States That Require a Prescription for Dispensing Ephedrine to an Ultimate User

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Florida

Florida Statutes Annotated
Title XXXIII. Regulation of Trade, Commerce, Investments, and Solicitations (Chapters 494-560)
Chapter 499. Drug, Cosmetic, and Household Products
Part I. Drugs; Devices; Cosmetics; Household Products
499.033. Ephedrine; 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, 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.

(2) A product containing ephedrine described in paragraphs (a)-(e) 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.

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

Idaho

Idaho Administrative Code
Agency 27. State Board of Pharmacy
Title 01.
Chapter 01. Rules of the Idaho State Board of Pharmacy
158. PRESCRIPTION DRUGS.

01. Designated Drugs. In addition to those drugs designated as prescription or legend drugs as defined in Section 54-1705(23), Idaho Code, the Idaho Board of Pharmacy includes preparations containing ephedrine or salts of ephedrine, as prescription drugs. (7-1-93)

02. Exempt Drugs. A product that meets all the criteria set forth in Subsection 158.02.a. is exempt from the designation as prescription drugs under Subsection 158.01 and exempt from inclusion as a Schedule II controlled substance under Section 37-2707, Idaho Code, unless it is being used or possessed as an immediate precursory of another controlled substance. (7-1-98)

a. Products containing a formula with a ratio of twelve and one half (12.5) milligrams ephedrine to two hundred (200) milligrams guaifenesin or twenty-five (25) milligrams ephedrine to four hundred (400) milligrams guaifenesin; and not exceeding a maximum of twenty-five (25) milligrams of ephedrine per tablet, capsule, or dose; and in addition to such formula, may include only inert or inactive ingredients or substance. (7-1-98)

b. Provided, however, that hemorrhoidal ointments containing not more than two tenths percent (.2%) Ephedrine Sulfate and suppositories not exceeding four (4) milligrams Ephedrine Sulfate per suppository are also exempt pursuant to Subsection 158.02. (7-1-98)

Illinois

Smith-Hurd Illinois Compiled Statutes Annotated
Chapter 720. Criminal Offenses
Offenses Against the Public
Act 570. Illinois Controlled Substances Act
Article II. Schedules of Controlled Substances

570/210. Schedule IV; enumeration

<Text of section effective Jan. 1, 2012. See, also, section effective until Jan. 1, 2012.>

§ 210. (a) The controlled substances listed in this Section are included in Schedule IV.

…

(h) Except as otherwise provided in Section 216, any material, compound, mixture, or preparation that contains any quantity of the following substance having a stimulant effect on the central nervous system, including its salts, enantiomers (optical isomers) and salts of enantiomers (optical isomers):

(1) Ephedrine, its salts, optical isomers and salts of optical isomers.

Smith-Hurd Illinois Compiled Statutes Annotated
Chapter 720. Criminal Offenses
Offenses Against the Public
Act 570. Illinois Controlled Substances Act
Article II. Schedules of Controlled Substances
570/216. Ephedrine

§ 216. **Ephedrine.**

(a) The following drug products containing ephedrine, its salts, optical isomers and salts of optical isomers shall be exempt from the application of Sections 312 and 313 of this Act if they: (i) may lawfully be sold over-the-counter without a prescription under the Federal Food, Drug, and Cosmetic Act; (ii) are labeled and marketed in a manner consistent with Section 341.76 of Title 21 of the Code of Federal Regulations; (iii) are manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse; and (iv) are not marketed, advertised, or labeled for the indications of stimulation, mental alertness, weight loss, muscle enhancement, appetite control, or energy:

(1) Solid oral dosage forms, including soft gelatin caplets, which are formulated pursuant to 21 CFR 341 or its successor, and packaged in blister packs of not more than 2 tablets per blister.

(2) Anorectal preparations containing not more than 5% ephedrine.

(b) The marketing, advertising, or labeling of any product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine, for the indications of stimulation, mental alertness, weight loss, appetite control, or energy, is prohibited. In determining compliance with this requirement the Department may consider the following factors:

(1) The packaging of the drug product;

(2) The name and labeling of the product;

(3) The manner of distribution, advertising, and promotion of the product;

(4) Verbal representations made concerning the product;

(5) The duration, scope, and significance of abuse or misuse of the particular product.

(c) A violation of this Section is a Class A misdemeanor. A second or subsequent violation of this Section is a Class 4 felony.

(d) This Section does not apply to dietary supplements, herbs, or other natural products, including concentrates or extracts, which:

(1) are not otherwise prohibited by law; and

(2) may contain naturally occurring ephedrine, ephedrine alkaloids, or pseudoephedrine, or their salts, isomers, or salts of isomers, or a combination of these substances, that:

(i) are contained in a matrix of organic material; and

(ii) do not exceed 15% of the total weight of the natural product.

(e) Nothing in this Section limits the scope or terms of the Methamphetamine Precursor Control Act.

