



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item X. Discussion and Consideration of Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) section 1744, Related to Drug Warnings

Attachment 1

Background:

At the April 2015 Board Meeting, the board approved proposed text to amend Section 1744 of Title 16 CCR, related to Drug Warnings. The 45 day comment period began on September 25, 2015 and ended November 9, 2015.

At the April 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 45-day comment period and initiated a 15-day comment period. The 15-day comment period began on May 11, 2016 and ended on May 26, 2016.

The Board received one comment during the 15-day comment period.

At this Meeting

The board will have the opportunity to discuss the regulation, the comment received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the April 2016 Board Meeting and noticed for 15-day comment on May 11, 2016.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a second 15 day comment period.

The **Attachment 1** contains:

1. A copy of the modified text as approved at the April 2016 Board Meeting.
2. The comment received during the 15-day comment period.
3. The comment received during the 45-day comment period.
4. The initial proposed text as noticed for 45-day comment on September 25, 2015.

Staff Recommendation: Adopt the regulatory language as noticed on May 11, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

Attachment 1

Drug Warnings

1744

**Drug Warnings
Modified Text
(As Approved at the
April 2016 Board
Meeting)**

Title 16. Board of Pharmacy

Modified Language

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. (Additionally, the modified text is listed in red for color printers.)

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

Pursuant to Business and Professions Code Section 4074, a pharmacist shall inform the patient or his or her representative of the harmful effects of certain drugs dispensed by prescription.

(a) Because ~~the~~ following classes of drugs may impair a person's ability to drive ~~operate~~ a motor vehicle or vessel, ~~operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

- (1) Muscle relaxants.
- (2) Analgesics ~~with central nervous system depressant effects.~~
- ~~(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines~~
- (4) Antidepressants with central nervous system depressant effects.
- (5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.
- (6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
- (7) Anticholinergic agents and other drugs ~~which~~ that may impair vision.
- (7) Any other drug which, based on the pharmacist's professional judgment, may impair a patient's ability to operate a vehicle or vessel.

(b) Because ~~the~~ following ~~are examples~~ classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall ~~provide a written warning notice on the label to include a written label on the drug container to~~ provide a written warning notice on the label to include a written label on the drug container to alert the patient about possible potentiating effects: ~~which may have harmful effects when taken in combination with alcohol.~~ These may or may not affect a person's ability to operate a motor vehicle:

- (1) Disulfiram and other drugs (e.g., chlorpropamide, metronidazole) which may cause a disulfiram-like reaction.
- (2) Mono amine oxidase inhibitors.
- (3) Nitrates.
- (4) Cycloserine.
- (5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).
- (6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022,~~4055~~ and 4074, Business and Professions Code.

**Drug Warnings
15-Day Comments
Comment Period
Closed
May 26, 2016**

Martinez, Lori@DCA

From: Rayburn Vlabel <rbvlabel@yahoo.com>
Sent: Tuesday, May 17, 2016 3:48 PM
To: Martinez, Lori@DCA
Subject: Comment on proposed Drug Warning
Attachments: 1744_pt.pdf

The following are my comments relative to the proposed language relating to Drug Warnings.

(1) "A pharmacist shall inform..." Exactly what does this mean, "to inform"? If that can be satisfied by putting a little sticker on the prescription bottle it is woefully inadequate. Minimally, these drug warning should be orally communicated to the patient (or representative).

(2) Why does the wording for the "label" differ in part (a) [...shall include a written label...] and in part (b) [...shall provide a written warning notice on the label...]...?

(3) In addition to a verbal warning and a warning label on the prescription container, the regulation should also include a requirement to include this specific warning information in the separate written information provided to the patient along with the prescription.

Thanks...

NOTICE IS HEREBY GIVEN that the Board of Pharmacy has proposed modifications to the text of Title 16 CCR § 1744, related to Drug Warning. Any person who wishes to comment on the proposed modifications may do so by submitting written comments beginning May 11, 2016 and ending at 5pm on May 26, 2016, to the following:

Contact Person: Agency Name: Address:

Email: Fax:

Lori Martinez
California State Board of Pharmacy 1625 North Market Blvd, Suite N 219 Sacramento, CA 95834
Lori.Martinez@dca.ca.gov
(916) 574-8618

Any responses to comments directly concerning the proposed modifications to the text of the regulations will be considered and responded to in the Final Statement of Reasons.

http://www.pharmacy.ca.gov/laws_regs/1744_pt.pdf

Ray

Ray Vrabel

Cell: (619) 417-8564

Sent from my iPad...

**Drug Warnings
45-Day Comments
Comment Period
Closed
November 9, 2015**



Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

November 5, 2015

Lori Martinez
Administration and Regulations Manager
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

Re: Proposed amendments to Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations

Dear Ms. Martinez:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. CVS Health appreciates the opportunity to submit comments on the proposed amendments to Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations regarding Drug Warnings. We would like to thank the Board for their continued vigilance to continuously improve the laws and rules that guide pharmacists serving California patients.

CVS Health appreciates the Board's effort to increase patient and consumer awareness regarding potentially dangerous side effects of certain prescription drugs that may impair one's ability to operate a motor vehicle or vessel and increased risks associated with consuming alcohol when taken in combination with specific drugs. The current language in 1744(b) indicates that the written warning notice must be on the label. Business and Professions Code 4074(b) specifically allows for compliance to be achieved by an auxiliary label that is affixed to the prescription container. We do request that the Board amend the language in 1744(b) to include a written label on the drug container in order to be consistent with warning language in 1744(a) and Business and Professions Code 4074(b). That consistency within the rule and the law provide clarity to practitioners working towards consistent compliance. The current and suggested language is outlined below.

Current Language:

(b) Because the following classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall provide a written warning notice on the label to alert the patient about possible potentiating effects

Suggested Language:

(b) Because the following classes of drugs pose a substantial risk to the person consuming the drug when taken in combination with alcohol, a pharmacist shall ~~provide a written warning notice on the label to~~ include a written label on the drug container to alert the patient about possible potentiating effects



Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

CVS Health appreciates the opportunity to submit comments for the proposed amendment of these rules. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

A handwritten signature in black ink that reads "Lauren Berton PharmD". The signature is written in a cursive, slightly slanted style.

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

Drug Warnings

Initial Proposed Text

Title 16. Board of Pharmacy

Proposed Language

To Amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1744. Drug Warnings

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(a) Because ~~the~~ the following classes of drugs may impair a person's ability to ~~drive~~ operate a motor vehicle or vessel, ~~operate machinery when taken alone or in combination with alcohol~~ a pharmacist shall include a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel:

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- (2) ~~Analgesics with central nervous system depressant effects.~~
- ~~(3) Antipsychotic drugs with central nervous system depressant effects including phenothiazines~~
- (4) Antidepressants with central nervous system depressant effects.
- ~~(5) Antihistamines, motion sickness agents, antipruritics, antinauseants, anticonvulsants and antihypertensive agents with central nervous system depressant effects.~~
- (6) All Schedule II, III, IV and V agents with central nervous system depressant effects. ~~or narcotic controlled substances as set forth in Health and Safety Code at Section 11055 et seq. prescribed in doses which could have an adverse effect on a person's ability to operate a motor vehicle.~~
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- (5) Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia).
- (6) Any other drug which, based upon a pharmacist's professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022, 4055 and 4074, Business and Professions Code.