

Article 54.5 140
Nontransplant Tissue Banks

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1 **12-140-101. Applicability of common provisions.** ARTICLES 1 AND 20 OF THIS TITLE
2 APPLY, ACCORDING TO THEIR TERMS, TO THIS ARTICLE 140.

3
4 **12-140-102. [Formerly 12-54.5-101] Definitions.** As used in this article *54.5 140*,
5 unless the context otherwise requires:

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

8 ~~(2) "Director" means the director of the division or the director's designee.~~
9 <{**Redundant with definitions common provision, 12-20-102 (6)**}>

10 ~~(3) "Division" means the division of professions and occupations created in section~~
11 ~~24-34-102.~~ <{**Redundant with definitions common provision, 12-20-102 (7).**}>

12 ~~(4) (2) "Human remains" means all or any portion of the physical remains of a dead~~
13 human who was born alive.

14 ~~(5) (3) (a) "Nontransplant tissue bank" means a person that, for any purpose other~~
15 than transplantation into a living human being, recovers, transports, distributes, screens,
16 stores, and arranges for the storage and distribution of human remains.

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

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

20 (II) A funeral establishment registered in accordance with section ~~12-54-110~~
21 **12-135-110**; or

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

23
24 **12-140-103. [Formerly 12-54.5-102] Registration required - repeal.** (1) (a) By July
25 1, 2019, each nontransplant tissue bank shall register with the director in the form and
26 manner determined by the director. The registration must include:

27 (I) The specific address of the nontransplant tissue bank;

1 (II) The full name and address of the designee appointed in accordance with
2 subsection (2)(a) of this section;

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

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

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

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

10 (c) ~~In accordance with section 24-34-105, the director may adjust the registration fee~~
11 ~~set under subsection (3) of this section and establish renewal fees and delinquency fees for~~
12 ~~reinstatement. If a nontransplant tissue bank fails to renew the registration in accordance with~~
13 ~~the schedule established by the director, the registration expires.~~ <{Redundant with renewal
14 / fee common provisions, 12-20-105 and 12-20-202. Recommend repeal.}>

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

17 (I) Be at least eighteen years of age;

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

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

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

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

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

30 (3) To register, a person must pay the fee set by the director. ~~The director shall set the~~
31 ~~registration fee to offset the division's direct and indirect costs of implementing this article~~
32 ~~54.5. The director shall transmit the fee to the state treasurer, who shall credit it to the~~
33 ~~division of professions and occupations cash fund created in section 24-34-105 PURSUANT~~
34 ~~TO SECTION 12-20-105.~~ <{Redundant with fee / disposition common provision, 12-20-105;
35 recommend amendment as indicated.}>

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

38
39 **12-140-104. [Formerly 12-54.5-103] Records and receipts.** (1) A nontransplant

1 tissue bank shall furnish to a person who delivers human remains to the nontransplant tissue
2 bank a receipt, which must be signed by both the nontransplant tissue bank and the person
3 who delivers the human remains. The nontransplant tissue bank shall retain a copy of the
4 receipt in its records in accordance with subsection (2) of this section. The receipt must
5 include the following:

- 6 (a) The date and time of the delivery;
- 7 (b) The name of the person who delivered the human remains;
- 8 (c) The name of the decedent;
- 9 (d) The name of any businesses with which the person delivering the human remains

10 is affiliated; and

11 (e) The name of the person who received the human remains on behalf of the
12 nontransplant tissue bank.

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

- 15 (a) The donor's full name and address;
- 16 (b) The date of donation;
- 17 (c) Documentation of the decedent's informed consent or the consent of the person
18 authorized by law to consent on behalf of the donor to the donation;

19 (d) A description of the human remains to be donated for scientific or educational
20 purposes;

21 (e) Decedent medical history, including any of the following if used by the
22 nontransplant tissue bank: Autopsy reports, donation questionnaires, and other donor or
23 decedent solicitation materials; and

- 24 (f) Tracking documentation of the transport of and delivery of human remains.

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

27
28 **12-140-105. [Formerly 12-54.5-104] Standards of practice.** (1) A nontransplant
29 tissue bank shall:

- 30 (a) Handle human remains in a safe and sanitary manner;
- 31 (b) Be equipped with instruments and supplies necessary to protect the health and
32 safety of the public and employees of the nontransplant tissue bank; and

33 (c) Affix identification to all human remains delivered to the nontransplant tissue
34 bank and provide tracking paperwork to match the identification.

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

38 (3) An incinerator that is used for the disposal of human remains and that is operated
39 by a registered nontransplant tissue bank need not be registered under part 3 of article ~~54~~ **135**

1 of this title 12. The incinerator may commingle tissue from medical or educational research
2 from multiple decedents.

3
4 **12-140-106. [Formerly 12-54.5-105] Disclosure.** (1) A nontransplant tissue bank
5 shall disclose, in clear and unambiguous terms, the following information to the donor or to
6 the person authorized by law to consent to donation:

7 (a) That the donated human remains may be distributed, in whole or in part, by the
8 nontransplant tissue bank;

9 (b) That the donated human remains may be returned, in whole or in part, to the
10 nontransplant tissue bank; and

11 (c) That the nontransplant tissue bank will be compensated for distribution of the
12 human remains.

13
14 **12-140-107. [Formerly 12-54.5-106] Discipline.** (1) The director may ~~deny, suspend,~~
15 ~~revoke, or place on probation a nontransplant tissue bank or issue a letter of admonition to~~
16 ~~an applicant for or holder of a nontransplant tissue bank registration~~ TAKE DISCIPLINARY OR
17 OTHER ACTION AS AUTHORIZED IN SECTION 12-20-404 if the nontransplant tissue bank or
18 applicant: <{Redundant with disciplinary authority common provision, 12-20-404.
19 Recommend amending as indicated.>

20 (a) Violates an order of the director, this article ~~54.5 140~~, or the rules established
21 under this article ~~54.5 140~~;

22 (b) Makes a material misstatement or omission in the registration or the application
23 for a registration;

24 (c) Violates federal law, Colorado law, or an ordinance or resolution of a political
25 subdivision of Colorado in the operation of the nontransplant tissue bank; or

26 (d) Has incurred disciplinary action related to the administration of a nontransplant
27 tissue bank in another jurisdiction. Evidence of this disciplinary action is prima facie
28 evidence for denial of registration or other disciplinary action if the violation would be
29 grounds for disciplinary action in this state.

30 (2) ~~To be valid, a proceeding to deny, suspend, revoke, or place on probation a~~
31 ~~registration must be conducted in accordance with sections 24-4-104 and 24-4-105. The~~
32 ~~director may use an administrative law judge employed by the office of administrative courts~~
33 ~~in the department of personnel to conduct a hearing~~ SECTION 12-20-403 GOVERNS
34 PROCEEDINGS UNDER THIS SECTION. <{Redundant with APA and disciplinary procedure
35 common provision, 12-20-403. Recommend amendment as indicated.>

36
37 **12-140-108. [Formerly 12-54.5-107] Violations and penalties.** A person who
38 violates this article ~~54.5 140~~ is guilty of a misdemeanor and, upon conviction, shall be

1 punished by a fine of not more than five thousand dollars, imprisonment in the county jail
2 for not more than eighteen months, or both the fine and imprisonment.