Chapter 246-883 WAC

PHARMACEUTICAL—SALES REQUIRING PRESCRIPTIONS

WAC 246-883-020 Identification of legend drugs for purposes of chapter 69.41 RCW.
WAC 246-883-025 Introductory trade or stock packages.
WAC 246-883-030 Ephedrine prescription restrictions.
WAC 246-883-040 Regulated steroids.
WAC 246-883-050 Theophylline prescription restrictions.

WAC 246-883-020 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2009 edition of the Drug Topics Red Book. Copies of the list of legend drugs as contained in the Drug Topics Red Book are available for public inspection at the headquarters office of the State Board of Pharmacy, 310 Israel Road S.E., P.O. BOX 47863, Olympia, Washington 98504-7863. To obtain copies of this list from the department, interested persons must submit a written request, indicating which format they wish to receive, and payment of the actual cost of the text or CD, including shipping and handling charges from the publisher. Requestors may also contact the publisher directly to obtain copies. The department takes no responsibility for periodic updates or online access. Arrangements for periodic updates or online access must be made directly with the publisher.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. These determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 18.64.005 and 69.41.075. 10-02-081, § 246-883-020, filed 1/5/10, effective 2/5/10. Statutory Authority: RCW 69.41.075 and 69.41.057(8). 02-14-049, § 246-883-020, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 69.41.075. 18.64.005. 06-06-078, § 246-883-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 69.41.075. 96-21-041, § 246-883-020, filed 10/11/96, effective 11/11/96. Statutory Authority: RCW 18.64.005. 92-09-070 (Order 264B), § 246-883-020, filed 4/14/92, effective 5/15/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-883-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.057]. 85-18-091 (Order 196), § 360-32-050, filed 9/4/85. Statutory Authority: RCW 18.64.005 and 69.41.075. 83-20-053 (Order 176), § 360-32-050, filed 9/29/83. Statutory Authority: RCW 69.41.075. 81-10-025 (Order 160), § 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149, Resolution No. 9/79), § 360-32-050, filed 9/5/79.]

WAC 246-883-025 Introductory trade or stock packages. Introductory trade or stock packages may be distributed by registered drug manufacturers to licensed pharmacies under the following conditions:

(1) The package shall be invoiced by the drug manufacturer as a no charge sale.

(2) The product shall be distributed by the manufacturer to the pharmacy by mail or common carrier.

(3) The drug's package shall not be marked as a sample or with any other labeling that is inconsistent with the claim that the manufacturer intended the package for sale.

(4) The manufacturer shall be limited to distributing one introductory package of each dosage strength of a product on a one-time basis to a pharmacy in order to familiarize and assure that a company's new product will be available in pharmacies. The quantity shall not be larger than one hundred solid dosage units or sixteen liquid ounces.

[Statutory Authority: RCW 18.64.005. 92-09-072 (Order 266B), § 246-883-025, filed 4/14/92, effective 5/15/92.]

WAC 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:

<table>
<thead>
<tr>
<th>TRADE NAME</th>
<th>EPHEDRINE CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMESAC capsule (Russ)</td>
<td>25 mg. ephedrine HCL</td>
</tr>
<tr>
<td>AZMA AID tablet (Various, eg Purepac)</td>
<td>24 mg. ephedrine HCL</td>
</tr>
<tr>
<td>BRONC-EASE PLUS (Natur-Pharma)</td>
<td>25 mg. ephedrine HCL</td>
</tr>
<tr>
<td>BRONCHODILATOR AND EXpectorANT (PDK Labs)</td>
<td>25 mg. ephedrine HCL</td>
</tr>
<tr>
<td>BRONITIN tablet (Whitehall)</td>
<td>24 mg. ephedrine HCL</td>
</tr>
<tr>
<td>BRONKAID tablet (Brecon)</td>
<td>24 mg. ephedrine sulfate</td>
</tr>
<tr>
<td>BRONKOLIXER (Sterling Winthrop)</td>
<td>12 mg. ephedrine</td>
</tr>
<tr>
<td>BRONKOTABS tablet (Brecon)</td>
<td>24 mg. ephedrine sulfate</td>
</tr>
<tr>
<td>EFEDRON nasal jelly (Hyrex)</td>
<td>0.6% ephedrine HCL in 20 g.</td>
</tr>
</tbody>
</table>
(3) Ma Huang or other botanical products of genus ephe-
dra 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,

(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 prod-
uct.

[Statutory Authority: RCW 18.64.005. 94-08-100, § 246-883-030, filed
4/6/94, effective 5/7/94; 93-05-046 (Order 333B), § 246-883-030, filed
2/17/93, effective 3/20/93. Statutory Authority: RCW 18.64.005 and chapter
18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-883-030, filed
8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and
69.41.075. 82-06-042 (Order 165), § 360-32-055, filed 3/2/82. Statutory
Authority: RCW 69.41.075. 81-10-025 (Order 160), § 360-32-055, filed
4/28/81. Statutory Authority: 1979 1st ex. s. c 139. 79-09-138 (Order 149,
Resolution No. 9/79), § 360-32-055, filed 9/5/79.]

