



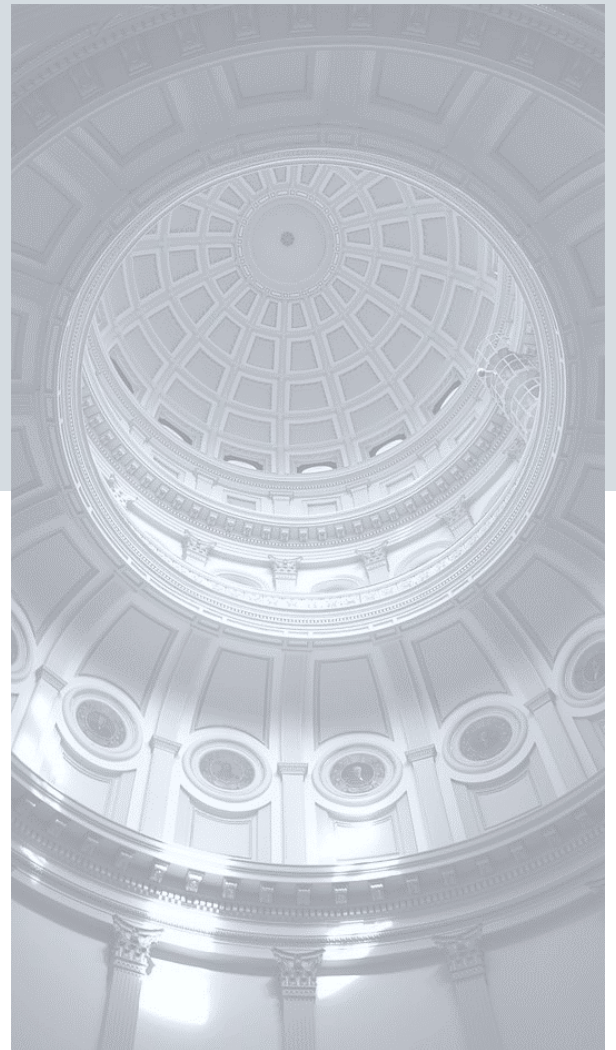
COLORADO

**Department of
Regulatory Agencies**

Colorado Office of Policy, Research &
Regulatory Reform

2023 Sunset Review

Regulation of Nontransplant
Tissue Banks



October 13, 2023



COLORADO

**Department of
Regulatory Agencies**

Executive Director's Office

October 13, 2023

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado General Assembly established the sunset review process in 1976 as a way to analyze and evaluate regulatory programs and determine the least restrictive regulation consistent with the public interest. Pursuant to section 24-34-104(5)(a), Colorado Revised Statutes (C.R.S.), the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) at the Department of Regulatory Agencies (DORA) undertakes a robust review process culminating in the release of multiple reports each year on October 15.

A national leader in regulatory reform, COPRRR takes the vision of their office, DORA and more broadly of our state government seriously. Specifically, COPRRR contributes to the strong economic landscape in Colorado by ensuring that we have thoughtful, efficient, and inclusive regulations that reduce barriers to entry into various professions and that open doors of opportunity for all Coloradans.

As part of this year's review, COPRRR has completed an evaluation of the regulation of nontransplant tissue banks. I am pleased to submit this written report, which will be the basis for COPRRR's oral testimony before the 2024 legislative committee of reference.

The report discusses the question of whether there is a need for the regulation provided under Article 140 of Title 12, C.R.S. The report also discusses the effectiveness of Director of the Division of Professions and Occupations in carrying out the intent of the statutes and makes recommendations for statutory changes for the review and discussion of the General Assembly.

To learn more about the sunset review process, among COPRRR's other functions, visit coprrr.colorado.gov.

Sincerely,

Patty Salazar
Executive Director





Sunset Review: Regulation of Nontransplant Tissue Banks

Background

What is regulated?

Nontransplant tissue banks (NTTBs) recover, transport, distribute, screen, store and arrange for the storage and distribution of human remains for any purpose other than transplantation into a human being.

Why is it regulated?

