation which recognizes nationally recognized accrediting agencies, such as the American Association of Tissue Banks (AATB) as competent and independent bodies capable of providing the oversight and regulation necessary to protect its citizenry without added cost to taxpayers.
 - Independent, nationally recognized third-party accrediting agencies such as the AATB are unbiased and exist for the sole purpose of ensuring compliance with rigorous standards enacted to protect body donors and ensure regimented, ethical practices.
 - It is important to note that more than twenty states reference or specifically rely upon the accreditation standards created, maintained, and enforced by the AATB in the regulation of NADOs.
 - In addition to recognizing national accreditation, such as that which can be obtained from the AATB, as a means of ensuring proper practice, oversight and governance, some states have even adopted legislation which expressly outlines what is necessary for a non- accredited NADO to exist and operate within their State, thereby ensuring robust requirements are in place to prevent 'bad actors' from being able to harm their citizenry.
 - Requirements for non-AATB accredited NADOs are generally enforced by the individual State Department(s) of Health or Department(s) of Regulatory Affairs.

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

Science Care is in favor of the Commission recommending adoption of Option 4 concurrent with recommending Option 1

As the November 2022 Staff Report cites, and as the SAB agreed within their response to the previous Staff Report generated in 2020, the statutes and structure which govern and oversee body donation within the State

of Texas are out of date and ambiguous. It is Science Care's recommendation that the State of Texas should craft and adopt legislation, specific to NADOs, which would be clearly applicable to NADOs and more effectively protect its citizenry. The legislative framework enacted in states such as Arizona, Colorado, and Florida each use AATB accreditation as a means of ensuring appropriate conduct by NADOs. Using these models as a roadmap, the Commission could ensure that the State of Texas has the best, most robust, and effective means of regulating whole body donations outside of a university setting while seeing that its citizenry is not saddled with the financial burden which comes with additional bureaucracy or agencies.

Specifically, Science Care would recommend that the Commission review and consider:

- Arizona Administrative Code Title 9. (Health Services) Chapter 9. Department of Health Services – Procurement Organizations; recently enacted rules pertaining to state oversight requirements of both nationally accredited and non-accredited NADOs.
- Colorado Code Title 12 (Professions and Occupations) Article 135 (Mortuaries and Crematories) Part 1 Mortuary Science Code § 12-135-105. Unlawful Acts Section 1.p., which states it is unlawful for a person owning an indirect interest with more than ten-percent ownership in a funeral establishment or for a person owning a direct interest in a funeral establishment to own an indirect interest with more than ten-percent ownership in a nontransplant tissue bank, as defined in section 12-140-102 (3), or to own a direct interest in a nontransplant tissue bank.
- Florida Statutes Chapter 765 Part V (Anatomical Gifts) § 765.10-765.541 Certification of procurement organizations; agency responsibilities
- Florida Statutes Chapter 765 Part V (Anatomical Gifts) § 765.10-765.542 Requirements to engage in organ, tissue or eye procurement.
- New York State Department of Health Certification

Pursuing Options 1 and 4 concurrently affords the State of Texas the best opportunity to ensure it is exceeding its obligation to protect its citizenry from 'bad actors' while being both a good steward of the State's financial resources and eliminating the potential for corruption, conflicts of interest, or unfair business practices. Having worked with a number of other states to ensure that body donors and their families are afforded the care, dignity, and respect they deserve by providing input throughout the legislative process, Science Care stands at the ready offering its experience and knowledge to the State of Texas as it navigates its own path forward. Working together, Science Care and the State of Texas can ensure all Texans contemplating body donation 1) have the individual liberty to make the End-Of-Life decision which best suits them, 2) are well-informed with regard to these decisions, 3) are protected by their state against negligent or predatory acts or undue coercion, 4) if electing whole body donation, are assured that their donation will be handled in accordance with the highest standards, and 5) are afforded these protections without the burden of additional bureaucracy and financial ramifications in the form of increased taxes and fee assessments.

We, once again, thank the Commission for the opportunity to provide feedback on its Staff Report, and are open to providing additional informational materials and answering any questions the Commission may have.

Best Regards,



Stephen Bathje
Vice President of Tissue Management
Science Care, Inc.

Senator Schwertner, Representative Holland, and esteemed members of the Commission:

My Name is Stephen Bathje, and I am the Vice President of Tissue Management for Science Care. I wanted to first take a moment to thank each of you, as well as the citizens of the Great State of Texas, for allowing me to speak with you and provide comments on behalf of the Science Care Program in relation to the Commission's review of the State Anatomical Board.

As the largest Non-Transplant Anatomical Donation Organization in the world, and knowing that tens of thousands of Texans are registered with our Program, we are both humbled by the opportunity to be a part of the process, and excited to be able to share our input with you as you work to determine the best path forward as it relates to the regulation of NADOs operating within the State of Texas.

