

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Drug Warnings

Sections Affected: Amend § 1744 of Article 5 of Division 17 of Title 16 Cal.Code Reg.

Specific Purpose of the Proposed Changes/Problems Addressed

The Board of Pharmacy (Board) proposes to amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of amending the board's regulations specific to drug warnings as part of the board's efforts to increase patient and consumer awareness regarding the potentially dangerous side-effects of certain prescription drugs and as a result of Assembly Bill (AB) 1136 (Levin, Chapter 304, Statutes of 2013), as specified below.

According to the National Highway Transportation Safety Administration (NHTSA) there was a marked increase in the number of drivers testing positive for drugs. In 2005, NHTSA found drugs in 28 percent of fatally injured drivers tested and in 2009, the number of fatally injured drivers testing positive for drugs increased to 33 percent nationally. Additionally, in February 2015, NHTSA released a fact sheet indicating that incidences of drugged driving are increasing. They reported that approximately 20.0 percent of drivers had tested positive for at least one drug in 2014. This was an increase of 3.7 percent over the reported 2007 result of 16.3 percent.

This proposal will increase patient and consumer awareness regarding the potentially dangerous side-effects of certain prescription drugs. The use of a warning label on a prescription medication container will serve to remind and educate patients as to the possible adverse side effects of certain prescription drugs and the increased risks associated with consuming alcohol when taking specific drugs. This education will combat the growing epidemic of drugged driving and increase the safety of residents traveling within California and individuals performing work on the roadways.

Amend 16 CCR §1744

The purpose of the board's proposal makes the following changes:

This section was renumbered accordingly based on deletions and additions to the defined drug classes.

Subdivision (a) amends and changes the term "drive" to "operate," removes the term "motor" and adds "vessel" to incorporate changes required in B&P section 4074(b). Additionally, "operate machinery when taken alone or in combination with alcohol" has been removed from the regulation to align the regulation with the requirements in B&P 4074(a)(1). Furthermore, "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" was added to incorporate the written label requirement of B&P 4074(b). Finally, "Because" as added and the "T" in "the" was reduced to lower case for grammatical clarity.

Subdivision (a)(2) was removed from the text as duplicative. Analgesics with central nervous system depressant effects are opioids, which are covered under subdivision (a)(6).

Subdivision (a)(3), now (a)(2), amends and adds “with central nervous system depressant effects” and removes “including phenothiazines” to specify that only antipsychotics that are central nervous system depressants require the written warning. Reference to phenothiazines was removed as the drug is not widely used any longer. Additionally, “with central nervous system depressant effects” was added as central nervous system depressants are sometimes referred to as sedatives and/or tranquilizers. They can slow brain activity; thereby increasing necessary reaction time when operating a vehicle or vessel. This increase in reaction time may impair a person’s ability to safely operate a vehicle or vessel.

Subdivision (a)(4), now (a)(3), amends and adds “with central nervous system depressant effects” to specify that only antidepressants that are central nervous system depressants require the written warning. “With central nervous system depressant effects” was added as central nervous system depressants are sometimes referred to as sedatives and/or tranquilizers. As such, they can slow brain activity; thereby increasing necessary reaction time when operating a vehicle or vessel. This increase in reaction time may impair a person’s ability to safely operate a vehicle or vessel.

Subdivision (a)(6), now (a)(5), amends and adds “agents with central nervous system” to specify that only those scheduled drugs that are central nervous system depressants require the written warning. Additionally, “effects” was added after “depression” for grammatical clarity. Central nervous system depressants are sometimes referred to as sedatives and/or tranquilizers. They can slow brain activity; thereby increasing necessary reaction time when operating a vehicle or vessel. This increase in reaction time may impair a person’s ability to safely operate a vehicle or vessel. Finally, “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” was removed in its entirety. This was removed for further clarity as Health and Safety Code section 11055 et seq lists the specific Schedule II, III, IV, and V controlled substances. These lists are extensive and not all controlled substances listed are central nervous system depressants.

Subdivision (a)(7), now (a)(6), amends and removes “and other drugs which” as this language is being added to new subdivision (a)(7). Additionally, “that” was added before “may” for grammatical clarity.

New subdivision (a)(7) adds the following: “Any other drug which, based on the pharmacist’s professional judgment, may impair a patient’s ability to operate a vehicle or vessel.” This subdivision was added to include the ability of a pharmacist to use their professional judgment for drug classes not specified and the “other drug” requirement previously included in previous subdivision (a)(6).

Subdivision (b) amends and changes the term “are examples” to “classes” in order to be more specific in the regulation requirements. Additionally, “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:” was added to incorporate the written label requirement of B&P 4074(b). Furthermore, “which may have harmful effects when taken in combination with alcohol. These may or may not affect a person’s ability to operator a motor vehicle:” was removed due to duplicity and it is unnecessary to state “may or may not,” there only needs to be a substantial risk. Finally, “Because” as added and the “T” in “the” was reduced to lower case for grammatical clarity.

New subdivision (b)(4) adds “Cycloserine” as alcohol should be avoided with this medication due to the adverse effects alcohol has with the medication.

New subdivision (b)(5) adds “Antidiabetic agents including insulin and sulfonylureas (due to risk of hypoglycemia)” as alcohol effects a person’s sugar level. Additionally, alcohol may interfere with the effects of antidiabetic medication.