Regulation of NTTBs began as a direct result of a funeral home and crematory in Colorado selling human remains without permission and returning non-human remains to families. Regulation helps to provide a minimal assurance that when people donate their bodies or those of their loved ones to science, that intent will be complied with.

Who is regulated?

There are three NTTBs registered in Colorado.

How is it regulated?

The Director of the Division of Professions and Occupations (Director) registers NTTBs. Each NTTB is required to have a designee who must have the authority to ensure the NTTB's compliance with the law.

What does it cost?

In fiscal year 22-23, the Director allocated 0.1 full-time equivalent employee and spent \$4,916 on the regulation of NTTBs.

What disciplinary activity is there?

Since program inception in 2019, there have been three complaints and no disciplinary actions related to NTTBs.

Key Recommendations

- Continue the regulation of NTTBs for nine years, until 2033.
- Grant to the Director, the authority to promulgate rules.

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Background

Sunset Criteria

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) within the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria¹ and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are guided by statutory criteria and sunset reports are organized so that a reader may consider these criteria while reading. While not all criteria are applicable to all sunset reviews, the various sections of a sunset report generally call attention to the relevant criteria. For example,

- In order to address the first criterion and determine whether the program under review is necessary to protect the public, it is necessary to understand the details of the profession or industry at issue. The Profile section of a sunset report typically describes the profession or industry at issue and addresses the current environment, which may include economic data, to aid in this analysis.
- To address the second sunset criterion--whether conditions that led to the initial creation of the program have changed--the History of Regulation section of a sunset report explores any relevant changes that have occurred over time in the regulatory environment. The remainder of the Legal Framework section addresses the fifth sunset criterion by summarizing the organic statute and rules of the program, as well as relevant federal, state and local laws to aid in the exploration of whether the program's operations are impeded or enhanced by existing statutes or rules.
- The Program Description section of a sunset report addresses several of the sunset criteria, including those inquiring whether the agency operates in the public interest and whether its operations are impeded or enhanced by existing statutes, rules, procedures and practices; whether the agency or the agency's board performs efficiently and effectively and whether the board, if applicable, represents the public interest.
- The Analysis and Recommendations section of a sunset report, while generally applying multiple criteria, is specifically designed in response to the fourteenth criterion, which asks whether administrative or statutory changes are necessary to improve agency operations to enhance the public interest.

¹ Criteria may be found at § 24-34-104, C.R.S.

These are but a few examples of how the various sections of a sunset report provide the information and, where appropriate, analysis required by the sunset criteria. Just as not all criteria are applicable to every sunset review, not all criteria are specifically highlighted as they are applied throughout a sunset review. While not necessarily exhaustive, the table below indicates where these criteria are applied in this sunset report.

Table 1
Application of Sunset Criteria

Sunset Criteria	Where Applied
(I) Whether regulation or program administration by the agency is necessary to protect the public health, safety, and welfare.	<ul style="list-style-type: none"> • Profile of the Industry • Recommendation 1
(II) Whether the conditions that led to the initial creation of the program have changed and whether other conditions have arisen that would warrant more, less, or the same degree of governmental oversight.	<ul style="list-style-type: none"> • History of Regulation
(III) If the program is necessary, whether the existing statutes and regulations establish the least restrictive form of governmental oversight consistent with the public interest, considering other available regulatory mechanisms.	<ul style="list-style-type: none"> • History of Regulation • Legal Summary
(IV) If the program is necessary, whether agency rules enhance the public interest and are within the scope of legislative intent.	<ul style="list-style-type: none"> • Legal Framework • Program Description and Administration
(V) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters.	<ul style="list-style-type: none"> • Legal Framework • Program Description and Administration • Recommendation 2
(VI) Whether an analysis of agency operations indicates that the agency or the agency's board or commission performs its statutory duties efficiently and effectively.	<ul style="list-style-type: none"> • Program Description and Administration
(VII) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates.	<ul style="list-style-type: none"> • Not applicable
(VIII) Whether regulatory oversight can be achieved through a director model.	<ul style="list-style-type: none"> • Program Description and Administration •
(IX) The economic impact of the program and, if national economic information is not available, whether the agency stimulates or restricts competition.	<ul style="list-style-type: none"> • Profile of the Industry