(Throughout my comments I will refer to Non-Transplant Anatomical Donation Organizations like Science Care as 'NADOs' in the interest of brevity, and to differentiate such organizations from the university-operated Willd Body Programs that the State Anatomical Board is currently tasked with regulating.)

To begin, I will give you a bit of my background, as this may provide insight into the some of the comments I intend to make throughout my statement.

My journey with Science Care began in 2009 upon taking an entry level position within the organization. Since then, I have held many different positions at Science Care, and have worked directly and extensively with donors, their families, researchers, academic institutions, emergency medical skills training organizations, medical device companies, and a host of other entities. Prior to having accepted a position at Science Care, like many other individuals throughout the country, I had no idea such an organization existed, nor was I aware of the vast, incalculable benefits to society that body donation has facilitated.

What I've come to learn over the last 13 years is that each whole-body donor is as unique and impactful on the lives of others through their donation as they were as an individual in life. Whether advancing disease research, providing necessary skills-training to emergency medical personnel or orthopedic surgeons, or advancing the anatomical knowledge of the next generation of medical professionals, every donor has a unique and profound positive impact on countless other lives, and as such, should be treated with the utmost care, and afforded the pinnacle of respect and dignity in return.

As an organization, Science Care believes our first and foremost obligation is to our donors and their families. In keeping with this belief, we are one hundred percent donor-centric in our facilitation of each precious gift.

From ensuring each donation is placeable with researchers, trainers, and educators prior to acceptance into our program, to obtaining all necessary consents and permitting in order to proceed with the donation, while adhering to rigorous standard operating procedures which safeguard the anonymity, dignity, and respect of each donor, as well as the traceability of all tissues procured from each donor, Science Care sets the standard of excellence when it comes to donor care, maximization of the gift, and

regulatory compliance.

Regulatory compliance comes easy when an organization takes pride in the manner in which it treats its donors and their families and considers proper care and respect for its donors its number one obligation.

The question at hand is which path to pursue to ensure every Texan who makes the decision to donate their body to science is protected by the State, and how best to regulate those non-university-operated organizations who have a hand in facilitating the gift.

Science Care knows a bit about regulation, or lack thereof. Shortly after our founding in 2000, Science Care recognized a lack of consistent regulation or standards and practices by which NADOs were operated or to which they could be held accountable. Born out of this realization, Science Care committed to pursuing (and was the first NADO to obtain) accreditation through the American Association of Tissue Banks.

The AATB is the same third-party organization which oversees and provides operating standards and regulations for organizations facilitating live tissue transplant. Though, to date, AATB accreditation is still voluntary for NADOs, numerous NADOs have followed the trail Science Care blazed nearly 20 years ago and have obtained their own AATB accreditation, increasing the overall organizational regulatory compliance of NADOS, and moreover, the standard of care provided to whole body donors. We make this point to underscore the fact that Science Care does not shrink from the opportunity of a dditional oversight or regulation. Quite the contrary; we welcome it.

Having reviewed the Commission's Staff Report and drawing on our 23 years of experience in the facilitation of body donation for non-transplant purposes, Science Care's suggestion would be that the Commission recommend that the State of Texas adopt an approach to regulating NADOs which incorporates Option 1 and Option 4 of the Staff Report, concurrently.

Option 1 would see the Anatomical Board of the State of Texas abolished as a stand-alone board and reconstituted as an advisory council to the Texas Higher Education Coordinating Board to coordinate and distribute whole body donations among higher education institutions and would remove the board's regulatory authority.

Adopting this option would see the State Anatomical Board return to (and be able to focus on) its primary, statutory obligations to the citizens of the State of Texas.

Because the SAB is not a fully resourced state agency, it lacks the resources and staffing not only to enforce current regulations as they may pertain to NADOs, but also the resources necessary to familiarize itself with the similarities and differences between university-operated willed body programs and NADOs to be able to develop, adopt, and enforce the necessary standards and practices by which NADOs operate. The operations of university willed body programs and NADOs are markedly different, and current standards and regulations would do a disservice to donors and their families electing to participate in NADO programs, as well as make it relatively impossible for NADOs to operate efficiently within the State of Texas.

It is important to note that concurrent operation of University-Operated Willing Body Programs and NADOs within the State of Texas is not foreseen to have a negative impact on the ability of Willing Body Programs within the State of Texas to acquire the donors necessary to meet the needs of these programs. In each instance where Science Care is contacted by the family of a donor is registered to donate their body to a program other than Science Care, we refer and provide contact information to the family for the proper entity with which the donor is registered. Additionally, presence of additional organizations which facilitate body donation to science within the State of Texas would have the effect of creating more awareness that such an end-of-life care options exist, and would see more potential donors exploring the different programs which are available to them, University-Operated Willing Body Programs included.

Option 4 would see the 88th Legislative Session take up the policy question of whether and how NADOs should be regulated in Texas.