Smith-Hurd Illinois Compiled Statutes Annotated
Chapter 720. Criminal Offenses
Offenses Against the Public
Act 570. Illinois Controlled Substances Act
Article III. Registration and Control of Manufacture, Distribution and Dispensing
570/312. Requirements for dispensing controlled substances

§ 312. Requirements for dispensing controlled substances.

(a) A practitioner, in good faith, may dispense a Schedule II controlled substance, which is a narcotic drug listed in Section 206 of this Act; or which contains any quantity of amphetamine or methamphetamine, their salts, optical isomers or salts of optical isomers; phenmetrazine and its salts; or pentazocine; and Schedule III, IV, or V controlled substances to any person upon a written or electronic prescription of any prescriber, dated and signed by the person prescribing (or electronically validated in compliance with Section 311.5) on the day when issued and bearing the name and address of the patient for whom, or the owner of the animal for which the controlled substance is dispensed, and the full name, address and registry number under the laws of the United States relating to controlled substances of the prescriber, if he or she is required by those laws to be registered….

…

Illinois Administrative Code
Title 77: Public Health
Chapter XX: Department of Alcoholism and Substance Abuse
Subchapter E: Controlled Substances Activities
Part 2070. Schedule of Controlled Substances
Subpart E. Schedule of Controlled Substances--Schedule IV(Refs & Annos)
2070.2105 Schedule IV--Enumeration

The controlled substances listed in these Sections 2070.2110 through 2070.2600 are included in Schedule IV.

Illinois Administrative Code
Title 77: Public Health
Chapter XX: Department of Alcoholism and Substance Abuse
Subchapter E: Controlled Substances Activities
Part 2070. Schedule of Controlled Substances
Subpart E. Schedule of Controlled Substances--Schedule IV(Refs & Annos)
2070.2655 Ephedrine

Ephedrine as the only active medicinal ingredient or in combination with therapeutically insignificant quantities of another active medicinal ingredient. Anything less than 200 milligrams of Guaifenesin shall be considered therapeutically insignificant.

Louisiana

Louisiana Statutes Annotated
Louisiana Revised Statutes
Title 40. Public Health and Safety
Chapter 4. Food and Drugs
Part X. Uniform Controlled Dangerous Substances Law
§ 962.1. Ephedrine products

A. Except as provided in Subsection B, any product that contains any quantity of ephedrine, 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.

B. The following products containing ephedrine shall be exempt from the provisions of Subsection A provided that such product may lawfully be sold over the counter without a prescription under the federal Food, Drug, and

Cosmetic Act, is labeled and marketed in a manner consistent with the pertinent OTC 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:

(1) Solid oral dosage forms (including soft gelatin caplets) that combine active ingredients in the following ranges for each dosage unit:

(a) Theophylline (100-130 mg), Ephedrine (12.56-24 mg).

(b) Theophylline (60-100 mg), Ephedrine (12.5-24 mg), Guaifenesin (200-400 mg).

(c) Ephedrine (12.5-25 mg), Guaifenesin (200-400 mg).

(d) Phenobarbital (not greater than 8 mg) in combination with ingredients of Subparagraph (a) or (b) of this Paragraph.

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

(a) Theophylline (not greater than 45 mg), Ephedrine (not greater than 36 mg), Guaifenesin (not greater than 100 mg), Phenobarbital (not greater than 12 mg).

(b) Phenylephephrine (not greater than 5 mg), Ephedrine (not greater than 5 mg), chlorpheniramine (not greater than 2 mg), dextromethorphan (not greater than 10 mg), ammonium C1 (not greater than 40 mg), ipecac fluid extract (not greater than 0.005 ml).

(3) Anorectal preparations containing less than five percent ephedrine.

(4) Any liquid compound, mixture, or preparation containing one-half percent or less of ephedrine.

C. The marketing, advertising, or labeling of any nonprescription product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine for the indication of stimulation, mental alertness, weight loss, appetite control, or energy is prohibited. The Department of Health and Hospitals, office of public health is authorized to adopt rules and regulations in accordance with the Administrative Procedure Act to exempt other nonprescription products from the prohibition contained herein. Such rules and regulations shall require a distributor or manufacturer seeking an exemption from the prohibition contained herein to clearly demonstrate that the nonprescription product is intended for use for a valid medicinal purpose and that the marketing of that product does not encourage, promote, or abet the abuse or misuse of ephedrine. In addition, such rules and regulations shall include the following factors for purposes of determining whether or not such an exemption should be granted:

(1) The packing of the product.

(2) The name and labeling of the product.

(3) The manner of distribution, advertising, and promotion of the product.

(4) Verbal representations made concerning the product.

(5) The duration, scope, and significance of abuse or misuse of the particular product.

D. Whoever violates any provision of this Section shall be fined not more than one thousand dollars or imprisoned for not more than six months, or both.

E. Notwithstanding any provision of law to the contrary, unless listed in another schedule, any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is a Schedule V controlled dangerous substance and shall be dispensed, sold, or distributed only in accordance with the provisions of R.S. 40:1049.1 et seq. Such products shall be exempt from the reporting for

Schedule V drugs as provided for in R.S. 40:1001 et. seq.