Sunset Criteria	Where Applied
(X) If reviewing a regulatory program, whether complaint, investigation, and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession or regulated entity.	<ul style="list-style-type: none"> • Program Description and Administration
(XI) If reviewing a regulatory program, whether the scope of practice of the regulated occupation contributes to the optimum use of personnel.	<ul style="list-style-type: none"> • Program Description and Administration
(XII) Whether entry requirements encourage equity, diversity, and inclusivity.	<ul style="list-style-type: none"> • Not available
(XIII) If reviewing a regulatory program, whether the agency, through its licensing, certification, or registration process, imposes any sanctions or disqualifications on applicants based on past criminal history and, if so, whether the sanctions or disqualifications serve public safety or commercial or consumer protection interests. To assist in considering this factor, the analysis prepared pursuant to subsection (5)(a) of this section must include data on the number of licenses, certifications, or registrations that the agency denied based on the applicant’s criminal history, the number of conditional licenses, certifications, or registrations issued based upon the applicant’s criminal history, and the number of licenses, certifications, or registrations revoked or suspended based on an individual’s criminal conduct. For each set of data, the analysis must include the criminal offenses that led to the sanction or disqualification.	<ul style="list-style-type: none"> • Not applicable
(XIV) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.	<ul style="list-style-type: none"> • Recommendations 1 and 2

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. Anyone can submit input on any upcoming sunrise or sunset review on COPRRR’s website at coprrr.colorado.gov.

The functions of the Director of the Division of Professions and Occupations (Director and Division, respectively), as enumerated in Article 140 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on September 1, 2024, unless continued by the General Assembly. During the year prior to this date, it is the duty of COPRRR to conduct an analysis and evaluation of the Director pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed regulation of nontransplant tissue banks (NTTBs) should be continued and to evaluate the performance of the Director and the Division. During this review, the Director must demonstrate that the program serves the public interest. COPRRR’s findings and recommendations are submitted via this report to the Office of Legislative Legal Services.

Methodology

As part of this review, COPRRR staff interviewed Division staff, representatives of registered NTTBs and officials with state and national industry associations; and reviewed complaint files, Colorado statutes and rules, and the laws of other states.

The major contacts made during this review include, but are not limited to:

- Cremation Association of North America
- Division of Professions and Occupations
- Donor Alliance
- National Funeral Directors Association
- State Anatomical Board

In July 2023, COPRRR staff conducted a survey of all registered nontransplant tissue banks. The survey was sent to three registrants and no emails were returned as undeliverable. The survey received one response, which is a 33.33 percent response rate. Since there are only three registrants and only one responded to the survey, survey results are not presented in this report because they were intended to be anonymous.

Profile of the Industry

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first criterion asks whether regulation or program administration by the agency is necessary to protect the public health, safety, and welfare.

To understand the need for regulation, it is first necessary to recognize what the industry does, who it serves and any necessary qualifications.

End of life decisions are easily among the most emotional and difficult decisions anyone can make whether they are making such decisions for themselves or those they care about. While a traditional funeral accompanied by a burial, cremation or both may be what most typically comes to mind when contemplating such decisions, body and tissue donation are also viable and common options.

First, there are at least two general types of tissue or body donation: donations intended for transplantation and donations that are intended for research. Donations intended for transplantation, as the term implies, consist of the donation of tissues or body parts, such as organs, that will be transplanted into another human being.

Donations intended for research, sometimes referred to as whole-body donations, are an option under several circumstances: if the deceased suffered from an illness or condition that renders the body or tissue unacceptable for transplant; if the deceased or surviving family want the body donated for the advancement of medical research or if the surviving family cannot afford cremation (which is often the most affordable option).

Thus, the decision to donate may be altruistic or financial. However, only whole-body donations are the subject of this sunset review, and even then, only a subset of such donations are made to nontransplant tissue banks. Nontransplant tissue banks (NTTBs) are the sole subject of this sunset review.