WAC 246-883-040 Regulated steroids. The board
finds that the following drugs shall be classified as steroids
for the purposes of RCW 69.41.310. The drugs designated
shall include the following and any synthetic derivatives or
any isomer, ester, salt, or derivative of the following that act
in the same manner on the human body from the attached list:

<table>
<thead>
<tr>
<th>TRADE NAME</th>
<th>EPHEDRINE CONTENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. MINI THINS asthma relief</td>
<td>25 mg. ephedrine</td>
</tr>
<tr>
<td>(BDI Pharmaceuticals)</td>
<td></td>
</tr>
<tr>
<td>11. PAZO HEMORRHOID suppositor</td>
<td>3.86 mg. ephedrine sulfate</td>
</tr>
<tr>
<td>(Bristol-Meyers)</td>
<td></td>
</tr>
<tr>
<td>12. PAZO HEMORRHOID ointment</td>
<td>0.2% ephedrine sulfate</td>
</tr>
<tr>
<td>(Bristol-Meyers)</td>
<td></td>
</tr>
<tr>
<td>13. PRIMATENE tablet</td>
<td>24 mg. ephedrine HCL</td>
</tr>
<tr>
<td>(Whitehall)</td>
<td></td>
</tr>
<tr>
<td>14. PRIMATENE M tablet</td>
<td>24 mg. ephedrine HCL</td>
</tr>
<tr>
<td>(Whitehall)</td>
<td></td>
</tr>
<tr>
<td>15. PRIMATENE P tablet</td>
<td>24 mg. ephedrine HCL</td>
</tr>
<tr>
<td>(Whitehall)</td>
<td></td>
</tr>
<tr>
<td>16. QUELIDRINE (Abbott)</td>
<td>5 mg. ephedrine HCL</td>
</tr>
<tr>
<td>17. TEDRAL tablet (Parke-Davis)</td>
<td>24 mg. ephedrine HCL</td>
</tr>
<tr>
<td>18. THEODRINE tablet (Rugby)</td>
<td>25 mg. ephedrine HCL</td>
</tr>
<tr>
<td>19. VATRONOL nose drops</td>
<td>0.5% ephedrine sulfate</td>
</tr>
<tr>
<td>(Vicks Health Care)</td>
<td></td>
</tr>
</tbody>
</table>

(1) Anabolicum
(2) Anadrol
(3) Anatrofin
(4) Anavar
(5) Androkon
(6) Andriol
(7) Andro
(8) bolandiol
(9) bolasterone
(10) boldenone
(11) boldenone undecylenate
(12) bolenol
(13) Bolfotan
(14) bolmantalate
(15) Cheque
(16) chlorotestosterone
(17) cistebol
(18) Deca Durabolin
(19) dehydrocholormethyl-testosterone
(20) Delarestyl
(21) Dianabol
(22) Dihydrolone
(23) dihydrotestosterone
(24) dimethazine
(25) Drive
(26) Drolban
(27) drostanolone
(28) Durabolin
(29) Durateston
(30) Equipoise
(31) Esiclene
(32) ethylestrenol
(33) Exoboline
(34) Finaject
(35) Fluoxymesterone
(36) formebolone
(37) Halotestin
(38) Halostein
(39) Hombreol
(40) Iontanyl
(41) Laurabolin
(42) Lipodex
(43) Maxibolin
(44) mesterolone
(45) metanabol
(46) methenolone acetate
(47) methenolone enanthate
(48) methandienone
(49) methandranone
(50) methandriol
(51) methandrostenolone
(52) methyltestosterone
(53) mibolerone
(54) Myagen
(55) Nandrolin
(56) nandrolone
(57) nandrolone decanoate
(58) nandrolone cyclotrate
(59) nandrolone phenpropionate
(60) Nelavar
(61) Nerbol
(62) Nilevar
(63) nisterime acetate
(64) Norbolethone
(65) Nor-Diethylin
(66) norethandrolone
(67) Normethazine
(68) Omnin
(69) oxandrolone
(70) oxymesterone
(71) oxymetholone
(72) Parabolan
(73) Permastril
(74) pizotyline
(75) Primobolone/Primobolan depot
(76) Primotestin/Primotestin depot
(77) Proviron
(78) Quinalone
(79) Quinbolone
(80) Restandol
(81) silandrine
(82) Sostanon
(83) Spectriol
(84) stanolone
(85) stanozolol
(86) stenbolone acetate
(87) Stromba
(88) Sustanon
(89) Tes-10
(90) Tes-20
(91) Tes-30
(92) Teslac
(93) testolactone
(94) testosterone
(95) testosterone cypionate
(96) testosterone enanthate
(97) testosterone ketolaurate
(98) testosterone phenylacetate
(99) testosterone propionate
(100) testosterone undecanoate
(101) Thiomucase
(102) tibolone
(103) trenbolone
(104) trenbolone acetate
(105) trestolone acetate
(106) Trophobolene
(107) Winstrol

[Statutory Authority: RCW 18.64.005 and 69.41.075. 92-12-035 (Order 277B), § 246-883-050, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-883-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. 89-22-048, § 360-32-060, filed 10/30/89, effective 11/30/89.]

**WAC 246-883-050 Theophylline prescription restrictions.** The board of pharmacy, pursuant to RCW 69.41.075, hereby identifies theophylline, or any of its salts in a solid or liquid form normally intended for oral administration in any quantity, as a legend drug subject to the restrictions of RCW 69.41.030. Provided, products containing 130 mg or less of theophylline per solid dosage unit or 130 mg or less per 5 ml of liquid forms, shall not be considered a legend drug and where the product contains other recognized therapeutic ingredients, may be sold or distributed without a prescription. Products with theophylline as the only active ingredient are identified as legend drugs.

[Statutory Authority: RCW 18.64.005. 92-09-070 (Order 264B), § 246-883-050, filed 4/14/92, effective 5/15/92.]