

AMENDED IN ASSEMBLY APRIL 24, 2000

CALIFORNIA LEGISLATURE—1999–2000 REGULAR SESSION

ASSEMBLY BILL

No. 2294

**Introduced by Assembly Member Davis and Senator Speier
(Coauthor: Assembly Member Mazzoni)**

February 24, 2000

An act to add ~~Section 11100.02~~ *Sections 11100.02 and 11100.03* to the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2294, as amended, Davis. Ephedrine: dietary supplements.

Existing law provides for the reporting of certain transactions involving ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine; the issuance of state permits for the conduct of business with respect to specified transactions involving ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine; limits on quantities of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine with regard to retail sale; and penalties for violations of any requirement in these provisions.

This bill would, in addition, (1) prohibit the sale or distribution of any dietary supplement product containing ephedrine, as defined, unless the product meets specified requirements; (2) impose requirements on product labels for dietary supplement products containing ephedrine; and (3)

impose requirements on companies that engage in direct marketing of any dietary supplement product containing ephedrine with respect to advertising and promotional literature. A violation of any of these requirements would be a misdemeanor. By creating new crimes, this bill would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11100.02 is added to the Health
2 and Safety Code, to read:

3 11100.02. (a) The sale or distribution of any dietary
4 supplement product containing ephedrine group
5 alkaloids *that are characterized, labeled, or advertised as*
6 *“all natural,” “natural,” “all herbal,” or “herbal”* is
7 prohibited unless the product complies with the
8 following requirements:

9 (1) The product contains no ~~chemically-synthesized~~
10 ~~synthetic ephedrine-group alkaloids~~.

11 (2) Each batch of the product shall be analyzed to
12 ensure that it contains the amount of total ephedrine
13 alkaloids listed on the product label.

14 (b) (1) The product label for any dietary supplement
15 product containing ephedrine group alkaloids shall
16 include the following statement:

17 “THIS PRODUCT HAS (INSERT THE AMOUNT OF
18 PRODUCT) MILLIGRAMS OF CONCENTRATED
19 EPHEDRINE GROUP ALKALOIDS PER SERVING IN
20 THE FORM OF HERBAL EXTRACTS.”

21



1 (2) The product label shall use standardized
2 nomenclature for the ephedrine ingredient in the
3 product so that the term “ephedrine,”
4 “pseudoephedrine,” or other ephedrine group alkaloid
5 name is used when referring to the active ingredients in
6 the product instead of, or in addition to, the botanical
7 name of the ephedrine group alkaloid.

8 (3) The product label shall state the amount in
9 milligrams of caffeine alkaloids and other ingredients per
10 serving that have a known stimulant effect (such as
11 yohimbine).

12 (4) The product label shall include a warning
13 statement for the consumption of ephedrine group
14 alkaloids that is conspicuously displayed on the label
15 information panel in distinct contrast to other printing or
16 graphics and in at least ¹/₁₆ inch type.

17 (5) The warning on the product label shall contain at
18 least the following information ~~at a minimum~~:

19 (A) WARNING: Not for use by individuals under the
20 age of 18. Do not use if pregnant or nursing. Consult a
21 physician or licensed qualified health care professional
22 before using this product if you have, or have a family
23 history of, heart disease, thyroid disease, diabetes, high
24 blood pressure, ~~recurrent headaches~~, depression or other
25 psychiatric condition, glaucoma, difficulty in urinating,
26 prostate enlargement, or seizure disorder, or if you are
27 using a monoamine oxidase inhibitor (MAOI) or any
28 other dietary supplement, prescription drug, or
29 over-the-counter drug containing ephedrine,
30 pseudoephedrine, or phenylpropanolamine (ingredients
31 found in certain allergy, asthma, cough or cold, and
32 weight control products).

33 (B) Exceeding recommended serving may cause
34 serious adverse health effects, including heart attack and
35 stroke.

36 (C) Discontinue use and call a physician or licensed
37 qualified health care professional immediately if you
38 experience rapid heartbeat, dizziness, severe headache,
39 shortness of breath, or other similar symptoms.