Louisiana Administrative Code
Title 48. Public Healthpgeneral
Part I. General Administration Subpart 1. General
Chapter 39. Controlled Dangerous Substances
§ 3945. Ephedrine Marketing, Advertising, or Labeling

A. General Rule. Pursuant to the statute, product containing ephedrine may be dispensed only by prescription unless: (a) it is enumerated as an exemption per R.S. 40:962(1)(B) or by the Department of Health and Hospitals review committee, (b) it may be lawfully sold over the counter per the federal Food, Drug and Cosmetic Act, (c) it is labeled and marketed in a manner consistent with OTC Tentative Final or Final Monograph, and (d) is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse. The marketing, advertising, or labeling of any nonprescription product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine for the indication of stimulation, mental alertness, weight loss, appetite control, or energy is prohibited unless the distributor or manufacturer is granted an exemption by the Department of Health and Hospitals.

B. Procedures for Seeking an Exemption

1. Distributors or manufacturers seeking an exemption from the prohibition set forth in Subsection A above must submit documentation which clearly demonstrates the following:

a. the nonprescription product is intended for use for a valid medicinal purpose, and

b. the marketing of the product does not encourage, promote, or abet the abuse or misuse of ephedrine.

2. A review committee composed of representatives from the following groups shall conduct a review of the documentation submitted by the distributor or manufacturer:

a. a pharmacist designated by the Board of Pharmacy,

b. a representative designated by the Board of Wholesale Drug Distributors,

c. a representative designated by the state health officer,

d. a representative designated by the Department of Health and Hospitals, Office of Alcohol and Drug Abuse,

e. a physician designated by the Board of Medical Examiners.

3. The following factors shall be considered by the review committee in determining whether an exemption should be granted, and information related to the factors shall be submitted by the distributor or manufacturer:

a. packaging of the product;

b. name and labeling of the product;

c. manner of distribution, advertising, and promotion of the product;

d. verbal representations made concerning the product; and

e. duration, scope, and significance of abuse or misuse of the particular product.

4. Following a review of the materials submitted by the manufacturer or distributor, the review committee shall report findings and recommendations to the secretary of the Department of Health and Hospitals, who will provide for written notification of the findings and recommendations to the applicant.

Missouri

Vernon's Annotated Missouri Statutes
Title XII. Public Health and Welfare
Chapter 195. Drug Regulations
Narcotic Drug Act

195.017. Substances, how placed in schedules--list of scheduled substances-- publication of schedules annually--electronic log of transactions to be maintained, when--certain products to be located behind pharmacy counter-- exemption from requirements, when--rulemaking authority

…

8. The controlled substances listed in this subsection are included in Schedule IV:

…

(6) Ephedrine, its salts, optical isomers and salts of optical isomers, when the substance is the only active medicinal ingredient;

…

Missouri Code of State Regulations
Title 19 - Department of Health and Senior Services
Division 30 - Division of Regulation and Licensure
Chapter 1 - Controlled Substances
19 CSR 30-1.002 Schedules of Controlled Substances

PURPOSE: Chapter 195, RSMo states in section 195.230, RSMo that the Department of Health shall prepare a list of all drugs falling within the purview of controlled substances. Upon preparation, a copy of the list shall be filed in the Office of the Secretary of State. It also requires, in section 195.017.11, RSMo, the Department of Health to revise and republish the schedules semiannually for two years from September 28, 1971, and annually after that.

(1) Schedules of Controlled Substances.

…

(D) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

…

6. **Ephedrine**. Any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including their salts, isomers and salts of isomers:

A. Ephedrine or its salts, optical isomers or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient.

…

Vernon's Annotated Missouri Statutes
Title XII. Public Health and Welfare
Chapter 195. Drug Regulations
Narcotic Drug Act
195.060. Controlled substances to be dispensed on prescription only, exception

1. Except as provided in subsection 3 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

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Minnesota

Minnesota Statutes Annotated
Health (Ch. 144-159)
Chapter 152. Drugs; Controlled Substances
Prescriptions
152.135. Restrictions on sales, marketing, and possession of ephedrine

Subdivision 1. Prescription status for ephedrine. Except as provided in this section, a material, compound, mixture, or preparation that contains any quantity of ephedrine, 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.

Subd. 2. Exceptions. (a) A drug product containing ephedrine, its salts, optical isomers, and salts of optical isomers is exempt from subdivision 1 if the drug product:

(1) may be lawfully sold over the counter without a prescription under the federal Food, Drug, and Cosmetic Act, United States Code, title 21, section 321, et seq.;

(2) is labeled and marketed in a manner consistent with the pertinent OTC Tentative Final or Final Monograph;

(3) is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse;

(4) is not marketed, advertised, or labeled for the indication of stimulation, mental alertness, weight loss, muscle enhancement, appetite control, or energy;

(5) is in solid oral dosage forms, including soft gelatin caplets, that combine 400 milligrams of guaifenesin and 25 milligrams of ephedrine per dose, according to label instructions; or is an anorectal preparation containing not more than five percent ephedrine; and

(6) is sold in a manner that does not conflict with section 152.02, subdivision 6.