Individuals who desire to donate their own body or the body of a loved one may make the donation directly to a medical school or to an NTTB. When a body is donated to a medical school, there is a greater likelihood that the body will remain intact. When a body is donated to an NTTB, there is a greater likelihood that the body will be dismembered, with different tissue being sent to different institutions, depending on the various needs of those institutions.

Since the sole focus of this sunset review is on NTTBs, the remainder of this discussion will focus on donations to such organizations.

The donation process can begin before or after death. Some individuals know before their passing that they would like to donate their bodies to science. Most NTTBs have

processes in place so that all of the necessary documentation is in place prior to passing. When the donor passes away, the NTTB is notified and arranges to collect the body.

In other cases, those responsible for making final arrangements for the deceased may opt to donate the body to an NTTB after death. Once the proper documents have been executed, the NTTB arranges to collect the body.

Regardless of whether the motivation to donate is altruistic or financial, donors and their estates pay nothing and, in return for the donation, the NTTB will pay for the filing of any necessary death certificates and cremation. In the case of cremation, typically only those portions of the body that are not used for research will be cremated and returned to the family.

Individuals may learn of whole-body donation and NTTBs through a variety of channels. Some may conduct their own research. Others may learn of the donation process through the facilities in which they pass, such as hospice or long-term care.

Once an NTTB takes custody of the donated remains, it will prepare them for distribution for a variety of research, education and training purposes:²

- Anatomy and physiology student education;
- Alzheimer's, dementia and Parkinson's research;
- Cranio-maxillofacial surgical technology;
- Dental surgery training and device development;
- Drug therapy;
- Emergency first responder training;
- Medical resident training;
- Minimally-invasive surgical technology;
- Musculoskeletal enhancements;
- Neurosurgery;
- Orthopedic device technology;
- Otolaryngology;
- Pain management;
- Robotic cardiac and thoracic surgical training;
- Sports medicine surgeon and physician development;
- Transplantation surgery training and technique development; and
- Many more.

Some NTTBs, particularly those accredited by the American Association of Tissue Banks (AATB), require those receiving donated bodies or tissue to outline their planned use, how the specimens will be utilized and how they will be disposed of.³

² American Association of Tissue Banks. *Non-Transplant Anatomical Donation*. Retrieved June 14, 2023, from www.aatb.org/nados

³ American Association of Tissue Banks. *Non-Transplant Anatomical Donation*. Retrieved June 14, 2023, from www.aatb.org/nados

While AATB offers an accreditation for NTTBs, only one of the three NTTBs registered in Colorado is also accredited by AATB. AATB's *Standards for Tissue Banking*, which apply to both NTTBs and tissue banks that work with tissue for transplantation, address topics such as:⁴

- General institutional requirements;
- Records management;
- Authorization and consent practices;
- Donor screening, testing and eligibility;
- Tissue processing, packaging, labeling, storage and distribution; and
- Establishment and maintenance of a quality program.

Tissue banks that accept donations for transplantation are heavily regulated by the federal government. However, no federal oversight of NTTBs exists. Rather, individual states must determine whether and how to regulate them. At least five states (Arizona, Colorado, Florida, New York and Oregon) have done so.

The ninth sunset criterion questions the economic impact of the program and, if national economic information is not available, whether the agency stimulates or restricts competition. One way this may be accomplished is to review the economics of the industry.

Since NTTBs typically cover the cost of cremation this is a reasonable expense to examine while evaluating this criterion. To ascertain the cost of cremation in Colorado in 2023, COPRR staff conducted a simple internet search and found a small sampling of prices from as low as \$695⁵ and as high as \$995.⁶ The small sample size suggests that prices around the state vary considerably, and some crematories likely charge much less and some much more than these figures suggest.

While these costs do not include things like transportation, storage, processing and administrative matters, they do include the retail cost of a basic cremation and provide some insight as to some of the economics involved.

Most NTTBs fund their operations by charging fees for the services provided to the end users of the donated tissue.⁷ Such fees can vary widely, ranging from several hundred dollars for certain types of tissue, to several thousands of dollars for entire bodies.