It is Science Care's position that the question of 'whether' is not a question at all. No entity, regardless of the industry or sector in which it operates, should go unregulated or without oversight. This is especially true when facilitating what can globally be referred to as end-of-life, or after care. Protection from negligent or predatory acts and coercion is an obligation each state has to its citizenry. Science Care has worked with multiple states over the years to aid in ensuring the enactment of proper regulatory protections, safeguards and oversight to prevent such issues.

The Staff Report presented two options relating to proposed regulation of NADOs. Following review of Option 2 (Transferring regulatory authority to the Texas Funeral Services Commission) and Option 3 (Restructuring the SAB as a fully resourced agency which is granted the authority to regulate NADOs), Science Care concluded that neither of these options is in the best interest of the State of Texas or its citizens.

Where both options may seem like appropriate resolutions, each is flawed in its own way.

Option 2 would see the Funeral Services Commission granted the authority to regulate NADOs. Science Care's extensive experience with State funeral boards or commissions prompts us to caution against recommendation or adoption of this option. In general, such commissions are comprised at least partially, if not fully, of active members and owners of funeral establishments and crematories. These entities generally tend to see NADOs as a threat (or as direct competition) to their business. Affording an entity that sees another as competition the opportunity to oversee and regulate a perceived competitive entity precipitates a conflict of interest.

Moreover, there have been instances across the country where traditional end-of-life or after care providers have established and operated NADOs concurrently with their primary business. Electing to have the TFSC regulate NADOs not only opens the door to the potential of allowing certain NADOs to set the standards and regulations by which NADOs must abide, but could also lead to negative impacts to decedents and their families as seen in other states (impacts which have been subsequently rectified in certain states by changing laws to prohibit funeral establishments from having more than a 10% stake or ownership in a NADO).

Option 3 would see the SAB restructured to be a fully resourced state agency with the authority to regulate NADOs. Given the inherent differences between the structure and operations of University-

Operated Willful Body programs and NADOs, alternative methods of regulating NADOs would be more efficient and likely less costly to the residents of the State of Texas.

Keeping the SAB's statutory obligations to the citizens of the State of Texas limited to overseeing the coordination and distribution of donated bodies to the state's 13 willful body programs would mean the SAB would be more efficient and effective at carrying out the mission for which it was originally conceived, and is currently structured for and tasked with achieving.

As alluded to earlier in my statement, Science Care has experience in aiding state governments in working toward and adopting measures which protect their citizens from bad actors while ensuring regulatory compliance when it comes to matters of health and safety.

To protect their citizens from the increased costs associated with oversight and regulation of NADOs, many states have opted to enact legislation which recognizes nationally recognized accrediting agencies, such as the American Association of Tissue Banks (AATB) as competent and independent bodies capable of providing the oversight and regulation necessary to protect its citizenry without added cost to taxpayers.

Independent, nationally recognized third-party accrediting agencies such as the AATB are unbiased and exist for the sole purpose of ensuring compliance with rigorous standards enacted to protect body donors and ensure regimented, ethical practices.

At current, more than twenty states reference (or specifically rely upon) the accreditation standards created, maintained, and enforced by the AATB.

In addition to recognizing national accreditation as a means of ensuring proper practice, oversight, and governance, some states have even adopted legislation which expressly outlines what is necessary for a non-accredited NADO to exist and operate within their state, thereby ensuring robust requirements are in place to prevent bad actors from being able to harm their citizenry.

It is Science Care's recommendation that the State of Texas should craft and adopt legislation, specific to NADOs, which would be clearly applicable to NADOs and would more effectively protect its citizenry. The legislative framework enacted in states such as Arizona, Colorado, and Florida each use AATB accreditation as a means of ensuring appropriate conduct by NADOs.

Science Care proposes that the Commission recommend these models be reviewed and used as a roadmap to ensure that the State of Texas has the best, most robust, and effective means of regulating whole body donations outside of a university setting while being good stewards of the state's financial resources and seeing that its citizenry is not saddled with the financial burden which comes with additional bureaucracy or state agencies.

Recommending Options 1 and 4 be pursued concurrently not only gives the citizens of Texas the protection and oversight they deserve, but also eliminates the potential for corruption, conflicts of interest, and unfair business practices while allowing for more efficient and effective regulation of NADOs. Additionally, recommendation of these options would allow the SAB to return its focus to its primary obligation of overseeing coordination and distribution of donated bodies to the State's

university-operated willful body programs.

Should the Commission make this suggestion, Science Care stands at the ready offering its experience and knowledge to the State of Texas as it navigates its own path forward. Working together, Science Care and the State of Texas can ensure all Texans contemplating body donation are well informed with regard to their decision, are protected against coercion, negligence, and predatory acts, are assured that their donation will be handled with the greatest of care in accordance with the highest standards, and are afforded each of these protections without the burden of additional bureaucracy and financial ramifications in the form of increased taxes and fee assessments.

Once again, I want to thank all of the members of the Committee for your time and consideration, and I am happy to take any questions you may have.