



United Food & Commercial Workers Union

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The Hon. Victor Law, R.Ph
President
Anne Sodergren
Acting Executive Officer
California State Board of Pharmacy
1625 N. Market Blvd, Suite N219,
Sacramento, CA 95834

**Re: PETITION FOR RULEMAKING TO IMPLEMENT BUSINESS & PROFESSIONS CODE SECTION 4113.5
(SB 1442 (WEINER)) REGARDING PHARMACIST ASSISTANCE**

Dear President Law and Acting Executive Officer Sodergren:

Pursuant to California Government Code sections 11340.6 and 11340.7, the United Food and Commercial Workers Union Western States Council (“UFCW”) on behalf of its more than 160,000 members, thousands of which work in licensed pharmacies, respectfully petition the Board of Pharmacy (“Board”) to adopt regulations pertaining to implementation and enforcement of Section 4113.5 of the Business and Professions Code. As provided for in the above-cited Government Code sections, UFCW below provides (i) the reason for the request, (ii) the authority of the state agency to take the action requested, and (iii) the substantive nature of the regulation requested (including a draft of its proposed terms).

I. THE REASONS WHY REGULATIONS ARE NEEDED TO IMPLEMENT BUSINESS & PROFESSIONS CODE SECTION 4113.5¹.

Patients, the Board, pharmacists, pharmacy technicians, and pharmacies subject to the new law will all benefit from regulations such as the ones below defining key statutory terms in section 4113.5 and establishing clear requirements for documenting compliance.

Many of the pivotal words and phrases in section 4113.5 resemble what the Office of Administrative Law describes as the “third type” of statutory provision:

A self-executing provision is so specific that no implementing or interpreting regulation is necessary to give it effect. An example is a statutory provision that provides: “The annual licensing fee is \$500.”

In contrast, a wholly-enabling statutory provision is one that has no legal effect without the enactment of a regulation. An example is a statute that provides: “The department may set an annual licensing fee up to \$500.” This type of statute cannot be legally enforced without a regulation setting the fee.

The third type, a statutory provision that is susceptible to interpretation, may be enforced without a regulation, ***but may need a regulation for its efficient enforcement.*** An example is a statute that provides: “There shall be adequate space between hospital beds.” Conceptually, this statute could be enforced on a case-by-case basis, but such enforcement would probably present significant difficulties.²

For there to be consistent, predictable, transparent, and objective enforcement of section 4113.5, formal regulations are required.

As a matter of law, the Board cannot interpret and enforce the key statutory terms in section 4113.5 consistently or predictably without formal rulemaking. This is because a “regulation” under the Government Code is broadly defined and encompasses almost any kind of consistent application of law:

“Regulation” means every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure.”³

Similarly, the Government Code specifically prohibits any state agency from making any use of a state agency rule which is a “regulation” as defined in Government Code section 11342.600 that should have, but has not been, adopted pursuant to the APA. “No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application,

¹ Unless otherwise noted, all “section” references hereinafter are to the Business & Professions Code.

² https://www.oal.ca.gov/wp-content/uploads/sites/166/2017/05/What_Is_a_Regulation.pdf p.1.(Emphasis added).

³ Government Code section 11342.600.

or other rule, which is a “regulation” under the APA unless it has been adopted as a regulation and filed with the Secretary of State pursuant to the APA.” (Government Code section 11340.5(a)).⁴

Respectfully, then, there are three choices for the Board when considering how to interpret and enforce such key statutory terms as “made available”, “reasonably unanticipated circumstance,” and “all reasonable action”:

- The Board can permit interpretation of these and many other terms to vary in each individual case, with investigators, DAGs, and the Executive Officer free to adopt vastly different interpretations on a case-by-case basis.
- The Board can adopt rules of thumb guiding the interpretation of such terms and risk being sued or challenged before the OAL for unlawful underground rulemaking.
- The Board can promulgate regulations defining these key terms and, while it is at it, offer what steps need to be taken for pharmacies to document compliance with the law.

Sound governance overwhelmingly favors the last choice and, respectfully, only an inapt devotion to secrecy and arbitrary unpredictability in the conduct of Board enforcement favors the first two.

More deeply, regulated entities and individuals deserve to know in advance what behavior and operations will and will not result in possible Board discipline. Patients likewise deserve the certainty of consistent, transparent, and therefore accountable Board enforcement of patient-protecting laws like section 4113.5. Moreover, the prospect of the Attorney General being willing to file an accusation rises with the predictability of an eventual victory; a prospect facilitated by defining key terms in advance, quasi-legislatively, instead of having expensively and unpredictably to litigate the meaning of each term in every case, over and over again, before different judges.