Regardless of the costs associated with acquiring a body or the income associated with dispersing its tissue, NTTBs may be organized as for-profit or not-for-profit entities.

⁴ American Association of Tissue Banks. *AATB Standards for Tissue Banking*. Retrieved June 20, 2023, from www.aatb.org/standards

⁵ Colorado Cremation Services. *Cremation Services From \$695*. Retrieved June 20, 2023, from legacycremationservices.com/cremation-services-cost/Colorado/

⁶ A Basic Cremation. *Direct Cremation Package*. Retrieved June 20, 2023, from coloradocremationservices.com

⁷ American Association of Tissue Banks. *Non-Transplant Anatomical Donation*. Retrieved June 14, 2023, from www.aatb.org/nados

Legal Framework

History of Regulation

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by the sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The first sunset and second sunset criteria question:

Whether regulation or program administration by the agency is necessary to protect the public health, safety, and welfare; and

Whether the conditions that led to the initial creation of the program have changed and whether other conditions have arisen that would warrant more, less or the same degree of governmental oversight.

One way that COPRRR addresses this is by examining why the program was established and how it has evolved over time.

Entities that harvest human tissue and organs for transplant have been regulated by the federal government and the state for many years. However, prior to 2018, entities accepting human remains (either whole bodies or portions thereof) for scientific research, also known as nontransplant tissue banks (NTTBs), were not regulated at any level in Colorado.

Senate Bill 18-234 (SB 234) introduced the regulation of nontransplant tissue banks in this state. The bill was passed as a direct result of a case involving a regulated funeral establishment and crematory on the Western Slope selling human remains without permission and returning containers of non-human remains to families. In most instances, these families never learned what ultimately happened to the remains of their loved ones.

This is the first sunset review of the regulatory program established under SB 234.

Legal Summary

The third, fourth and fifth sunset criteria question:

Whether the existing statutes and regulations establish the least restrictive form of governmental oversight consistent with the public interest, considering other available regulatory mechanisms;

Whether agency rules enhance the public interest and are within the scope of legislative intent; and

Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters.

A summary of the current statutes and rules is necessary to understand whether regulation is set at the appropriate level and whether the current laws are impeding or enhancing the agency's ability to operate in the public interest.

An NTTB is,

a person that, for any purpose other than transplantation into a living human being, recovers, transports, distributes, screens, stores, and arranges for the storage and distribution of human remains.⁸

Importantly, this definition specifically excludes:⁹

- Eye banks that are licensed, accredited or regulated under state or federal law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes;¹⁰
- Organ procurement organizations designated by the Secretary of the U.S. Department of Health and Human Services as such;¹¹
- Tissue banks that are licensed, accredited or regulated under state or federal law to engage in the recovery, screening, testing, processing storage or distribution of a portion of the human body other than eyes or organs;¹²
- Registered funeral establishments; and
- Registered crematories.

⁸ § 12-140-102(3)(a), C.R.S.

⁹ § 12-140-102(3)(b), C.R.S.

¹⁰ § 15-19-202(10), C.R.S.

¹¹ § 15-19-202(16), C.R.S.

¹² § 15-19-202(31), C.R.S.

As of July 1, 2019, each NTTB operating in Colorado must register with the Director of the Division of Professions and Occupations (Director and Division, respectively). To register, an NTTB must provide the Director with:¹³

- The NTTB's address,
- The full name and address of the NTTB's designee,
- The date the NTTB began operating,
- The type of services provided,
- A description of the NTTB's premises and equipment, and
- Pay the applicable fee.

To be appointed as an NTTB's designee, an individual must:¹⁴

- Be at least 18 years old,
- Possess at least two years of experience working for an NTTB,
- Be employed by the NTTB the designee represents,
- Possess the authority to require the NTTB's personnel to comply with applicable law, and
- Not serve as a designee for more than one NTTB unless each additional NTTB is operated under common ownership and management and certain geographical conditions apply.