1 ~~(D) Individuals who consume caffeine with this~~
2 ~~product may experience serious adverse health effects.~~
3 *(D) Individuals who are sensitive to the effects of*
4 *caffeine should consult a licensed health care professional*
5 *before consuming this product.*
6 (6) The product label shall include a toll-free
7 telephone number to permit consumers to report adverse
8 effects to the State Department of Health Services.
9 (7) All labeling, except that affixed to the product
10 container, all prerecorded or scripted radio and television
11 advertising, and all promotional literature shall include
12 the following warning:
13 “This product” (optional: may use any specific reference
14 to the product) “has ephedrine group alkaloids in the
15 form of herbal extracts” (optional: from ma huang or
16 other named herb) “and may cause serious adverse
17 health effects. Read the label and follow directions.”
18
19 (c) (1) All advertising and promotional literature
20 shall be reviewed and approved by the company
21 responsible for the manufacture of the dietary
22 supplement product containing ephedrine *group*
23 *alkaloids* and a copy shall be submitted to the State
24 Department of Health Services.
25 (2) Companies that engage in direct marketing of
26 dietary supplement products containing ephedrine shall
27 incorporate into contracts with distributors, franchisees,
28 or independent contractors the following conditions:
29 (A) No claims about the product which have not been
30 approved in writing by the company may be made.
31 (B) No medical claims may be made.
32 (C) Distributors, franchisees, or independent
33 contractors shall be required to direct consumers to read
34 the product label prior to purchase or consumption.
35 ~~(D) Distributors, franchisees, or independent~~
36 ~~contractors shall be required to advise consumers under~~
37 ~~the care of a physician or with a chronic condition to~~
38 ~~consult with a physician prior to purchasing the product.~~
39 (E)



1 (D) Distributors, franchisees, or independent
2 contractors shall be required to refer any person who
3 makes a complaint about side effects to a physician or
4 licensed qualified health care professional.

5 (3) Companies that engage in direct marketing of
6 dietary supplement products containing ephedrine shall
7 effectively respond to distributors, franchisees, or
8 independent contractors to prevent the distribution of
9 unauthorized literature.

10 (4) Distributors, franchisees, or independent
11 contractors shall be trained by companies that engage in
12 direct marketing of dietary supplement products
13 containing ephedrine to refer medical questions to a
14 physician and shall not be authorized to give medical
15 advice.

16 (5) (A) No claims shall be made for the use of dietary
17 supplement products containing ephedrine, as a “legal”
18 alternative to illicit drugs, in order to achieve an
19 alteration of consciousness or euphoria, or for the use of
20 dietary supplement products containing ephedrine as a
21 drug for the diagnosis, cure, mitigation, treatment, or
22 prevention of any disease.

23 (B) To determine compliance with this requirement,
24 the State Department of Health Services may consider
25 the following factors:

26 (i) The product packaging.

27 (ii) The name and container labeling of the product.

28 (iii) Advertising and promotional materials created by
29 the company responsible for the manufacture or
30 distribution of the product.

31 (6) ~~Prior to~~ *Within 60 days of* the distribution by a
32 company of any dietary supplement product containing
33 ephedrine, the company shall submit *a copy of* the
34 product label to the State Department of Health Services.

35 (d) For the purposes of this section, “ephedra,”
36 “ephedra extract,” or “ephedrine” means a source of any
37 ephedrine alkaloid, including, but not limited to,
38 ephedrine, pseudoephedrine, norephedrine,
39 norpseudoephedrine, N-methylephedrine, or
40 N-methylpseudoephedrine, that is either derived from



1 natural sources such as the herb Ephedra sinica,
2 Ma-Huang, or Chinese Ephedra, or is synthetically
3 produced.

4 (e) A violation of this section is a misdemeanor.

5 SEC. 2. Section 11100.03 is added to the Health and
6 Safety Code, to read:

7 11100.03. (a) The sale or distribution of any dietary
8 supplement product containing ephedrine group
9 alkaloids is prohibited unless the product complies with
10 the following requirement:

11 (1) Each batch of the product shall be analyzed to
12 ensure that it contains the amount of total ephedrine
13 alkaloids listed on the product label.

14 (b) (1) The product label for any dietary supplement
15 product containing ephedrine group alkaloids shall
16 include the following statement:

17
18 “THIS PRODUCT HAS (INSERT THE AMOUNT OF
19 PRODUCT) MILLIGRAMS OF SYNTHETIC
20 EPHEDRINE (IF ANY) AND (INSERT THE AMOUNT
21 OF PRODUCT) MILLIGRAMS OF CONCENTRATED
22 GROUP ALKALOIDS PER SERVING IN THE FORM
23 OF HERBAL EXTRACTS.”

24
25 (2) The product label shall use standardized
26 nomenclature for the ephedrine ingredient in the
27 product so that the term “ephedrine,”
28 “pseudoephedrine,” or other ephedrine group alkaloid
29 name is used when referring to the active ingredients in
30 the product instead of, or in addition to, the botanical
31 name of the ephedrine group alkaloid.

32 (3) The product label shall state the amount in
33 milligrams of caffeine alkaloids and other ingredients per
34 serving that have a known stimulant effect (such as
35 yohimbine).

36 (4) The product label shall include a warning
37 statement for the consumption of ephedrine group
38 alkaloids that is conspicuously displayed on the label
39 information panel in distinct contrast to other printing or
40 graphics and in at least $\frac{1}{16}$ inch type.



