

Adopted	Rejected
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# COMMITTEE REPORT

<b>YES:</b>	<b>11</b>
<b>NO:</b>	<b>0</b>

## MR. SPEAKER:

*Your Committee on Public Health, to which was referred House Bill 1038, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill **be amended** as follows:*

- 1 Page 3, line 23, after "that" insert ":".
- 2 Page 3, line 23, after "are" begin a new line block indented and
- 3 insert:
- 4 "(1)".
- 5 Page 3, line 25, strike "13" and insert "**13(b)**".
- 6 Page 3, line 25, delete "chapter." and insert "chapter; **or**".
- 7 Page 3, between lines 25 and 26, begin a new line block indented
- 8 and insert:
- 9 "**(2) is provided by a blood center under section 13(h) of this**
- 10 **chapter and the blood or plasma is labeled as required by 21**
- 11 **CFR 606.121(h).**".
- 12 Page 5, line 19, delete "A" and insert "**Subject to 21 CFR**
- 13 **610.40(g), a**".

- 1 Page 6, line 7, strike "or a".
- 2 Page 6, line 8, strike "blood component".
- 3 Page 6, delete line 42.
- 4 Page 7, delete lines 1 through 15, begin a new paragraph and insert:
- 5 "SECTION 16. IC 16-41-12-20 IS AMENDED TO READ AS
- 6 FOLLOWS [EFFECTIVE JULY 1, 2013]: Sec. 20. (a) Except as
- 7 provided in subsection (c), a responsible head (as defined in 21 CFR
- 8 600.10(a)) shall supervise the operations of a blood center.
- 9 (b) Except as provided in subsection (d), each blood center must
- 10 employ a medical director who is a licensed physician and who:
- 11 (1) is certified or eligible for certification in:
- 12 (A) clinical pathology; or
- 13 (B) the operation of a blood bank;
- 14 by the American Board of Pathology; or
- 15 (2) has:
- 16 (A) received a minimum of one (1) year of specialized training
- 17 in blood banking; or
- 18 (B) equivalent experience and training.
- 19 (c) The medical director shall supervise and is responsible for the
- 20 following:
- 21 (1) The proper performance of all medical procedures in the blood
- 22 center.
- 23 (2) The continuous application of quality assurance procedures in
- 24 the blood center.
- 25 (d) A blood center collecting blood ~~products~~ exclusively for further
- 26 manufacturing or research purposes under programs subject to and
- 27 licensed by the federal Food and Drug Administration must employ a
- 28 medical director who is a licensed physician to supervise the donor
- 29 screening process. A blood center that utilizes blood ~~products~~ for a
- 30 purpose other than manufacturing or research under this subsection is
- 31 subject to the penalties described in section 21 of this chapter."
- 32 Page 7, line 21, delete "IC 16-41-12-2.5)," and insert
- 33 "**IC 16-41-12-2.5)**".
- 34 Page 7, line 21, strike "a blood".
- 35 Page 7, line 22, strike "component,".
- 36 Page 7, line 30, strike "or a blood component".
- 37 Page 7, line 32, strike "or blood component".
- 38 Page 7, line 34, strike "a blood component,".

- 1 Renumber all SECTIONS consecutively.  
(Reference is to HB 1038 as introduced.)

**and when so amended that said bill do pass.**

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Representative Clere