(b) Subdivisions 1 and 3 shall not apply to products containing ephedra or ma huang and lawfully marketed as dietary supplements under federal law.

…

Subd. 6. Penalty. A person who violates this section is guilty of a misdemeanor.

Mississippi

Annotated Mississippi Code
Title 41. Public Health
Chapter 29. Poisons, Drugs and Other Controlled Substances
Article 3. Uniform Controlled Substances Law

§ 41-29-117. Schedule III

(A) The controlled substances listed in this section are included in Schedule III.

SCHEDULE III

…

(d) Any material, compound, mixture or preparation which contains any quantity of ephedrine or pseudoephedrine.

…

Annotated Mississippi Code
Title 41. Public Health
Chapter 29. Poisons, Drugs and Other Controlled Substances
Article 3. Uniform Controlled Substances Law

§ 41-29-137. Prescriptions

…

(b) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or IV, as set out in Sections 41-29-117 and 41-29-119, shall not be dispensed without a written or oral valid prescription of a practitioner. The prescription shall not be filled or refilled more than six (6) months after the date thereof or be refilled more than five (5) times, unless renewed by the practitioner.

…

Nebraska

Revised Statutes of Nebraska Annotated
Chapter 28. Crimes and Punishments
Article 4. Drugs and Narcotics

28-405. Controlled substances; schedules; enumerated

The following are the schedules of controlled substances referred to in the Uniform Controlled Substances Act:

…

Schedule IV

(a) Any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

…

(g)(1) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance, including its salts, optical isomers, and salts of such optical isomers: Ephedrine.

(2) The following drug products containing ephedrine, its salts, optical isomers, and salts of such optical isomers, are excepted from subdivision (g)(1) of Schedule IV if they (A) are stored behind a counter, in an area not accessible to customers, or in a locked case so that a customer needs assistance from an employee to access the drug product; (B) are sold by a person, eighteen years of age or older, in the course of his or her employment to a customer eighteen years of age or older with the following restrictions: No customer shall be allowed to purchase, receive, or otherwise acquire more than three and six-tenths grams of ephedrine base during a twenty-four-hour period; no customer shall purchase, receive, or otherwise acquire more than nine grams of ephedrine base during a thirty-day period; and the customer shall display a valid driver's or operator's license, a Nebraska state identification card, a military identification card, an alien registration card, or a passport as proof of identification; (C) are labeled and marketed in a manner consistent with the pertinent OTC Tentative Final or Final Monograph; (D) are manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse; and (E) are not marketed, advertised, or represented in any manner for the indication of stimulation, mental alertness, euphoria, ecstasy, a buzz or high, heightened sexual performance, or increased muscle mass:

(i) Primatene Tablets;

(ii) Bronkaid Dual Action Caplets; and

(iii) Pazo Hemorrhoidal Ointment

…

Revised Statutes of Nebraska Annotated
Chapter 28. Crimes and Punishments
Article 4. Drugs and Narcotics
28-414. Controlled substance; prescription; transfer; destruction; requirements

…

(2)(a) Except as otherwise provided in this subsection or when administered directly by a practitioner to an ultimate user, a controlled substance listed in Schedule III, IV, or V of section 28-405 shall not be dispensed without a

written or oral medical order. Such medical order is valid for six months after the date of issuance. Authorization from a practitioner authorized to prescribe is required to refill a prescription for a controlled substance listed in Schedule III, IV, or V of section 28-405. Such prescriptions shall not be refilled more than five times within six months after the date of issuance. Original prescription information for any controlled substance listed in Schedule III, IV, or V of section 28-405 may be transferred between pharmacies for purposes of refill dispensing pursuant to section 38-2871.

…

New Mexico

Code of New Mexico Rules
Title 16. Occupational and Professional Licensing
Chapter 19. Pharmacists
Part 17. Dangerous Drugs and Dangerous Drug Research
16.19.17. DANGEROUS DRUGS AND DANGEROUS DRUG RESEARCH

…

B. **'Dangerous Drug'** as defined in the New Mexico Drug, Device and Cosmetic Act 26-1-2F.

(1) The following substance(s) has(have) been declared by the N.M. board of pharmacy as 'Dangerous Drugs' in accordance with the Drug, Device and Cosmetic Act 26-1-18 NMSA and the Uniform Licensing Act (61-1-1 to 61-1-31 NMSA 1978). The board of pharmacy shall by regulation declare a substance a 'dangerous drug' when necessary and notification shall be sent to all registered pharmacies in the state within sixty days of the adoption of the regulation. Ephedrine, USP, as ephedrine hydrochloride or ephedrine sulfate or as any other salt form. Any compound, mixture, or preparation containing one-half percent (0.5%) or less of ephedrine or of any salt form of ephedrine is exempt from the above. The following drug products containing ephedrine, USP, as ephedrine hydrochloride or ephedrine sulfate are exempted from this schedule: Bronkaid· Caplets and Primatene· Tablets. These products are exempt because they are approved for sale over the counter without a prescription under federal law, are labeled and marketed in a manner consistent with the pertinent OTC tentative final or final monograph, are manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse, and are not marketed, advertised or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement.