New subdivision (b)(6) adds “Any other drug which, based on the pharmacist’s professional judgment, may pose a substantial risk to the person consuming the drug when taken in combination with alcohol.” This subdivision was added to include the ability for a pharmacist to use their professional judgment for drug classes not specified. As all drugs pose some risk to the person, the pharmacist shall use their judgment when assessing the risk to the person if combined with alcohol.

Business and Professions Code section 4055 is removed from the References cited to ensure compliance with the Administrative Procedures Act.

Factual Basis/Rationale

Business and Professions Code (B&P) Section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

Business and Professions Code section 4022 generally defines dangerous drugs and dangerous devices.

Business and Professions Code section 4074 generally authorizes the board to determine the drug or drug type requiring a drug risk warning.

Prior to July 1, 2014, Pharmacy Law required a pharmacist to inform a patient orally or in writing of the harmful effects of a drug: (1) if the drug posed a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug could impair a person’s ability to drive a motor vehicle, and (2) the drug was determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

AB 1136 (Levine, Chapter 304, Statutes of 2013), amended B&P section 4074 to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel, if in the pharmacist’s professional judgment, the drug may impair a person’s ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

Existing regulation at CCR Section 1744 provides the specific drug classes which trigger a pharmacist’s notice to patients where a patient’s ability to operate a vehicle (and now a vessel) may be impaired. Additionally, the existing regulation identifies the specific drug classes that

may impair a person's ability to drive a motor vehicle, operate machinery or may have harmful effects if taken in combination with alcohol.

The proposed regulation amends CCR section 1744 to include the written label requirement. Additionally, the drug classes requiring the written label are being amended and updated based on discussions with industry professionals. The drug classes identified in this regulation have not been amended this 1983. As new drug classes have been established that may impair a person's ability to operate a vehicle or vessel or may have harmful effects if taken in combination with alcohol, it is necessary to amend and update the regulation.

Underlying Data

1. Assembly Bill 1136 (Levine, Chapter 304, Statutes of 2013).
2. National Highway Traffic Safety Administration *2013-2014 Fact Sheet: National Roadside Survey of Alcohol and Drug Use by Drivers* (<http://www.nhtsa.gov/Driving+Safety/Research+&+Evaluation/Alcohol+and+Drug+Use+By+Drivers>).
3. National Highway Traffic Safety Administration *Traffic Safety Facts*, November 2010 (<http://www-nrd.nhtsa.dot.gov/Pubs/811415.pdf>).
4. Relevant Meeting Minutes from Board of Pharmacy Meeting held April 21-22, 2015 (Pages 11-14).

Business Impact

The Board has made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, existing law, implemented July 1, 2014, requires pharmacists to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription. The proposed regulation amends the specific drug classes that require those written or oral instructions, based on feedback from industry professionals.

The proposed regulation affects any pharmacy licensed by the Board that dispenses the specific drug classes identified in the proposed text to patients. The Board is not including in its business impact those hospital pharmacies and licensed clinics that dispense prescription drug medications to inpatients, nor does it include licensed correctional facility pharmacies that dispense prescription drug medications to inmates.

Economic Impact Assessment

This regulatory proposal will have the following effects:

It will not create or eliminate jobs within the State of California because the proposed regulation defines the drug classes requiring oral or written notification. The requirement to perform the notification is specified in Business and Professions Code section 4074. This regulation is updating an existing requirement to include new drug classes that may impair a person's ability to operate a vehicle or vessel or may have harmful effects if taken in combination with alcohol and is not imposing a new requirement.

It will not create new business or eliminate businesses within the State of California because the proposed regulation defines the drug classes requiring oral or written notification. The requirement to perform the notification is specified in Business and Professions Code section 4074. This regulation is updating an existing requirement to include new drug classes that may impair a person's ability to operate a vehicle or vessel or may have harmful effects if taken in combination with alcohol and is not imposing a new requirement.

It will not affect the expansion of businesses currently doing business within the State of California the proposed regulation defines drug classes requiring oral or written notification. This notification is currently required under existing law and this regulation specifies additional drug classes that require notification.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulations will allow for patients to be better educated as to the harmful effects of a prescription drug when mixed with alcohol and their ability to safely operate a vehicle or vessel. This education may prevent patients from consuming alcohol while taking the prescription drug, which would lead to fewer impaired vehicle or vessel operators on the road, a reduction in traffic collisions and fatalities, and a reduction in adverse drug reactions for California residents.

This regulatory proposal benefits worker safety because the proposed regulations will allow for patients to be better educated as to the harmful effects of a prescription drug when mixed with alcohol and their ability to safely operate a vehicle or vessel. This education may prevent patients from consuming alcohol while taking the prescription drug, which would lead to fewer impaired vehicle or vessel operators on the road, a reduction in traffic collisions and fatalities, and a reduction in adverse drug reactions for California residents.

The regulatory proposal does not affect the state's environment because the proposed regulation is updating an existing requirement to include new drug classes that may impair a person's ability to operate a vehicle or vessel or may have harmful effects if taken in combination with alcohol and is not imposing a new requirement.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law begin implemented or made specific.