



April 28, 2020

Gregory Lippe, President
Anne Sodergren, Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Dr #100, Sacramento, CA 95833

Via email to Lori Martinez at Lori.Martinez@dca.ca.gov

Re: Public comment of California Society of Health-System Pharmacists (CSHP) regarding proposed section 1714.3 to Article 2 of Division 17 of Title 16 of the California Code of Regulations

Dear President Lippe and Executive Officer Sodergren:

On behalf of the thousands of pharmacy professionals California Society of Health-System Pharmacists (CSHP) represents we are and continue to be extremely concerned regarding the unacceptable working conditions of our community pharmacists. Recent revelations published in the New York Times, January 31, 2020, “How Chaos at Chain Pharmacies Is Putting Patients at Risk” have once again raised the ongoing issue of detrimental work conditions community pharmacists must endure.¹

The New York Times article is not the first to call out concerns with community pharmacy working conditions and the direct harm to the public. In 2016 the Chicago Tribune investigation revealed, “Pharmacies miss half of dangerous drug combinations.”² In 2017, the United Food and Commercial Workers Union expressed concerns with pharmacists dealing with dangerous levels of understaffing, leaving them with no support even as they are being required to provide increased services to patients, in addition to their normal duties. These concerns culminated in the formation of a sub-committee of the State Senate focused on workforce issues in the Pharmacy industry created by former Senator Josh Newman. Testimony of the hardships of community pharmacists was presented at a Senate sub-committee hearing at Cal State Fullerton on October 2, 2017.³

The outcomes of the Senate sub-committee, in part, led to the passage of Senate Bill 1442 (Senator Weiner: Community Pharmacy Staffing). Senate Bill (SB)1442 was intended to address pharmacists’ work environments by requiring an individual “be made available” to assist the pharmacist as needed. After passage of the bill, CSHP members continued to express their frustration that the bill, although well meaning, failed to improve their work conditions. CSHP members have stated that when they ask for help, they are frequently told there is no one available. As expressed by a CSHP

¹ <https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html>

² <https://www.chicagotribune.com/investigations/ct-drug-interactions-pharmacy-met-20161214-story.html>

³ https://ufcw135.com/wp-content/uploads/2018/07/2017_November_TheWorker-Galley-Final.pdf

community pharmacist member; “the law (SB 1442) would have gone a long way to address my untenable work situation if only it was enforced.”

It has become apparent that some have taken advantage of the perceived ambiguities in SB 1442’s enacted Business and Professions Code Section 4113.5 by not honoring the intent of providing pharmacists with competent assistance so they can fulfill their obligations and reduce the mental and physical stress they experience. Community pharmacists continue to be subjected to work environments that present a danger to patients, the public and the pharmacists themselves. As one CSHP community pharmacist member stated regarding her situation; “every night I go home, and I hope I haven’t hurt someone.”

CSHP, out of significant concern for the ongoing lack of available and qualified assistance raised by community pharmacists and the potential harm to the patients they serve, sent a letter to the Board, on February 18, 2020, requesting inspections of retail pharmacies by Board of Pharmacy inspectors to ascertain compliance with Business and Professions Code 4113.5. Herein attached as Attachment A.

Pharmacists are clinicians, whose primary focus must be on the patient not only to fulfill their legal obligations such as ensuring their corresponding responsibility of patient safety but also their professional duty to serve and protect their patients. For a pharmacist to serve in any other role is detrimental to their patients and should not be condoned or tolerated. We applaud the Boards leadership to promulgate regulations to clarify and strengthen the Boards ability to implement Business and Professions Code Section 4113.4. As stated by the Board, that statute was adopted in order to alleviate a severe problem regarding public and patient safety when pharmacists are left to work alone in community pharmacies and cannot adequately fulfill their professional and legal responsibilities. We concur with the Boards actions to clearly set forth the expectations on promoting quality pharmacist delivered care by requiring qualified individuals assist him or her with non-pharmacist duties. The proposed regulatory text provides clarity to the mandates and intent of the enabling law and as such we are in general support.

Since the inception of the proposed regulations, we are, as a society, undergoing an unprecedented crisis that is stretching our health care system, at times, beyond its limits. The emergence of the COVID-19 pandemic has highlighted, across the globe, the critical role pharmacists serve, thereby furthering the paramount necessity to have supportive and qualified personnel assist pharmacists so they can focus on performing their clinical duties. This necessity has been recognized by the Board in the issuance of multiple waivers including relaxing staffing ratios of pharmacists to pharmacy technicians to address the COVID-19 pandemic response.