The uncodified findings and declarations supporting section 4113.5 underscore the patient-protecting importance of the law.⁵ This law is too important to leave enforcement to chance.

⁴ See, for e.g., *Engelmann v. State Board of Education* (1991) 2 Cal.App. 4th 47 (to the extent that any of the agency rules depart from, or embellish upon, express statutory authorization and language, the agency will need to promulgate regulations).

⁵ *The Legislature finds and declares as follows:*

(a) Licensed pharmacists are health care professionals whose training and experience play a vital role in protecting public health.

(b) Pharmacists are legally and ethically bound to advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications as well as monitor the health and progress of those patients to ensure that they are using their medications safely and effectively.

(c) Pursuant to Section 4001.1 of the Business and Professions Code, the highest priority for the regulation of pharmacists is protection of the public.

(d) The duties of a pharmacist include preventing the abuse of prescription opioids. In August 2013, the California State Board of Pharmacy revoked the licenses of both a pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. Four patients died as a result of the pharmacist’s actions.

(e) The California State Board of Pharmacy’s decision and order in that case identifies “red flags” that pharmacists are legally obligated to watch for before filling such a prescription. These “red flags” include:

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- (1) Irregularities on the face of the prescription itself.
 - (2) Nervous patient demeanor.
 - (3) The age or presentation of patient (e.g., youthful patients seeking chronic pain medications).
 - (4) Multiple patients all with the same address.
 - (5) Multiple prescriptions for the same patient for duplicate therapy.
 - (6) Requests for early refills of prescriptions.
 - (7) Prescriptions written for an unusually large quantity of drugs.
 - (8) Prescriptions written for duplicative drug therapy.
 - (9) Initial prescriptions written for strong opiates.
 - (10) Long distances traveled from the patient's home to the prescriber's office or to the pharmacy.
 - (11) Irregularities in the prescriber's qualifications in relation to the type of medications prescribed.
 - (12) Prescriptions that are written outside of the prescriber's medical specialty.
 - (13) Prescriptions for medications with no logical connection to an illness or condition.
- (f) In 2013, the Governor signed legislation that significantly expanded the scope of practice of pharmacists. Pharmacists are now, without a prescription from a physician, permitted to vaccinate their patients, aid them in the administration of self-administered hormonal contraception, and provide nicotine replacement products. The California State Board of Pharmacy has by regulation promulgated extensive protocols governing each of these new duties.
- (g) For self-administered hormonal contraception, the California Code of Regulations requires a pharmacist to complete the following steps:
- (1) Ask the patient to use and complete the self-screening tool.
 - (2) Review the self-screening answers and clarify responses if needed.
 - (3) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
 - (4) Before furnishing self-administered hormonal contraception, ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.
 - (5) When a self-administered hormonal contraceptive is furnished, provide the patient with appropriate counseling and information on the product furnished, including:
 - (A) Dosage.
 - (B) Effectiveness.
 - (C) Potential side effects.
 - (D) Safety.
 - (E) The importance of receiving recommended preventative health screenings.
 - (F) That self-administered hormonal contraception does not protect against sexually transmitted infections.
 - (h) For nicotine replacement products, the California Code of Regulations requires a pharmacist to complete the following steps:
 - (1) Review the patient's current tobacco use and past quit attempts.
 - (2) Ask the patient screening questions related to pregnancy, heart attacks, history of heart ailments, chest pain, or nasal allergies.
 - (3) Review the instructions for use with every patient using a nicotine replacement product.
- (i) For vaccines, Section 1746.4 of Title 16 of the California Code of Regulations requires a pharmacist to notify each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider.
- (j) Notwithstanding the number, complexity, and importance of a pharmacist's duties, including those new obligations described above, the Legislature has heard uncontradicted testimony that licensed pharmacists are left alone for indeterminate periods of time in the pharmacy and are, simultaneously, required by such establishments to perform nonpharmacist functions such as staffing cash registers and assisting consumers in purchasing prescriptions, groceries, and other nonpharmacy goods. Survey information of pharmacists working in pharmacies reinforces the testimony.
- (k) Staffing inadequacies like these interfere with the professional responsibilities of licensed pharmacists, including those requiring time and professional judgment listed above, and pose a risk to the public health because it leaves

II. THE AUTHORITY FOR THE REGULATIONS.

Statutory authority for the Board to promulgate regulations such as the one offered below arises from two statutes:

- Section 4001.1 which provides: “Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.”
- Section 4005 which reposes in the Board broad discretion to decide to promulgate regulations in the public’s interest: “(a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy ...”

