A bill to be entitled

An act relating to prescription drugs; amending s. 499.033, F.S.; requiring products containing ephedrine or a related compound to be dispensed by prescription only; providing a definition; providing rulemaking authority; repealing s. 893.1495, F.S., relating to the retail sale of ephedrine and related compounds; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 499.033, Florida Statutes, is amended to read:

499.033 Ephedrine and related compounds; prescription required. ~~Ephedrine is declared to be a prescription drug.~~

(1) ~~Except as provided in subsection (2),~~ Any product that contains any quantity of ephedrine or a related compound~~, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine~~ may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs. As used in this section, the term "ephedrine or a related compound" means ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers.

~~(2) A product containing ephedrine described in paragraphs (a)-(c) is exempt from subsection (1) if it may lawfully be sold over the counter without a prescription under the federal act; is labeled and marketed in a manner consistent with the~~

~~pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular product; the need to provide medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other facts as may be relevant to and consistent with public health and safety.~~

~~(a) Solid oral dosage forms that combine active ingredients in the following ranges for each dosage unit:~~

~~1. Theophylline (100-130mg), ephedrine (12.5-24mg).~~

~~2. Theophylline (60-100mg), ephedrine (12.5-24mg), guaifenesin (200-400mg).~~

~~3. Ephedrine (12.5-25mg), guaifenesin (200-400mg).~~

~~4. Phenobarbital (not greater than 8mg) in combination with the ingredients of subparagraph 1. or subparagraph 2.~~

~~(b) Liquid oral dosage forms that combine active ingredients in the following ranges for each (5ml) dose:~~

~~1. Theophylline (not greater than 45mg), ephedrine (not greater than 36mg), guaifenesin (not greater than 100mg), phenobarbital (not greater than 12mg).~~

~~2. Phenylephrine (not greater than 5mg), ephedrine (not~~

~~greater than 5mg), chlorpheniramine (not greater than 2mg), dextromethorphan (not greater than 10mg), ammonium chloride (not greater than 40mg), ipecac fluid extract (not greater than 0.005ml).~~

~~(c) Anorectal preparations containing less than 5 percent ephedrine.~~

~~(d) Nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine.~~

~~(e) Any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.~~

(2)~~(3)~~ The department may implement this section by rule.

Section 2. Section 893.1495, Florida Statutes, is repealed.

Section 3. This act shall take effect July 1, 2012.