



January 28, 2015

SENATE BILL No. 323

DIGEST OF SB 323 (Updated January 26, 2015 12:39 pm - DI 104)

Citations Affected: IC 16-41.

Synopsis: Waste blood specimen requirements. Adds retention and destruction requirements to the state department of health's epidemiological survey and research system for waste blood specimens. Specifies consent required under certain circumstances concerning waste blood specimens. Requires a fee to be assessed for certain people applying to use samples of the waste blood specimens. Specifies when identifiable information of waste blood specimens can be released, and sets forth requirements.

Effective: July 1, 2015.

Head, Becker, Kruse

January 8, 2015, read first time and referred to Committee on Family & Children Services.
January 27, 2015, reported favorably — Do Pass.

SB 323—LS 6342/DI 104



January 28, 2015

First Regular Session 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

SENATE BILL No. 323

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

- 1 SECTION 1. IC 16-41-17-10 IS AMENDED TO READ AS
2 FOLLOWS [EFFECTIVE JULY 1, 2015]: Sec. 10. (a) The state
3 department shall develop the following:
4 (1) A registry for tracking and follow-up of all newborns and
5 individuals for screening.
6 (2) A centralized program that provides follow-up, diagnosis,
7 management, and family counseling and support, including
8 equipment, supplies, formula, and other materials, for all infants
9 and individuals identified as having one (1) of the disorders listed
10 in section 2 of this chapter.
11 (3) A laboratory quality assurance program, including proficiency
12 testing.
13 (4) A statewide network of genetic evaluation and counseling
14 services.
15 (5) A system for using, for epidemiological survey and research
16 purposes, any waste blood specimen generated under this chapter.

SB 323—LS 6342/DI 104



1 **The system must include the following:**

2 **(A) A schedule for:**

3 **(i) the retention of waste blood specimens for not more**
 4 **than eighteen (18) years based on the date of receipt of**
 5 **the waste blood specimen by the designated laboratory;**
 6 **and**

7 **(ii) the destruction of waste blood specimens.**

8 **(B) General consent by the custodial parent or guardian to**
 9 **allow the state department to release a waste blood**
 10 **specimen to be used as allowed under this section.**

11 **(C) A fee for the administration of the activities described**
 12 **in this section concerning the system developed under this**
 13 **subdivision that is assessed to a person applying for the use**
 14 **of samples of waste blood specimens for epidemiological**
 15 **survey and research purposes. A fee under this clause:**

16 **(i) is separate from; and**

17 **(ii) may not be included as part of;**

18 **the newborn screening fee allowed under subsection (b).**

19 (b) The program described in subsection (a) shall be funded by
 20 collection of a newborn screening fee for each newborn screened by a
 21 designated laboratory.

22 (c) The state department shall set the fee and procedures for
 23 disbursement under rules adopted under IC 4-22-2. The fee must be
 24 based upon the projected cost of the program. The proposed fee must
 25 be approved by the budget agency before the rule is adopted.

26 (d) The designated laboratory shall assess, collect, and deposit the
 27 fees established under subsection (c) in the newborn screening fund
 28 established under section 11 of this chapter.

29 (e) The state department shall annually review the newborn
 30 screening fee.

31 (f) **This subsection applies only to waste blood specimens**
 32 **collected after June 30, 2015.** Waste blood specimens used for the
 33 purpose of implementing the system described under subsection (a)(5)
 34 may not include the name or other identifying characteristics that
 35 would identify **limited identifiable information in accordance with**
 36 **the federal Health Insurance Portability and Accountability Act**
 37 **(HIPAA) regulations set forth in 45 C.F.R. 164.514(e) concerning**
 38 the individual submitting the specimen. **Additional identifiable**
 39 **information may not be released concerning the individual**
 40 **submitting the specimen unless the custodial parent or guardian**
 41 **has given consent that is in addition to and separate from the**
 42 **general consent given under subsection (a)(5)(B).**



- 1 **(g) After June 30, 2015, the state department may transmit a**
- 2 **sample of a waste blood specimen to a third party involved in**
- 3 **epidemiological survey or research as allowed in subsection (a)(5)**
- 4 **at the request of a custodial parent or guardian if the request meets**
- 5 **the following requirements:**
- 6 **(1) The request is in writing.**
- 7 **(2) The request is signed by the custodial parent or guardian.**
- 8 **(3) The request identifies clearly the third party and where**
- 9 **the specimen is to be transmitted.**
- 10 **(h) Waste blood specimens released under the system**
- 11 **implemented under subsection (a)(5) may be released only at the**
- 12 **discretion of the state department.**



COMMITTEE REPORT

Madam President: The Senate Committee on Family & Children Services, to which was referred Senate Bill No. 323, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill DO PASS.

(Reference is to SB 323 as introduced.)

GROOMS, Chairperson

Committee Vote: Yeas 5, Nays 0