III. PROPOSED DRAFT OF REGULATION SECTION 1718.2

UFCW respectfully proposes and requests the following regulation:

Add Article 2, Title, Division 17, section 1714.2 of the California Code of regulations:

(a) Pursuant to section 4113.5 of the Business & Professions Code, the following terms shall have the following meanings:

(1) “Pharmacist employee” means any licensee who is employed full or part time by a community pharmacy not listed in Business & Professions Code section 4113.5(b) to engage in activities for which, in whole or in part, a license is required pursuant to section 4200.

(2) “Another employee of the pharmacy” means any person employed by a community pharmacy who is on the premises of the pharmacy, whose duties include, in whole or in part, work in the pharmacy, whether or not a pharmacy technician licensed pursuant to section 4115 or a pharmacist licensed pursuant to section 4200, and who may lawfully work behind a pharmacy counter with pharmacists pursuant to training provided by the employer in such laws that include, but are not limited to, the Health Insurance Portability and Accountability Act.

(3) “An employee of the establishment within which the pharmacy is located” means a person, whether employed full or part time, whether or not a pharmacist or pharmacist technician, who is on the premises of a business within which a pharmacy is located, and may include a manager or supervisor.

licensed pharmacists an insufficient amount of time to perform their licensed functions safely and lawfully, exercise their professional discretion, and comply with their legal and ethical obligations to protect the health and well-being of patients.

(4) “Made available” means employees have been scheduled and designated in writing by their employer to work behind the pharmacy counter of a community pharmacy upon request of the pharmacist on duty for the hours the pharmacy is open to the public, who are present in the establishment as scheduled, and who have been instructed by their employer in writing:

(A) immediately to remove him or herself from her other duties to assist the requesting pharmacist behind the pharmacy counter without leaving the pharmacy for the duration of the hours the pharmacy is open to the public or for as long as the pharmacist requests assistance.

(B) to work under the direction of the pharmacist offering such assistance as the pharmacist may lawfully request.

(5) “Reasonably unanticipated circumstances” means when employees of the pharmacy or establishment who were scheduled and designated in writing to be made available and who, less than twenty-four hours in advance of their shift:

(A) suffers illness, injury, or a family emergency such that the employees do not attend work as scheduled or designated for the entirety of the time they were scheduled and designated to work and assist the pharmacist, or

(B) are terminated, suspended, or placed on leave such that the employees do not attend work as scheduled or designated for the entirety of the time they were scheduled or designated to work and assist the pharmacist.

(6) “All reasonable action” means when a community pharmacy cannot identify another employee of the pharmacy or establishment who is on the premises who can be assigned to assist the pharmacist on the premises without the pharmacy or establishment having to close for business or who is at another community pharmacy owned by the same company and within five miles as the community pharmacy where the pharmacist requests assistance.

(b) A community pharmacy shall not delegate to or otherwise require a pharmacist or pharmacy technician, in whole or in part, to any duties imposed upon a community pharmacy pursuant to this section.

(c) A community pharmacy shall document compliance with this section by specifically documenting:

(A) which employees are scheduled and designated to assist the pharmacist during every day the pharmacy is open to the public,

(B) the written policies and procedures for identifying employees in the pharmacy or establishment who can be assigned to assist the pharmacist in the event of a reasonably unanticipated circumstance, and

(C) if no employees are designated or scheduled to assist the pharmacist in advance of the pharmacy opening to the public, a narrative documenting each instance of a

pharmacist requesting assistance, the time it took for the employee assisting the pharmacist to arrive in the pharmacy, the duration of the assistance, and the identity of the employee who assisted, with the pharmacist who requested the assistance affirming the accuracy of the narrative or offering a different version of events on the same document.

Pursuant to the Government Code, please respond to this petition within 30 days. Thank you, in advance, as we move to implement this important law protecting the public.

Respectfully submitted:

A handwritten signature in black ink that reads "Amber Baur". The signature is written in a cursive, flowing style.

Amber Baur, Executive Director
UFCW Western States Council

CC: Hon. Dean Grafilo, Director, Department of Consumer Affairs
Hon Scott Weiner, Hon. Jeff Stone