HOUSE COMMITTEE AMENDMENTS

2015 Regular Session

Amendments proposed by House Committee on Health and Welfare to Reengrossed Senate Bill No. 39 by Senator Mills

AMENDMENT NO. 1

On page 4, at the end of line 10, change "**or (c) of**" to "**(c), or (f) of**"

AMENDMENT NO. 2

On page 4, at the end of line 12, change "**or (c) of this**" to "**(c), or (f) of this**"

AMENDMENT NO. 3

On page 4, at the beginning of line 15, change "**(b), or (c)**" to "**(b), (c), or (f)**"

AMENDMENT NO. 4

On page 4, line 17, delete "**(d)**" and insert in lieu thereof "**(f)**"

AMENDMENT NO. 5

On page 4, between lines 17 and 18, insert the following:

"**(f) A person who holds an approved new drug application under the United States Food and Drug Administration or holds a biologics license issued by the United States Food and Drug Administration for such product; or, if such product is not the subject of an approved application or license, the person who manufactured the product.**"

AMENDMENT NO. 6

On page 4, between lines 25 and 26, insert the following:

"**(15) "Prescription drug" means a drug for human use which, because of its toxicity or other potentiality for harmful effects, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which is limited by a United States Food and Drug Administration new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.**

(16) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution); however, "product", as used in this Chapter, does not include any of the following:

(a) Blood or blood components intended for transfusion.

(b) A radioactive drug or radioactive biological product regulated by the Nuclear Regulatory Commission or by a state pursuant to an agreement with the Nuclear Regulatory Commission.

(c) An imaging drug.

(d) An intravenous product that, by its formulation, is intended for replenishment of fluids and electrolytes or calories, for use to maintain the equilibrium of water and minerals in the body, or for irrigation or sterile water whether for such purpose or injection.

(e) Any medical gas.

(f) A homeopathic drug marketed in accordance with applicable guidance under the Federal Drug Supply Chain Security Act.

(g) A drug compounded in compliance with the Federal Food, Drug, and Cosmetic Act."

AMENDMENT NO. 7

On page 4, at the beginning of line 26, change "**(15)**" to "**(17)**"

AMENDMENT NO. 8

On page 4, line 28, after "**following**" and before the colon "**:**" insert "**purposes**"

AMENDMENT NO. 9

On page 5, at the beginning of line 2, change "**(16)**" to "**(18)**"

AMENDMENT NO. 10

On page 5, delete line 9 in its entirety and insert the following:

"**(19) "Transaction" means the transfer of a product between persons**"

AMENDMENT NO. 11

On page 5, line 10, after "**occurs**" and before the period "**.**" insert a comma "**,**" and "**but does not include a transaction that is exempted from the definition by rules of the board or federal law**"

AMENDMENT NO. 12

On page 5, at the beginning of line 11, change "**(18)**" to "**(20)**"

AMENDMENT NO. 13

On page 5, line 12, delete "**including**" and insert in lieu thereof "**that includes**"

AMENDMENT NO. 14

On page 5, line 13, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 15

On page 5, at the beginning of line 14, change "**(19)**" to "**(21)**"

AMENDMENT NO. 16

On page 5, line 15, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 17

On page 5, line 16, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 18

On page 5, line 17, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 19

On page 5, line 20, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 20

On page 5, at the beginning of line 28, change "**(20)**" to "**(22)**"

AMENDMENT NO. 21

On page 5, line 29, after "**transaction**" and before the colon "**:**" insert "**meets all of the following conditions**"

AMENDMENT NO. 22

On page 6, line 2, delete "**and as required by the board**"

AMENDMENT NO. 23

On page 6, line 3, delete "**legend drug or legend device**" and insert in lieu thereof "**product**"

AMENDMENT NO. 24

On page 6, at the end of line 4, change "**and**" to a period "**.**"

AMENDMENT NO. 25

On page 6, delete line 5 in its entirety

AMENDMENT NO. 26

On page 6, line 7, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 27

On page 6, line 8, delete "**legend drug**" and insert in lieu thereof "**product**"

AMENDMENT NO. 28

On page 6, delete lines 14 through 25 in their entirety and insert in lieu thereof the following:

"~~(15)~~ **(23)** "Wholesale ~~drug~~ distribution" means the distribution ~~or sale~~ of legend drugs or legend devices to **a person** other than the consumer or patient, ~~including but not limited to distribution by manufacturers, repackagers, own label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, pharmacies, brokers, agents, and wholesale drug distributors~~ **except as exempted in the standards of the Federal Drug Supply Chain Security Act as the act pertains to wholesale distribution**."

"~~(16)~~ **(24)** "Wholesale ~~drug~~ distributor" means any person ~~who sells or distributes legend drugs or legend devices to other than the consumer or patient, including but not limited to manufacturers, repackagers, own label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, brokers, agents, and pharmacies~~ **engaged in wholesale distribution**."

AMENDMENT NO. 29

On page 7, line 1, delete "seven" and insert "**eight**"

AMENDMENT NO. 30

On page 7, line 2, delete "and" and insert a comma "**,**"

AMENDMENT NO. 31

On page 7, line 3, after "industry" and before the period "." insert a comma "**,**" and "**and one of whom shall be actively engaged in the medical device industry**"

AMENDMENT NO. 32

On page 7, line 12, after "**may**" and before the colon ":" insert "**perform all of the following functions**"

AMENDMENT NO. 33

On page 8, line 16, after "**and**" and before "**Federal**" insert "**the**"

AMENDMENT NO. 34

On page 8, line 17, delete "**the**" and insert in lieu thereof "**those**"

AMENDMENT NO. 35

On page 8, line 18, delete the comma "," and insert a semicolon "**;**"

AMENDMENT NO. 36

On page 8, line 19, delete "thereto" and insert "**to those Acts**"

AMENDMENT NO. 37

On page 8, at the beginning of line 20, change "**C. The board shall**" to "**C.(1) The board may**"

AMENDMENT NO. 38

On page 8, line 21, after "**security**" and before the period "**.**" insert "**in accordance with regulations promulgated by the secretary of the United States Department of Health and Human Services.**"

AMENDMENT NO. 39

On page 8, between lines 21 and 22, insert the following:

"**(2) This Subsection shall not apply to manufacturers or affiliates or co-licensed partners of manufacturers.**"

AMENDMENT NO. 40

On page 8, line 29, after "**Chapter**" and before the period "." insert "**and all applicable requirements of federal law and regulation**"

AMENDMENT NO. 41

On page 9, at the beginning of line 18, delete "in" and insert "**by**"

AMENDMENT NO. 42

On page 11, line 16, after "Chapter." delete the remainder of the line and delete line 17 in its entirety and insert "**Posting of a bond shall not be a cause for dissolution of the injunction.**"

AMENDMENT NO. 43

On page 12, at the end of line 25, delete "distribution"

AMENDMENT NO. 44

On page 12, line 26, after "business" and before "**as defined**" insert "**of distribution**"

AMENDMENT NO. 45

On page 13, line 10, delete "the" and insert "**their**"

AMENDMENT NO. 46

On page 13, between lines 26 and 27, insert the following:

"Section 3. The Louisiana State Law Institute is hereby directed to change instances of "Louisiana Board of Wholesale Drug Distributors" to "Louisiana Board of Drug and Device Distributors" in R.S. 17:2048.51(O)(1)(c)(xviii), R.S. 36:259(W), R.S. 40:1003(6)(d), and any other provision of law as may be necessary for conformance with the provisions of R.S. 37:3463 as amended by Section 1 of this Act."

AMENDMENT NO. 47

On page 13, line 27, change "Section 3." to "Section 4."