



July 23, 2019

Greg Lippe
Chair, Legislation and Regulation Committee
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

RE: Proposed Regulations Related to Implementation of Business and Professions Code Section 4113.5 (SB 1442, Statutes of 2018)

Dear Mr. Lippe:

I am writing on behalf of the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) to express our concerns regarding the proposed regulations related to the *Implementation of Business and Professions Code Section 4113.5 (SB 1442, Statutes of 2018)*. While we are supportive of the Board providing direction to pharmacies as to their requirements under B&P Code Section 4113.5 and are supportive of many of the provisions in the proposed regulations, we have a few concerns with certain provisions which we believe are unworkable and over-prescriptive. Our concerns are as follows:

Designating only one person or persons is overly restrictive due to staffing changes

Pharmacy staffing fluctuates every day and by the hour. This is mainly due to circumstances that are out of management's control, such as employees not showing up to work due to an emergency or illness, or employees having to leave or take a needed break from working hours. It is crucial that pharmacies have the ability to address these fluctuations and have the ability to modify who is designated and not have limits on those that are "designated" for the day or week. We would suggest the following changes to the proposed regulation:

- (1) **Designate persons that** ~~Designate the names of one or more persons who~~ will be available to assist the pharmacist:

Duties assigned a designated person should be directed by the pharmacy and pharmacist

This designated person's main responsibility is to assist the pharmacists in times when they need support for a great volume of patients or they need to take a short break. The provisions of the proposed regulations pertaining to those duties to be performed by the designated person would authorize them to input data and information into the pharmacy computer that they may not be qualified to handle. Section 1793.3 would allow a designated person the ability to "type a

prescription label or otherwise enter prescription information into a computer record system.” These tasks should be delegated only when a pharmacy believes the individual has been trained and has the capability.

- (2) Determine that ~~each the~~ designated persons is are able, at a minimum, to perform the duties of non-licensed pharmacy personnel as determined in the policies and procedures; ~~as specified in Section 1793.3~~

An employee who clears a background check is not always authorized to handle controlled substances

While CRA and NACDS members are not opposed to ensuring employees who would assist the pharmacist are criminal background checked, we are concerned that there are many un-licensed pharmacy employees who are not authorized to handle controlled substances. The authorization to handle controlled substances is reserved for a very few employees that are licensed or certified and thus have access to the supply of controlled substances in a locked box or area in a pharmacy. We would want to clarify that an employee who is background checked is cleared to work in the pharmacy to assist the pharmacist but does not need to have access to controlled substances. We would suggest the following changes to the proposed regulations:

- (3) Determine that each designated person or persons qualifies qualify to ~~access controlled substances~~ provide assistance in a pharmacy by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;

The five minute requirement does not take into account emergencies, employee breaks or other unexpected staffing issues

The specified ‘five minute requirement’ is much too restrictive for pharmacies to comply with under all circumstances. CRA and NACDS do not dispute the goal that pharmacies should have an employee available to respond as soon as practically possible to a pharmacist request, however, there are circumstances that are out of the control of the pharmacy that must be taken into account. SB 1442 recognized that there was a need for these exceptions. We would ask that the five minute requirement be removed and replaced with ‘in a reasonable amount of time’ and that the SB 1442 exceptions be incorporated into the proposed regulations as follows:

- (4) Ensure that a designated person responds and is able to assist the pharmacist within ~~five minutes~~ a reasonable amount of time after the pharmacist’s request. Exceptions to this requirement include: another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee’s termination or resignation and the pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

The requirement for a pharmacist to “document the response time” is extremely cumbersome and will impact pharmacy workflow and impact patient care

The requirement for pharmacists to document the “time between the request and arrival of the designated person at the pharmacy” will be entirely too cumbersome and unworkable for

pharmacists. The pharmacists would need to keep some type of log book to catalogue every time they call for assistance. This recordkeeping requirement will only divert pharmacist's time from assisting patients while doing nothing to ensure patient safety. CRA and NACDS would suggest the following changes to the proposed regulatory language:

(b) (2) The process for the pharmacist to request assistance and ~~to document the~~ the intended goal for a response time between the request and arrival of the designated person or persons at the pharmacy.

We appreciate the Board of Pharmacy's interest in this important issue. We would ask that the Legislation and Regulation Committee take the time to discuss these proposed regulations in detail and not make any quick decisions on such an important policy issue. Please do not hesitate to reach out to Jennifer Snyder at (916) 549-7817 or jsnyder@capitoladvocacy.com if there are any questions or concerns about CRA and NACDS's comments.

Sincerely,



Rachel Michelin
President
California Retailers Association



Mary Staples
Director, State Government Affairs
National Association of Chain Drug Stores

cc: Anne Sodergren, Acting Executive Officer, Board of Pharmacy