Map and Application of States That Require a Prescription for Dispensing Ephedrine

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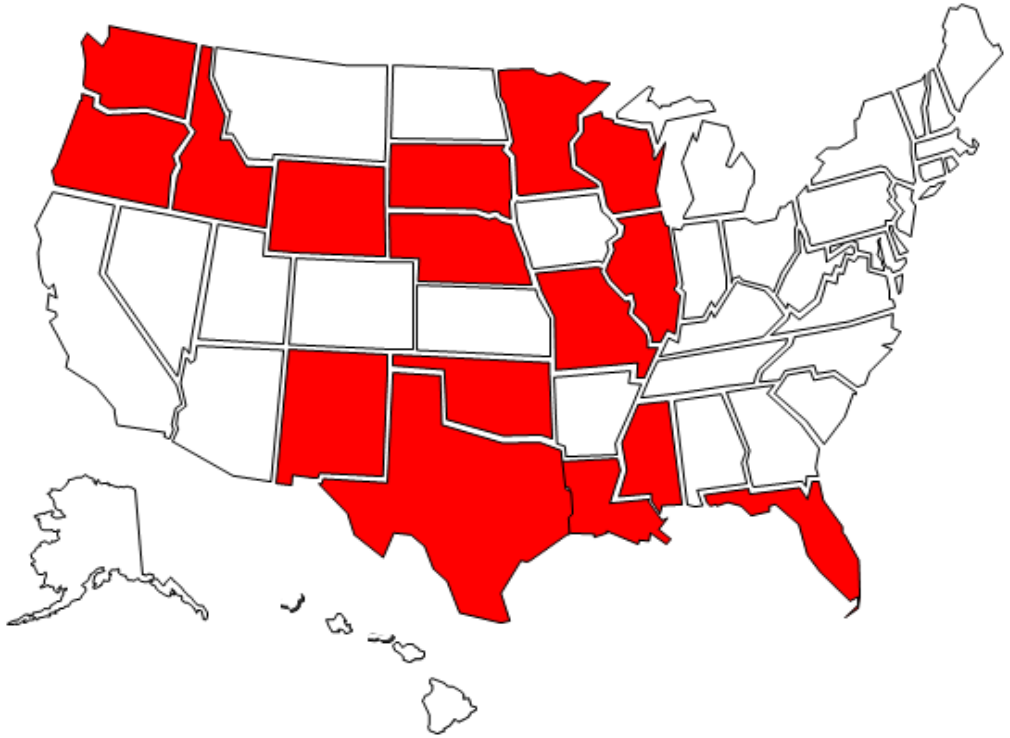
States That Require a Prescription for Dispensing Ephedrine to an Ultimate User



Many state scheduling requirements only apply to a limited number of products, and many states create exemptions from scheduling requirements. For a complete list of scheduling applications and exemptions please reference the chart below.

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Application and Exemptions of Prescription Requirements for Ephedrine

State	Classification	Application and Exemptions
Florida	Prescription Drug	Applies to 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. Products listed below are exempted if they may belawfully sold over the counter without a prescription under the federal act, and are labeled and marketed in a manner consistent with the pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph. Exempted products must also be 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. Exempts: 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 theophylline, ephedrine, or guaifenesin. Exempts 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). Exempts: anorectal preparations containing less than 5 percent ephedrine; nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine; any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.
Idaho	Designated Drug	Applies to preparations containing ephedrine or salts of ephedrine. Exempts: 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; hemorrhoidal ointments containing not more than two tenths percent (.2%) Ephedrine Sulfate and suppositories not exceeding four (4) milligrams Ephedrine Sulfate per suppository.

State	Classification	Application and Exemptions
Illinois	Schedule IV	Applies to ephedrine as the only active medicinal ingredient or in combination with therapeutically insignificant quantities of another active medicinal ingredient. Exempts: (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, and (2) anorectal preparations containing not more than 5% ephedrine Products listed above are exempted if they: (i) may be 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. Exempts 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.
Louisiana	Prescription Drug	Applies to 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. Exemptedproducts must be products that: may be lawfully sold over the counter without a prescription under the federal Food, Drug, and Cosmetic Act, are labeled and marketed in a manner consistent with the pertinent OTC Tentative Final or Final Monograph, are manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, and meet specified marketing and labeling requirements. Exempts 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 Theophylline, Ephedrine, Guaifenesin. Exempts 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.
Missouri	Schedule IV	Applies to ephedrine, its salts, optical isomers and salts of optical isomers, when the substance is the only active medicinal ingredient.