An NTTB must disclose to the donor or the person authorized to consent to the donation, that the NTTB will be compensated for distribution of the remains and that donated remains, in whole or in part, may be distributed by and returned to the NTTB.¹⁵

Upon taking delivery of human remains, an NTTB must provide a receipt to the person delivering the remains, signed by both the person delivering the remains and the NTTB. The receipt must include:¹⁶

- The date and time of delivery,
- The name of the person who delivered the remains and the name of any business with which they are affiliated,
- The name of the decedent, and
- The name of the person who accepted the remains on behalf of the NTTB.

The NTTB must retain the receipt, as well as the following records, for three years:¹⁷

- The donor's name and address;
- The date of donation;

¹³ §§ 12-140-103(1)(a) and 12-140-103(3), C.R.S.

¹⁴ § 12-140-103(2), C.R.S.

¹⁵ § 12-140-106, C.R.S.

¹⁶ § 12-140-104(1), C.R.S.

¹⁷ §§ 12-140-104(1) and (2), C.R.S.

-
- Documentation of informed consent, executed either by the decedent or the person authorized to consent on the decedent's behalf;
 - A description of the remains to be donated for scientific or educational purposes;
 - The decedent's medical history; and
 - Tracking documents relating to the transport and delivery of the remains.

To facilitate compliance with the last bullet-point above, an NTTB must affix identification to the remains and provide tracking paperwork to match the identification.¹⁸

An NTTB must handle the remains in a safe and sanitary manner, and it must possess the equipment necessary to protect the health and safety of the public and the NTTB's employees.¹⁹

Unidentified or unharvested remains must not be commingled prior to delivery to a registered funeral establishment or registered crematory.²⁰ However, if the NTTB operates its own incinerator, it need not register as a crematory, and it may commingle tissue from medical or educational research from multiple decedents.²¹

The Director may issue a letter of admonition; place a registrant on probation; or deny, revoke or suspend any registration if the NTTB or applicant:²²

- Violates an order of the Director, state law or the Director's rules;
- Makes a material misstatement or omission in the registration or application for registration;
- Violates federal law, Colorado law or an ordinance or resolution of a political subdivision in the operation of the NTTB; or
- Has been disciplined as an NTTB in another jurisdiction.

Additionally, a person who violates section 12-140-101, *et seq.*, C.R.S., which includes the NTTB regulatory statute, commits a class 1 Misdemeanor.²³

Finally, it is unlawful for either of the following to own more than a 10 percent indirect interest or any direct interest in an NTTB:²⁴

- A person who owns more than a 10 percent indirect interest in a funeral home or crematory, or
- A person who owns any direct interest in a funeral home or crematory.

¹⁸ § 12-140-105(1)(c), C.R.S.

¹⁹ §§ 12-140-105(1)(a) and (1)(b), C.R.S.

²⁰ § 12-140-105(2), C.R.S.

²¹ § 12-140-105(3), C.R.S.

²² § 12-140-107(1), C.R.S.

²³ §§ 12-140-108 and 12-135-108, C.R.S.

²⁴ §§ 12-135-105(1)(p) and 12-135-301(3), C.R.S.

Program Description and Administration

In a sunset review, the Colorado Office of Policy, Research and Regulatory Reform (COPRRR) is guided by sunset criteria located in section 24-34-104(6)(b), Colorado Revised Statutes (C.R.S.). The fifth and sixth sunset criteria question:

Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures, and practices and any other circumstances, including budgetary, resource, and personnel matters; and

Whether an analysis of agency operations indicates that the agency or the agency's board or commission performs its statutory duties efficiently and effectively.

In part, COPRRR utilizes this section of the report to evaluate the agency according to these criteria.

Statute vests the Director of the Division of Professions and Occupations (Director and Division, respectively) with the authority to regulate nontransplant tissue banks (NTTBs). In practice, day-to-day regulatory activities are performed by Division staff.

Since the NTTB program began in January 2019, no data are available for years prior to this.

Table 2 provides program expenditures and the number of full-time equivalent (FTE) employees dedicated to program implementation for the fiscal years indicated.

Table 2
Agency Fiscal Information

Fiscal Year	Total Program Expenditures	FTE
19-20	\$0	0.06
20-21	\$1,414	0.05
21-22	\$1,915	0.05
22-23	\$4,916	0.1

The FTE reported in fiscal year 19-20 were dedicated to program startup.