(2) A dangerous drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe such drug.

…

Oklahoma

Oklahoma Statutes Annotated
Title 63. Public Health and Safety
Chapter 2. Uniform Controlled Dangerous Substances Act
Article II. Standards and Schedules
§ 2-210. Schedule IV

A. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant or depressant effect on the central nervous system:

…

34. Ephedrine, its salts, optical isomers, and salts of optical isomers as the only active ingredient, or in combination with other active ingredients;

…

B.

…

2. At the request of any person, the Director may exempt any other drug product containing ephedrine from being included as a Schedule IV controlled substance if such product:

a. is labeled and marketed in a manner consistent with the pertinent OTC tentative final or final monograph issued by the FDA, and

b. is manufactured and distributed for legitimate medicinal use and in a manner that reduces or eliminates the likelihood of abuse.

…

3. In making a determination regarding a drug product, the Director, after notice and hearing, shall consider the following:

a. the history and current pattern of abuse,

b. the name and labeling of the product,

c. the intended manner of distribution, advertising and promotion of the product, and

d. other factors as may be relevant to and consistent with the public health and safety.

4. The hearing shall be held in accordance with the Administrative Procedures Act.

5. A list of current drug products meeting exemption requirements under this subsection may be obtained from the Bureau upon written request.

…

Oklahoma Statutes Annotated
Title 63. Public Health and Safety
Chapter 2. Uniform Controlled Dangerous Substances Act
Article III. Regulation of Manufacture, Distribution, Dispensing, Prescribing, Administering and Using for Scientific Purposes of Controlled Dangerous Substances
Prescriptions
§ 2-309. Prescriptions

…

B. 1. Except for dosages medically required for a period not to exceed forty-eight (48) hours which are administered by or on direction of a practitioner, other than a pharmacist, or medication dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled dangerous substance included in Schedule III or IV, which is a prescription drug as determined under regulation promulgated by the Board of Pharmacy, may be dispensed without a written or oral prescription.

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Oklahoma Administrative Code
Title 475. Oklahoma Bureau of Narcotics and Dangerous Drugs Control
Chapter 10. Requirements for Registration
475:10-1-24. Ephedra/mahuang exemption

Products meeting the following criteria are exempt from application of Sections 2-210, 2-322, and 2-402 of the Uniform Controlled Dangerous Substances Act [O.S. Title 63, §§ 2-210, 2-322, 2-402]:

(1) Dietary supplements containing naturally occurring ephedrine alkaloids, provided that all of the following conditions are met:

(A) the alkaloids are contained in an unadulterated naturally occurring organic material; and,

(B) the product contains no hydrochloride or sulfate salts of ephedrine alkaloids; and,

(C) the product contains, per dosage unit or serving, not more than 25 milligrams of ephedrine alkaloids; and,

(D) the product is packaged with a prominent label securely affixed to each package that states the amount in milligrams of ephedrine alkaloids in a serving or dosage unit; the amount of food product or dietary supplement that constitutes a serving or dosage unit; the maximum recommended dosage unit of ephedrine alkaloids for a healthy adult; and that improper use of the product may be hazardous to a person's health; and,

(E) the product is labeled and marketed as “ephedra” or “mahuang” and not as “ephedrine.” It shall be acceptable to include descriptions of the ephedra alkaloids such as “contains 25 mg. of naturally occurring ephedrine alkaloids.” And,

(2) In the course of selling, offering for sale, or otherwise distributing a product described in section 10-1-24 (A), a person shall not advertise or represent in any manner that the product causes euphoria, ecstasy, a “buzz”, or “high”, or an altered mental state, heightens sexual performance, or because it contains ephedrine alkaloids, increases muscle mass.

Oregon

Oregon Revised Statutes Annotated
Title 37. Alcoholic Liquors; Controlled Substances; Drugs
Chapter 475. Controlled Substances; Illegal Drug Cleanup; Paraphernalia; Precursors
Uniform Controlled Substances Act
(Records)
475.185. Prescriptions

<Text subject to final change by the Oregon Office of the Legislative Counsel.>

…

(3) Except when dispensed directly by a practitioner to an ultimate user, a controlled substance included in Schedule III or IV may not be dispensed without a written, oral or electronically transmitted prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date on which it was issued and a prescription authorized to be refilled may not be refilled more than five times. Additional quantities of the controlled substances listed in Schedule III or IV may only be authorized by a practitioner through issuance of a new prescription.