State	Classification	Application and Exemptions
Minnesota	Prescription Drug	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. Exempts products 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. Products must: 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.;be labeled and marketed in a manner consistent with the pertinent OTC Tentative Final or Final Monograph; be manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse; not marketed, advertised, or labeled for the indication of stimulation, mental alertness, weight loss, muscle enhancement, appetite control, or energy; be sold in a manner that does not conflict with MN ST 152.02, subdivision 6.
Mississippi	Schedule III	Applies to any material, compound, mixture or preparation which contains any quantity of ephedrine or pseudoephedrine. No exemptions
Nebraska	Schedule IV	Applies to any material, compound, mixture, or preparation which contains any quantity ephedrine including its salts, optical isomers, and salts of such optical isomers. Exempts the following products when sold in compliance with specified sales and marketing requirements: (i) Primatene Tablets; (ii) Bronkaid Dual Action Caplets; and (iii) PazoHemorrhoidal Ointment.
New Mexico	Dangerous Drug	Applies to ephedrine, USP, as ephedrine hydrochloride or ephedrine sulfate or as any other salt form. Exempts any compound, mixture, or preparation containing one-half percent (0.5%) or less of ephedrine. Exempts Bronkaid· Caplets and Primatene· Tablets 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.
Oklahoma	Schedule IV	Applies to any product containing ephedrine, its salts, optical isomers, and salts of optical isomers as the only active ingredient, or in combination with other active ingredients. Exempts 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;(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 (F) specified marketing requirements are met.
Oregon	Schedule III	Products that containephedrine or the salts of ephedrine as an active ingredient. No exemptions

State	Classification	Application and Exemptions
South Dakota	Schedule III	Applies to any material, compound, mixture, or preparation which contains any quantity of ephedrine having a potential for abuse associated with a stimulant effect on the central nervous system. Exempts 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	Prescription Drug	Applies toany drug product containing ephedrine, its salts, optical isomers or salts of optical isomers. Exempts: (1)solid dosage forms that combine active ingredients 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), ephedrineHCl (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	Legend Drug	Applies to ephedrine, or any of its salts in a solid or aqueous form normally intended for oral administration, in any quantity. Exempts: AMESAC capsule (Russ)25 mg. ephedrine HCL; AZMA AID tablet (Various, egPurepac) 24 mg. ephedrine HCL; BRONC-EASE PLUS (Natur-Pharma) 25 mg. ephedrine HCL; BRONCHODILATOR AND EXPECTORANT (PDK Labs) 25 mg. ephedrine; HCL BRONITIN tablet (Whitehall) 24 mg. ephedrine HCL; BRONKAID tablet (Breon) 24 mg. ephedrine sulfate BRONKOLIXER (Sterling Winthrop) 12 mg. ephedrine; BRONKOTABS tablet (Breon) 24 mg. ephedrine sulfate; EFEDRON nasal jelly (Hyrex) 0.6% ephedrine HCL in 20 g; MINI THINS asthma relief (BDI Pharmaceuticals) 25 mg. ephedrine; PAZO HEMORRHOID suppositor (Bristol-Meyers) 3.86 mg. ephedrine sulfate; PAZO HEMORRHOID ointment (Bristol-Meyers) 0.2% ephedrine sulfate; PRIMATENE tablet (Whitehall) 24 mg. ephedrine HCL; PRIMATENE M tablet (Whitehall) 24 mg. ephedrine HCL; PRIMATENE P tablet (Whitehall) 24 mg. ephedrine HCL; QUELIDRINE (Abbott) 5 mg. ephedrine HCL; TEDRAL tablet (Parke-Davis) 24 mg. ephedrine HCL; THEODRINE tablet (Rugby)25 mg. ephedrine HCL; VATRONOL nose drops (Vicks Health Care) 0.5% ephedrine sulfate; 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; 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 negates the exemption. Allows exemptions for such products to stand if, prior to the distributing of any such product in the state of Washington, the manufacturer:provides the board with the formulation of any such product; 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 Receives the board's approval to market such product.

State	Classification	Application and Exemptions
Wisconsin	Schedule IV	Applies to products with ephedrine as the only active medicinal ingredient or if there are only therapeutically insignificant quantities of another active medicinal ingredient.
Wyoming	Dangerous Drug	Applies toall single entity ephedrine containing products, without exemptions. Applies to all combination of ephedrine products, but exempts any ephedrine containing product indicated for topical treatment of hemorrhoids,and any ephedrine containing product which includes as one of the active ingredients, guaifenesin in a quantity equal to or greater than 400mg per dose.