

AMENDED IN ASSEMBLY APRIL 13, 2009

CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 995

Introduced by Assembly Member Block

February 27, 2009

An act to amend Section 1639.01 of, and to add Section 1643.3 to, the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

AB 995, as amended, Block. Tissue bank licensing.

Existing law requires the *State Department of Public Health-Care Services* to establish regulations, as specified, governing the operation and maintenance of tissue banks licensed in California. Existing law allows for the revocation or suspension of a tissue bank's license for specified reasons. Violation of these provisions is a misdemeanor.

This bill would require the collection, processing, storage, or distribution of human tissue by licensed tissue banks and tissue for use in California to comply with the 12th edition of Standards for Tissue Banking as published by the American Association of Tissue Banks, *and would require future amendments of these standards to be adopted as regulations, if approved by the department.* This bill would also allow the department to impose on licensed ~~and unlicensed~~ tissue banks, as an alternative to suspension or revocation of a tissue bank's license, a civil administrative penalty of ~~up to \$100 per infraction or immediate jeopardy, up to a maximum amount of \$3,050 day of noncompliance per violation not to exceed an aggregate of \$3,000 per day of noncompliance.~~

Because the bill would make changes to the definition of a crime, it constitutes a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1639.01 of the Health and Safety Code
2 is amended to read:

3 1639.01. (a) Notwithstanding Section 1639, no person shall
4 engage in the collection, processing, storage, or distribution of
5 human tissue unless the tissue is collected, prepared, labeled,
6 stored, and distributed in accordance with the standards set forth
7 in the 12th edition of Standards for Tissue Banking as published
8 by the American Association of Tissue Banks and in effect on May
9 1, 2008. These shall be the standards for all licensed tissue banks
10 operating in California or providing tissue to be used in California.

11 (b) *Amendments to, or later editions of, the Standards for Tissue*
12 *Banking shall be adopted as regulations upon approval of the*
13 *department not later than 90 days after publication by the*
14 *association. This section shall not be subject to the rulemaking*
15 *requirements of Chapter 3.5 (commencing with Section 11340) of*
16 *Part 1 of Division 3 of Title 2 of the Government Code.*

17 SEC. 2. Section 1643.3 is added to the Health and Safety Code,
18 to read:

19 1643.3. As an alternative to revocation or suspension of a
20 license issued under this chapter, the department may impose an
21 alternative civil administrative penalty of ~~up to one hundred dollars~~
22 ~~(\$100) per infraction or day of noncompliance per violation,~~
23 ~~including an immediate jeopardy, up to a maximum amount of~~
24 ~~three thousand fifty dollars (\$3,050) per day of noncompliance.~~
25 *violation except that the aggregate penalty per day shall not exceed*
26 *three thousand dollars (\$3,000). This penalty may be imposed*
27 *only after notice and an opportunity to respond in accordance with*
28 *Section 100171 and may also be imposed upon nonlicensed tissue*
29 *banks. 100171.*

1 SEC. 3. No reimbursement is required by this act pursuant to
2 Section 6 of Article XIII B of the California Constitution because
3 the only costs that may be incurred by a local agency or school
4 district will be incurred because this act creates a new crime or
5 infraction, eliminates a crime or infraction, or changes the penalty
6 for a crime or infraction, within the meaning of Section 17556 of
7 the Government Code, or changes the definition of a crime within
8 the meaning of Section 6 of Article XIII B of the California
9 Constitution.

O