…

Oregon Revised Statutes Annotated
Title 37. Alcoholic Liquors; Controlled Substances; Drugs
Chapter 475. Controlled Substances; Illegal Drug Cleanup; Paraphernalia; Precursors
Precursor Substances

475.973. Unlawful possession of ephedrine, pseudoephedrine or phenylpropanolamine; unlawful distribution of ephedrine, pseudoephedrine or phenylpropanolamine

<Text subject to final change by the Oregon Office of the Legislative Counsel.>

(1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance. Except as otherwise provided in this paragraph, the State Board of Pharmacy shall adopt rules to classify ephedrine, pseudoephedrine and phenylpropanolamine as Schedule III controlled substances. The Schedule III classification may be modified by the State Board of Pharmacy if the State Board of Pharmacy finds that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine under a Schedule III designation do not significantly reduce the number of methamphetamine laboratories within the state.

(b) Records of transactions involving products containing ephedrine, pseudoephedrine or phenylpropanolamine are subject to inspection by the State Board of Pharmacy and law enforcement agencies. A person required to make or maintain records of transactions involving products containing ephedrine, pseudoephedrine or phenylpropanolamine shall forward the records to the Department of State Police if directed to do so by the department. Failure to forward records as required by this paragraph is a Class A misdemeanor.

(2) This section does not apply to products that the State Board of Pharmacy, upon application of a manufacturer, exempts by rule because the product is formulated to effectively prevent conversion of the active ingredient into methamphetamine or its salts or precursors. Upon notification from the Department of State Police that the department has probable cause to believe that a product exempted under this subsection does not effectively prevent conversion of the active ingredient into methamphetamine or its salts or precursors, the State Board of Pharmacy may issue an emergency rule revoking the exemption for the product pending a full hearing.

Oregon Administrative Rules Compilation
Chapter 855. Board of Pharmacy
Division 80. Schedule of Controlled Substances

855-080-0023 Schedule III

Schedule III consists of the drugs and other substances by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR part 1308.13; and

…

(2) Products containing ephedrine or the salts of ephedrine as an active ingredient.

…

South Dakota

South Dakota Codified Laws
Title 22. Crimes
Chapter 22-42. Controlled Substances and Marijuana

22-42-4.1. Prescription required to dispense Schedule III or Schedule IV substance--Refill restricted--Felony

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled drug or substance included in Schedule III or Schedule IV may be dispensed without a written or oral prescription. Such prescription may not be filled or refilled more than six months after the date thereof or be refilled more than five

times after the date of the prescription, unless renewed by the practitioner. A violation of this section is a Class 5 felony.

South Dakota Codified Laws
Title 34. Public Health and Safety
Chapter 34-20B. Drugs and Substances Control
34-20B-19. Stimulants specifically included in Schedule III

Any material, compound, mixture, or preparation is included in Schedule III which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

…

(4) Ephedrine.

South Dakota Codified Laws
Title 34. Public Health and Safety
Chapter 34-20B. Drugs and Substances Control
34-20B-19.1. Ephedrine defined

For the purposes of § 34-20B-19, the term, ephedrine includes ephedra, herbs and herbal products that contain ephedrine alkaloids, including ma huang, Chinese ephedra, ephedra sinica, ephedra herb powder, epitonin, or any extract of those substances, but the term does not include any drug that contains ephedrine and is lawfully sold, transferred, or furnished over the counter with or without a prescription pursuant to § 34-20B-21.

South Dakota Codified Laws
Title 34. Public Health and Safety
Chapter 34-20B. Drugs and Substances Control
34-20B-21. Exception from Schedule III of stimulants and depressants used in medicinal preparations

The department may by rules promulgated pursuant to chapter 1-26 except any compound, mixture, or preparation containing any stimulant, depressant substance, or anabolic steroid listed in §§ 34-20B-19, 34-20B-20, and 34-20B-22 if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant, depressant, or anabolic steroid effect. Such admixtures shall be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant, depressant, or anabolic steroid effect.

Administrative Rules of South Dakota
Department of Health (Articles 44:06 to 44:68)
Article 44:58 Drug Control
Chapter 44:58:13 Exempted Schedule III Substances
44:58:13:01. Exempted Schedule III substances.

The following combinations of medicinal ingredients and Schedule III substances are exempt from control under the act or this article:

…

(7) Products that contain ephedrine in quantities at or less than:

(a) 25 milligrams in combination with 400 milligrams of quaifenesin, packaged in blister packs of not more than two tablets per blister; and

(b) Five percent by weight in an anorectal preparation in combination with other active medicinal ingredients.

Texas

Texas Administrative Code
Title 25. Health Services
Part 1. Department of State Health Services
Chapter 229. Food and Drug
Subchapter Y. Regulations to Set Standards for the Formulation, Sale and Distribution of Dietary Supplements Containing Ephedrine from Natural Ephedra Alkaloids and to Restrict the Sale and Distribution of Certain Drug Products Containing Ephedrine
§ 229.464. Regulations to Restrict the Sale and Distribution of Certain Drug Products Containing Ephedrine

(a) Drug products containing single ingredient ephedrine, its salts, optical isomers or salts of optical isomers, are dangerous drugs as defined in the Health and Safety Code, Chapter 483, relating to Dangerous Drugs.