As Table 2 illustrates, both staffing and expenditures remained relatively constant until fiscal year 22-23. The increase in expenditures can be attributed to increased costs associated with increased charges by the Governor's Office of Information Technology, which resulted in increased costs for all of the Division's programs.

The NTTB program has been administratively housed in a unit consisting of 16 director model programs, the staff of which consists of two Program Directors (Program Management II), two Program Supervisors (Technician IV), a compliance monitoring position (Technician IV), an enforcement specialist (Technician IV) and three program/unit specialists (Administrative Assistant III).

As of August 2023, staff dedicated solely to the NTTB program consists of 0.05 FTE Program Management II. The Program Director provides overall management of the program, personnel, performance management, complaint resolution, stakeholder engagement, outreach and education and implementation of the statute.

The number of FTE reflected in Table 2 above does not include employees in the centralized offices of the Division that provide management, licensing, administrative, technical, and investigative support to the Director. However, the cost of those FTE is reflected in the total program expenditures.

The NTTB program is cash funded, meaning that registration fees are used to cover program expenditures. Table 3 illustrates the fees that have been assessed since program implementation.

Table 3
Fees

Fiscal Year	Initial	Renewal
18-19	\$1,325	\$1,025
19-20	\$1,325	\$1,025
20-21	\$1,325	\$500
21-22	\$1,325	\$500
22-23	\$1,000	\$250

While the fee assessed for an initial registration has remained largely unchanged, decreasing only in fiscal year 22-23, the fees to renew a registration have been reduced substantially since program implementation. These decreases can largely be attributed the low numbers of complaints and disciplinary actions, as discussed below.

Registration

The eleventh sunset criterion questions whether the scope of practice of the regulated occupation contributes to the optimum use of personnel.

In part, COPRRR utilizes this section of the report to evaluate the program according to this criterion.

To obtain a registration as an NTTB, the following must be provided to the Director:

- The date the NTTB began doing business,
- The services provided by the NTTB,
- Description of the NTTB's premises and equipment,
- Whether the NTTB holds a license or registration as such in any other jurisdiction,
- Appointed Designee Affidavit, and
- The required fee.

Table 4 below illustrates, for the fiscal years indicated, the number of registered NTTBs.

Table 4
Registration Information

Fiscal Year	New	Renewal	Total
18-19	1	0	1
19-20	4	0	4
20-21	0	4	4
21-22	0	3	3
22-23	0	3	3

The data in Table 4 illustrate that the number of registered NTTBs has remained remarkably constant and low since program inception.

Complaints & Disciplinary Activity

The eighth and tenth sunset criteria require COPRRR to examine whether regulatory oversight can be achieved through a director model, and whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession or regulated entity.

In part, COPRRR utilizes this section of the report to evaluate the program according to these criteria.

Since program inception, the Director has received three complaints against NTTBs, none of which resulted in disciplinary action.

In October 2019, just a few months after the registration requirement took effect, the Director received a notice that an NTTB was not yet registered. Division staff contacted the NTTB and by December of the same year, the NTTB had registered.

In March 2022, the Division learned of news reports regarding human remains that were stolen from a vehicle. A short investigation revealed that the remains were being returned to the registered NTTB for final disposition, and the courier, in violation of the courier's own policies, left the remains in an unattended vehicle overnight, which is when they were stolen. While the case was ultimately dismissed a month later since no violation of the statute had occurred, the remains were never recovered.

The final complaint was received in June 2022. It alleged that the donor's remains were supposed to be returned to the donor's family within two years of donation, but they had not been. When the family was unable to communicate with the NTTB and learned that the NTTB had gone out of business, they filed a complaint with the Director. Like the family, Division staff was unable to locate or communicate with the owner of the dissolved NTTB and ultimately dismissed the case in February 2023. The location of the donor's remains were never discovered.

From the time the complaint in fiscal year 19-20 was received until final disposition, a total of 41 days elapsed. In fiscal year 21-22, the average time to close a case was 36 days.

