January 24, 2014

# SENATE BILL No. 285

DIGEST OF SB 285 (Updated January 22, 2014 12:26 pm - DI 84)

**Citations Affected:** IC 16-18; IC 16-42; IC 35-48.

**Synopsis:** Insulin and Tramadol. Adds insulin to the definition of "legend drug". Provides that insulin may be sold for retail sale by a pharmacy only to an individual who possesses a prescription from certain practitioners. Designates Tramadol (Ultram) as a schedule III controlled substance.

**Effective:** July 1, 2014.

## Grooms

January 13, 2014, read first time and referred to Committee on Health and Provider Services.
January 23, 2014, reported favorably — Do Pass.

January 24, 2014

Second Regular Session 118th General Assembly (2014)

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 2013 Regular Session and 2013 First Regular Technical Session of the General Assembly.

# SENATE BILL No. 285

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

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

SECTION 1. IC 16-18-2-199 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 199. "Legend drug", for purposes of IC 16-42, means a drug that is:

(1) subject to 21 U.S.C. 353(b)(1); ~~or~~

(2) listed in the Prescription Drug Product List as:

(A) published in United States Department of Health and Human Services Approved Drug Products with Therapeutic Equivalence Evaluations, Tenth Edition, (1990); and

(B) revised in United State Department of Health and Human Services, Approved Drug Products with Therapeutic Equivalence Evaluations, Cumulative Supplement to the Tenth Edition, Number 10 (1990); **or**

**(3) insulin.**

SECTION 2. IC 16-42-19-29 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: **Sec. 29. A legend drug that is**

**composed wholly or partly of insulin may be sold for retail sale by a pharmacy only to an individual who possesses a prescription from one (1) of the following:**

**(1) A physician licensed under IC 25-22.5.**

**(2) A veterinarian licensed to practice veterinary medicine in Indiana.**

**(3) An advanced practice nurse who meets the requirements of IC 25-23-1-19.5.**

**(4) A physician assistant licensed under IC 25-27.5 who is delegated prescriptive authority under IC 25-27.5-5-6.**

SECTION 3. IC 35-48-2-8, AS AMENDED BY P.L.22-2008, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2014]: Sec. 8. (a) The controlled substances listed in this section are included in schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on April 1, 1986, as excepted compounds under 21 CFR 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or that is the same except that it contains a lesser quantity of controlled substances (1405).

(2) Benzphetamine (1228).

(3) Chlorphentermine (1645).

(4) Clortermine (1647).

(5) Phendimetrazine (1615).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:

(A) amobarbital (2126);

(B) secobarbital (2316);

(C) pentobarbital (2271); or

(D) any of their salts;

and one (1) or more other active medicinal ingredients which are

not listed in any schedule.

(2) Any suppository dosage form containing:

(A) amobarbital (2126);

(B) secobarbital (2316);

(C) pentobarbital (2271); or

(D) any of their salts;

and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt thereof (2100).

(4) Chlorhexadol (2510).

(5) Embutramide (2020).

(6) Lysergic acid (7300).

(7) Lysergic acid amide (7310).

(8) Methyprylon (2575).

(9) Sulfondiethylmethane (2600).

(10) Sulfonethylmethane (2605).

(11) Sulfonmethane (2610).

(12) A combination product containing Tiletamine and Zolazepam or any salt thereof (Telazol) (7295).

(13) Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. (2012).

(d) Nalorphine (a narcotic drug) (9400).

(e) Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following limited quantities:

(1) Not more than 1.8 grams of codeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium (9803).

(2) Not more than 1.8 grams of codeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9804).

(3) Not more than 300 milligrams of dihydrocodeinone, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium (9805).

(4) Not more than 300 milligrams of dihydrocodeinone, per 100

milliliters or not more than 15 milligrams per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts (9806).

(5) Not more than 1.8 grams of dihydrocodeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9807).

(6) Not more than 300 milligrams of ethylmorphine, per 100 milliliters or not more than 15 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9808).

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9809).

(8) Not more than 50 milligrams of morphine, per 100 milliliters or per 100 grams with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts (9810).

(9) Buprenorphine (9064).

(f) Anabolic steroid (as defined in 21 U.S.C. 802(41)(A) and 21 U.S.C. 802(41)(B)).

(g) The board shall except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections (b) through (e) from the application of any part of this article if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

(h) Any material, compound, mixture, or preparation which contains any quantity of Ketamine (7285).

(i) Hallucinogenic substances:

Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product (7369).

**(j) Tramadol (Ultram).**

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 285, 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 285 as introduced.)

Committee Vote: Yeas 11, Nays 0

Senator Miller Patricia, Chairperson