1 (5) *The warning on the product label shall contain at*
2 *least the following information:*

3 (A) *WARNING: Not for use by individuals under the*
4 *age of 18. Do not use if pregnant or nursing. Consult a*
5 *physician or licensed qualified health care professional*
6 *before using this product if you have, or have a family*
7 *history of, heart disease, thyroid disease, diabetes, high*
8 *blood pressure, depression or other psychiatric condition,*
9 *glaucoma, difficulty in urinating, prostate enlargement,*
10 *or seizure disorder; or if you are using a monoamine*
11 *oxidase inhibitor (MAOI) or any other dietary*
12 *supplement, prescription drug, or over-the-counter drug*
13 *containing ephedrine, pseudoephedrine, or*
14 *phenylpropanolamine (ingredients found in certain*
15 *allergy, asthma, cough or cold, and weight control*
16 *products).*

17 (B) *Exceeding recommended serving may cause*
18 *serious adverse health effects, including heart attack and*
19 *stroke.*

20 (C) *Discontinue use and call a physician or licensed*
21 *qualified health care professional immediately if you*
22 *experience rapid heart beat, dizziness, severe headache,*
23 *shortness of breath, or other similar symptoms.*

24 (D) *Individuals who are sensitive to the effects of*
25 *caffeine should consult a licensed health care professional*
26 *before consuming this product.*

27 (6) *The product label shall include a toll-free*
28 *telephone number to permit consumers to report adverse*
29 *effects to the State Department of Health Services.*

30 (7) *All labeling, except that affixed to the product*
31 *container, all prerecorded or scripted radio and television*
32 *advertising, and all promotional literature shall include*
33 *the following warning:*

34
35 *“This product” (optional: may use any specific reference*
36 *to the product) “has ephedrine group alkaloids and may*
37 *cause serious adverse health effects. Read the label and*
38 *follow directions.”*

39



1 (c) (1) All advertising and promotional literature
2 shall be reviewed and approved by the company
3 responsible for the manufacture of the dietary
4 supplement product containing ephedrine group
5 alkaloids and a copy shall be submitted to the State
6 Department of Health Services.

7 (2) Companies that engage in direct marketing of
8 dietary supplement products containing ephedrine
9 group alkaloids shall incorporate into contracts with
10 distributors, franchisees, or independent contractors the
11 following conditions:

12 (A) No claims about the product which have not been
13 approved in writing by the company may be made.

14 (B) No medical claims may be made.

15 (C) Distributors, franchisees, or independent
16 contractors shall be required to direct consumers to read
17 the product label prior to purchase or consumption.

18 (D) Distributors, franchisees, or independent
19 contractors shall be required to refer any person who
20 makes a complaint about side effects to a physician or
21 licensed qualified health care professional.

22 (3) Companies that engage in direct marketing of
23 dietary supplements products containing ephedrine shall
24 effectively respond to distributors, franchisees, or
25 independent contractors to prevent the distribution of
26 unauthorized literature.

27 (4) Distributors, franchisees, or independent
28 contractors shall be trained by companies that engage in
29 direct marketing of dietary supplement products
30 containing ephedrine to refer medical questions to a
31 physician and shall not be authorized to give medical
32 advice.

33 (5) (A) No claims shall be made for the use of dietary
34 supplement products containing ephedrine, as a “legal”
35 alternative to illicit drugs, in order to achieve an
36 alteration of consciousness or euphoria, or for the use of
37 dietary supplement products containing ephedrine as a
38 drug for the diagnosis, cure, mitigation, treatment, or
39 prevention of any disease.



1 (B) To determine compliance with this requirement,
2 the State Department of Health Services may consider
3 the following factors:

4 (i) The product packaging.

5 (ii) The name and container labeling of the product.

6 (iii) Advertising and promotional materials created by
7 the company responsible for the manufacture or the
8 distribution of the product.

9 (6) Within 60 days of the distribution by a company of
10 any dietary supplement product containing ephedrine,
11 the company shall submit a copy of the product label to
12 the State Department of Health Services.

13 (d) For the purposes of this section, “ephedra,”
14 “ephedra extract,” or “ephedrine” means a source of any
15 ephedrine alkaloid, including, but not limited to,
16 ephedrine, pseudoephedrine, norephedrine,
17 norpseudoephedrine, N-methylephedrine, or
18 N-methylpseudoephedrine, that is either derived from
19 natural sources such as the herb *Ephedra sinica*,
20 *Ma-Huang*, or Chinese *Ephedra*, or is synthetically
21 produced.

22 (e) A violation of this section is a misdemeanor.

23 SEC. 3. No reimbursement is required by this act
24 pursuant to Section 6 of Article XIII B of the California
25 Constitution because the only costs that may be incurred
26 by a local agency or school district will be incurred
27 because this act creates a new crime or infraction,
28 eliminates a crime or infraction, or changes the penalty
29 for a crime or infraction, within the meaning of Section
30 17556 of the Government Code, or changes the definition
31 of a crime within the meaning of Section 6 of Article
32 XIII B of the California Constitution.