Analysis and Recommendations

The final sunset criterion questions whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest. The recommendations that follow are offered in consideration of this criterion, in general, and any criteria specifically referenced in those recommendations.

Recommendation 1 – Continue the regulation of nontransplant tissue banks for nine years, until 2033.

The first sunset criterion questions whether regulation is necessary to protect the public health, safety and welfare.

Senate Bill 18-234 introduced the regulation of nontransplant tissue banks (NTTBs) in Colorado. The bill was passed as a direct result of a case involving a regulated funeral establishment and crematory on the Western Slope selling human remains without permission and returning containers of non-human remains to families. In most instances, these families never learned what ultimately happened to the remains of their loved ones.

Section 12-140-101, *et seq.*, Colorado Revised Statutes (C.R.S.), vests in the Director of the Division of Professions and Occupations (Director and Division, respectively) the authority to register NTTBs, receive and investigate complaints against them and take disciplinary action when warranted.

An NTTB is,

a person that, for any purpose other than transplantation into a living human being, recovers, transports, distributes, screens, stores, and arranges for the storage and distribution of human remains.²⁵

Thus, the Director does not regulate entities that recover human remains that will be transplanted into others, and the Director does not regulate entities, such as medical schools, that accept human remains that are not intended for distribution. In other words, the regulatory program at issue is confined to those entities that recover or accept human remains that are redistributed, often for research or educational purposes.

Regardless, the nuanced distinctions between the various types of donation can be lost on many, particularly at a time of grievous loss. When situations similar to what occurred on the Western Slope occur, they can blemish otherwise legitimate industry participants and similar industries that serve to advance science and education. In this

²⁵ § 12-140-102(3)(a), C.R.S.

manner, regulation of NTTBs can help to maintain the integrity of a system that serves to protect the public health and welfare.

Indeed, what happened on Colorado's Western Slope is hardly an isolated incident. In 2017, Reuters ran a six-part series documenting multiple instances where human remains were sold for questionable purposes and without the knowledge or consent of families. As recently as summer 2023, reports of human remains being stolen from the Harvard Medical School morgue resulted in criminal indictments on the East Coast.

Although only three NTTBs are registered in Colorado and there has been no disciplinary action taken against any of them, the potential for harm remains high. When people donate their own bodies or those of their loved ones to science, there needs to be some assurance that their intent will be complied with. The NTTB registration program serves to provide that minimal assurance.

Additionally, Colorado's registration program contains a key element to help prevent the events that occurred on the Western Slope from happening again. It is unlawful for either of the following to own more than a 10 percent indirect interest or any direct interest in an NTTB: ²⁶

- A person who owns more than a 10 percent indirect interest in a funeral home or crematory, or
- A person who owns any direct interest in a funeral home or crematory.

These restrictions on ownership help to reduce the financial incentives of diverting human remains without authorization.

For all these reasons, the General Assembly should continue the regulation of NTTBs for nine years, until 2033. Given the relatively low number of registrants, complaints and disciplinary actions, a longer continuation period, such as nine years, is justified.

²⁶ §§ 12-135-105(1)(p) and 12-135-301(3), C.R.S.

Recommendation 2 – Grant to the Director, the authority to promulgate rules.

Section 12-140-101, *et seq.*, C.R.S., grants the Director the authority to register NTTBs, to receive and investigate complaints against them and to take disciplinary action when warranted. These are all standard regulatory tools.

However, the Director lacks a key authority that is present in virtually all regulatory programs—the authority to promulgate rules. Such authority would enable the Director to define any necessary terms and to more clearly establish regulatory requirements and processes. Clarity generally leads to greater compliance.

Given the relatively small size of this program and the dearth of complaints, this has not yet created a problem. However, no reason for the lack of authority is readily apparent.

The fifth sunset criterion asks, in part, whether the agency’s operations are impeded by statutes, rules, procedures or any other circumstances. The lack of rulemaking authority may impede the Director’s ability to regulate NTTBs in a comprehensive manner and should be remedied.

Therefore, the General Assembly should grant to the Director, the authority to promulgate rules.