…

(c) Any drug product containing ephedrine, its salts, optical isomers or salts of optical isomers shall not be sold, distributed, introduced into commerce, manufactured, produced, packaged, exposed, offered, possessed or held for sale, dispensed or given away in this state except as dispensed upon the prescription of a licensed practitioner.

(d) The following formulations are exempt from the designation as dangerous drugs under subsection (a) of this section, and the dispensing restrictions under subsection (c) of this section:

(1) solid dosage forms that combine active ingredients must be in the following ranges for each recommended dose: ephedrine, its salts, optical isomers or salts of optical isomers not to exceed 12.5 milligrams (mg) combined with at least 200 mg guiafenesin; ephedrine, its salts, optical isomers or salts of optical isomers not to exceed 25 mg combined with at least 400 mg guiafenesin;

(2) liquid oral dosage forms that combine active ingredients in the following ranges for each 5 milliliter (ml) dose: dextromethorphan HBr (not more than 10 mg), chlorpheniramine maleate (not more than 2 mg), ephedrine HCl (not more than 5 mg), phenylephrine (not more than 5 mg), ammonium chloride (not more than 40 mg), ipecac fluidextract (not more than 0.005 ml);

(3) anorectal preparations containing less than 5.0% ephedrine;

(4) nasal decongestant preparations containing 0.5% or less ephedrine; and

(5) any ephedrine-containing drug product that is marketed pursuant to an approved new drug application under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, et seq.

Washington

Revised Code of Washington Annotated
Title 69. Food, Drugs, Cosmetics, and Poisons
Chapter 69.41. Legend Drugs--Prescription Drugs
69.41.030. Sale, delivery, or possession of legend drug without prescription or order prohibited--Exceptions--Penalty

(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a commissioned medical or dental officer in the United States armed forces or public health service in the discharge of his or her official duties, a duly licensed physician or dentist employed

by the veterans administration in the discharge of his or her official duties, a registered nurse or advanced registered nurse practitioner under chapter 18.79 RCW when authorized by the nursing care quality assurance commission, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or any of the following professionals in any province of Canada that shares a common border with the state of Washington or in any state of the United States: A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed advanced registered nurse practitioner, or a veterinarian licensed to practice veterinary medicine: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouse operator, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment: PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW shall prevent a family planning clinic that is under contract with the health care authority from selling, delivering, possessing, and dispensing commercially prepackaged oral contraceptives prescribed by authorized, licensed health care practitioners.

(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a commissioned medical or dental officer in the United States armed forces or public health service in the discharge of his or her official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his or her official duties, a registered nurse or advanced registered nurse practitioner under chapter 18.79 RCW when authorized by the nursing care quality assurance commission, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or any of the following professionals in any province of Canada that shares a common border with the state of Washington or in any state of the United States: A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed advanced registered nurse practitioner, or a veterinarian licensed to practice veterinary medicine: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouse operator, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment: PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW shall prevent a family planning clinic that is under contract with the health care authority from selling, delivering, possessing, and dispensing commercially prepackaged oral contraceptives prescribed by authorized, licensed health care practitioners.

(2)(a) A violation of this section involving the sale, delivery, or possession with intent to sell or deliver is a class B felony punishable according to chapter 9A.20 RCW.

(b) A violation of this section involving possession is a misdemeanor.

Washington Administrative Code
Title 246. Health, Department of
Chapter 246-883. Pharmaceutical-Sales Requiring Prescriptions
246-883-030. Ephedrine prescription restrictions.

(1) The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030.

(2) The following products containing ephedrine or its salts in the amount of 25 mg. or less per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts are exempt from subsection (1) of this section:

TRADE NAME	EPHEDRINE CONTENT	
1.	AMESAC capsule (Russ)	25 mg. ephedrine HCL
2.	AZMA AID tablet (Various, eg Purepac)	24 mg. ephedrine HCL
3.	BRONC-EASE PLUS (Natur-Pharma)	25 mg. ephedrine HCL
4.	BRONCHODILATOR AND EXPECTORANT (PDK Labs)	25 mg. ephedrine HCL
5.	BRONITIN tablet (Whitehall)	24 mg. ephedrine HCL
6.	BRONKAID tablet (Breon)	24 mg. ephedrine sulfate
7.	BRONKOLIXER (Sterling Winthrop)	12 mg. ephedrine
8.	BRONKOTABS tablet (Breon)	24 mg. ephedrine sulfate
9.	EFEDRON nasal jelly (Hyrex)	0.6% ephedrine HCL in 20 g.
10.	MINI THINS asthma relief (BDI Pharmaceuticals)	25 mg. ephedrine
11.	PAZO HEMORRHOID suppositor (Bristol-Meyers)	3.86 mg. ephedrine sulfate
12.	PAZO HEMORRHOID ointment (Bristol-Meyers)	0.2% ephedrine sulfate
13.	PRIMATENE tablet (Whitehall)	24 mg. ephedrine HCL
14.	PRIMATENE M tablet (Whitehall)	24 mg. ephedrine HCL
15.	PRIMATENE P tablet (Whitehall)	24 mg. ephedrine HCL
16.	QUELIDRINE (Abbott)	5 mg. ephedrine HCL
17.	TEDRAL tablet (Parke-Davis)	24 mg. ephedrine HCL
18.	THEODRINE tablet (Rugby)	25 mg. ephedrine HCL
19.	VATRONOL nose drops (Vicks Health Care)	0.5% ephedrine sulfate

(3) Ma Huang or other botanical products of genus ephedra used in their natural state and containing 25 mg. or less of ephedrine per recommended dosage as a preparation for human consumption are not legend drugs for the purposes of this section.

