Article 54.5 140
Nontransplant Tissue Banks

12-140-101. Applicability of common provisions. Articles 1 and 20 of this title 12 apply, according to their terms, to this Article 140.

12-140-102. [Formerly 12-54.5-101] Definitions. As used in this article 54.5 140, unless the context otherwise requires:

(1) "Designee" means an individual designated by a nontransplant tissue bank registered in accordance with section 12-54.5-102 12-140-103.

(2) "Director" means the director of the division or the director's designee.

(3) "Division" means the division of professions and occupations created in section 24-34-102. (Redundant with definitions common provision, 12-20-102 (6).)

(4) "Human remains" means all or any portion of the physical remains of a dead human who was born alive.

(5) (a) "Nontransplant tissue bank" means 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.

(b) "Nontransplant tissue bank" does not include:

(I) An eye bank, an organ procurement organization, or a tissue bank, as those terms are defined in section 15-19-202 (10), (16), and (31), respectively;

(II) A funeral establishment registered in accordance with section 12-54-110 12-135-110; or

(III) A crematory registered in accordance with section 12-54-303 12-135-303.

12-140-103. [Formerly 12-54.5-102] Registration required - repeal. (1) (a) By July 1, 2019, each nontransplant tissue bank shall register with the director in the form and manner determined by the director. The registration must include:

(I) The specific address of the nontransplant tissue bank;
(II) The full name and address of the designee appointed in accordance with subsection (2)(a) of this section;

(III) The date the nontransplant tissue bank began doing business;

(IV) The type of services provided by the nontransplant tissue bank; and

(V) A description of the nontransplant tissue bank’s premises and equipment.

(b) Each nontransplant tissue bank registration is subject to renewal pursuant to a schedule established by the director in accordance with section 24-34-102 (8) and in the form and manner determined by the director. EXPIRATION, REINSTATEMENT, AND DELINQUENCY FEE PROVISIONS OF SECTION 12-20-202 (1) AND (2).

(c) In accordance with section 24-34-105, the director may adjust the registration fee set under subsection (3) of this section and establish renewal fees and delinquency fees for reinstatement. If a nontransplant tissue bank fails to renew the registration in accordance with the schedule established by the director, the registration expires.

(2) (a) Each nontransplant tissue bank shall appoint an individual as the designee of the nontransplant tissue bank. A designee must:

(I) Be at least eighteen years of age;

(II) Have at least two years of experience working for a nontransplant tissue bank;

(III) Be employed by the registered nontransplant tissue bank that the designee represents;

(IV) Have the authority within the nontransplant tissue bank's organization to require that personnel comply with this article 54.5 140; and

(V) Not be designated for more than one nontransplant tissue bank unless each additional nontransplant tissue bank is operated under common ownership and management and unless each additional nontransplant tissue bank is sixty miles or less from all other nontransplant tissue banks held under the same common ownership.

(b) If, after initial registration, the nontransplant tissue bank appoints a new designee in accordance with subsection (2)(a) of this section, the nontransplant tissue bank shall notify the director within thirty days after appointing the designee.

(3) To register, a person must pay the fee set by the director. The director shall set the registration fee to offset the division’s direct and indirect costs of implementing this article 54.5. The director shall transmit the fee to the state treasurer, who shall credit it to the division of professions and occupations cash fund created in section 24-34-105 pursuant to section 12-20-105.

(4) This section is repealed, effective September 1, 2024. Before its repeal, this section is scheduled for review in accordance with section 24-34-104.

12-140-104. [Formerly 12-54.5-103] Records and receipts. (1) A nontransplant
tissue bank shall furnish to a person who delivers human remains to the nontransplant tissue bank a receipt, which must be signed by both the nontransplant tissue bank and the person who delivers the human remains. The nontransplant tissue bank shall retain a copy of the receipt in its records in accordance with subsection (2) of this section. The receipt must include the following:

(a) The date and time of the delivery;
(b) The name of the person who delivered the human remains;
(c) The name of the decedent;
(d) The name of any businesses with which the person delivering the human remains is affiliated; and
(e) The name of the person who received the human remains on behalf of the nontransplant tissue bank.

(2) A nontransplant tissue bank shall maintain for at least three years at its registered location the following records:

(a) The donor's full name and address;
(b) The date of donation;
(c) Documentation of the decedent's informed consent or the consent of the person authorized by law to consent on behalf of the donor to the donation;
(d) A description of the human remains to be donated for scientific or educational purposes;
(e) Decedent medical history, including any of the following if used by the nontransplant tissue bank: Autopsy reports, donation questionnaires, and other donor or decedent solicitation materials; and
(f) Tracking documentation of the transport of and delivery of human remains.

(3) A nontransplant tissue bank shall keep complete and accurate records and make the records open for inspection by the director.

12-140-105. [Formerly 12-54.5-104] Standards of practice. (1) A nontransplant tissue bank shall:

(a) Handle human remains in a safe and sanitary manner;
(b) Be equipped with instruments and supplies necessary to protect the health and safety of the public and employees of the nontransplant tissue bank; and
(c) Affix identification to all human remains delivered to the nontransplant tissue bank and provide tracking paperwork to match the identification.

(2) A nontransplant tissue bank shall not commingle unidentified or unharvested human remains prior to transfer to a crematory or funeral establishment, as those terms are defined in section 12-54-102(5) and (12) 12-135-103(8) and (16), respectively.

(3) An incinerator that is used for the disposal of human remains and that is operated by a registered nontransplant tissue bank need not be registered under part 3 of article 54-135.
of this title 12. The incinerator may commingle tissue from medical or educational research from multiple decedents.

12-140-106. [Formerly 12-54.5-105] Disclosure. (1) A nontransplant tissue bank shall disclose, in clear and unambiguous terms, the following information to the donor or to the person authorized by law to consent to donation:

(a) That the donated human remains may be distributed, in whole or in part, by the nontransplant tissue bank;
(b) That the donated human remains may be returned, in whole or in part, to the nontransplant tissue bank; and
(c) That the nontransplant tissue bank will be compensated for distribution of the human remains.

12-140-107. [Formerly 12-54.5-106] Discipline. (1) The director may deny, suspend, revoke, or place on probation a nontransplant tissue bank or issue a letter of admonition to an applicant for or holder of a nontransplant tissue bank registration if the nontransplant tissue bank or applicant: (a) Violates an order of the director, this article 54.5, or the rules established under this article 140; (b) Makes a material misstatement or omission in the registration or the application for a registration;
(c) Violates federal law, Colorado law, or an ordinance or resolution of a political subdivision of Colorado in the operation of the nontransplant tissue bank; or
(d) Has incurred disciplinary action related to the administration of a nontransplant tissue bank in another jurisdiction. Evidence of this disciplinary action is prima facie evidence for denial of registration or other disciplinary action if the violation would be grounds for disciplinary action in this state.

(2) To be valid, a proceeding to deny, suspend, revoke, or place on probation a registration must be conducted in accordance with sections 24-4-104 and 24-4-105. The director may use an administrative law judge employed by the office of administrative courts in the department of personnel to conduct a hearing. SECTION 12-20-403 GOVERNS PROCEEDINGS UNDER THIS SECTION.

12-140-108. [Formerly 12-54.5-107] Violations and penalties. A person who violates this article 54.5 is guilty of a misdemeanor and, upon conviction, shall be
punished by a fine of not more than five thousand dollars, imprisonment in the county jail for not more than eighteen months, or both the fine and imprisonment.