(4) Any reformulation of listed products which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms shall negate the exemption. The manufacturers of listed products shall notify the board of any reformulation which increases the ephedrine content to more than 25 mg. of ephedrine per solid dosage unit or per 5 ml. of liquid forms prior to distributing that product in the state of Washington.

(5) Manufacturers of products containing 25 mg. or less of ephedrine per solid dosage unit or per 5 ml. of liquid forms in combination with other ingredients in therapeutic amounts may gain exemption from subsection (1) of this section if, prior to the distributing of any such product in the state of Washington, the manufacturer:

(a) Provides the board with the formulation of any such product;

(b) Provides the board samples of all dosage forms in which the product is to be marketed in the packaging in which the product is to be marketed; and

(c) Receives the board's approval to market such product.

Wisconsin

Wisconsin Statutes Annotated
Controlled Substances (Ch. 961)
Chapter 961. Uniform Controlled Substances Act
Subchapter II. Standards and Schedules
961.20. Schedule IV

Unless specifically excepted by state or federal law or regulation or more specifically included in another schedule, the following controlled substances are listed in schedule IV:

…

(2m) Stimulants. Any material, compound, mixture, or preparation which contains any quantity of any of the following substances having a stimulant effect on the central nervous system, including any of their salts, isomers and salts of isomers that are theoretically possible within the specific chemical designation:

…

(ak) Ephedrine, if ephedrine is the only active medicinal ingredient or if there are only therapeutically insignificant quantities of another active medicinal ingredient.

…

Wisconsin Administrative Code
Pharmacy Examining Board
Chapter Phar 8 Requirements for Controlled Substances
Phar 8.05 Dispensing.

…

(2) A pharmacist may dispense a controlled substance listed in schedule II, III or IV only pursuant to a prescription order issued by an individual practitioner. The order shall be initialed and dated by the dispensing pharmacist as of the date the prescription is dispensed. If the person accepting the medication pursuant to any prescription order for a schedule II controlled substance, specified in s. 961.16, Stats., is not personally known to the pharmacist, there shall be written in ink, on the reverse side, the printed name, signature and address of the person.

…

Wyoming

Wyoming Statutes Annotated
Title 33. Professions and Occupations
Chapter 24. Pharmacy
Article 1. In General
§ 33-24-131. Exemptions; sale of certain articles

The provisions of this act [§§ 33-24-101 through 33-24-301] shall not apply to the sale at wholesale or sale by any method at retail of economic poisons, medical and dental supplies, cosmetics, dietary foods, or nonnarcotic, nonprescription, prepackaged medicinal preparations contained in distinctive and original unbroken containers, when such medicinal preparations are identified by and sold under a trade name of the manufacturer or primary distributor thereof and are sold or offered for sale to the general public, if such articles meet the requirements of state and federal food, drug and cosmetic laws; provided however, that notwithstanding the above, any drug, medicinal preparation, or substance for use by man which is determined by the state board of pharmacy, after notice to the manufacturer or primary distributor thereof, and opportunity to be heard pursuant to the provisions of the

Wyoming Administrative Procedure Act [§§ 16-3-101 through 16-3-115], as having a depressant or stimulant effect on the central nervous system or its hallucinogenic effect, or as habit forming, or as a drug or product which, because of its toxicity or other potentiality for harmful effect, or method of use, or the collateral measures necessary for such use is not safe for use except under the supervision of a practitioner licensed by law to prescribe such substances, may be designated by rule as a dangerous drug which shall be restricted to sale on prescription of a practitioner licensed by law to prescribe such substances.

Wyoming Rules and Regulations
Department of Administration and Information
Pharmacy, Bd. of
Chapter 11. Dangerous Drug Regulations
Section 3. Additions to Dangerous Substance List.

Pursuant to § 33-24-131 and Wyoming Administrative Procedure Act § 16-3-101 through § 16-3-115, the Board has designated the following drug(s) as a Dangerous Drug(s), and is hereby added to the Dangerous Substance List.

(a) Ephedrine, all single entity containing products, no exemptions.

…

(c) Ephedrine, all combination products, except the following.

(i) Any ephedrine containing product indicated for topical treatment of hemorrhoids.

(ii) Any ephedrine containing product which includes as one of the active ingredients, guaifenesin in a quantity equal to or greater than 400mg per dose.