The promulgation of regulations is intended to address and correct identified issues with the overarching goal of patient protection and safety. With that in mind and the extraordinary lessons we are learning as we manage COVID-19 outcomes, it is imperative that the proposed regulations mandate work environments whereby pharmacists can provide quality patient care by ensuring continual provision of qualified and supportive individuals to assist with non-pharmacist activities. Such provision of continual support will further facilitate pharmacists having adequate time to provide patient care now and for future expectations such as administration of a COVID-19 vaccine or the newly passed legislation allowing pharmacists to provide HIV preventative therapies. Senate Bill 159 (Senator Weiner) signed into law in 2019, authorizes pharmacists, after completing specific training, to care for individuals who are seeking either pre-exposure or post exposure care to prevent HIV transmission without a physician prescription or prior authorization. This law will go into effect later this year further

expanding the clinical role and responsibility our community pharmacists will embrace as stewards of the community health.

CSHP is grateful for the extension of the public comment period and the opportunity to provide input on these important patient-centered and pharmacist care driven regulations. Our general comments are as follows with a mock-up of the language in track changes (Attachment B) and a final version without track changes (Attachment C).

1. Change “pharmacy employee” to qualified person as defined by section 1793.3. (CCR T16: Other Non-Licensed Pharmacy Personnel). The use of employee implies the individual is employed by the pharmacy or establishment whereas, the individual may be via contracted services. Addition of “qualified” with reference to section 1793.3 enhances clarity as to the expectations of the individual who will be working with the pharmacist.
2. Require that pharmacists will, at all times, have a qualified person working with them to assist the pharmacist when the pharmacy is open. For pharmacists to perform both their legal and ethical obligations they must have the sufficient time for these duties and not be distracted by or mandated to perform tasks that can be performed by non-pharmacists.
3. Change the word “designate” to “schedule” for section 1714.3(a)(1) to recognize there will always be a qualified person to assist the pharmacist. Add in scheduling an on call persons to be available if an originally schedule person is unable to work the scheduled shift.”
4. Add in “document” that individuals deemed qualified to have access to controlled substances in section 1714.3(a)(4). This is intended to ensure that there is a process in place to ascertain access and documentation exists for each person who is deemed qualified to have access.
5. Remove language referencing requesting assistance pursuant to Business and Professions Code section 4113.5 given the suggested change to require a qualified person to assist the pharmacist at all times when the pharmacy is open.
6. Require four years of maintaining the required policies and procedures.

Respectfully submitted on behalf of CSHP’s Board of Directors, its members, the public, and patients we serve.



Loriann DeMartini, PharmD, MPH, BCGP
Chief Executive Officer
California Society of Health System Pharmacists.



February 18, 2020

Ms. Anne Sodergren
Executive Officer,
California Board of Pharmacy
2720 Gateway Oaks, Dr., Suite 100
Sacramento, California 95833

Subject: Request inspections of retail pharmacies by Board of Pharmacy Inspectors to ascertain compliance with Business and Professions Code 4113.5

Dear Ms. Sodergren,

We seek your attention to the article published on January 31, 2020 in the New York Times, “How Chaos at Chain Pharmacies Is Putting Patients at Risk.” To ascertain the extent of these findings in our state, we reached out to our fellow pharmacist members, who provide services to communities in retail settings, and were shocked to hear resounding validation to the work environment concerns depicted in the article. Some of the testimonies noted in the article and confirmed by California pharmacists include:

“My fellow pharmacists and pharmacy technicians are at our breaking point. Chain pharmacy practices are preventing us from taking care of our patients and putting them at risk of dangerous medication errors.”

New Jersey Pharmacist

“Something needs to be done about this before lives are lost. Our patients depend on us for their safety and wellness. We have to live up to their expectations.”

North Carolina Pharmacist

“I am under stress each and every day to meet the volume metrics dictated by the corporation at the expense of providing direct patient care and counseling. I am frequently denied additional staff when I ask for assistance.”

California Pharmacist

The work conditions of retail pharmacists depicted in the article and confirmed by California pharmacists are a direct threat to the public’s safety and aren’t a new issue for California. In fact, Senate Bill 1442 (Weiner), effective January 1, 2019, was designed to specifically address the work environment of retail pharmacists with amendments to the Business and Professions Code (Section 4113.5) regarding staffing at community/retail pharmacies.

As quoted in the bill analysis “*pharmacists are simply unable to discharge their varied and complex duties while also answering the telephone, dealing with multiple customers in line, shuttering the entire pharmacy every time they have to step away, etc. Without another person to help address constant interruptions, many pharmacists find that they cannot even step away to use the restroom, let alone take the time to verify that a patient knows how to use their medication and is not addicted to opioids.*”

It has been brought to our attention, concerns of inadequate staffing are most significant after 6:00 p.m. and during the weekends. As such, we respectfully request you to deploy Board of Pharmacy Inspectors to conduct after hours and weekend inspections of retail pharmacies to ascertain compliance with Business and Professions Code (BPC) 4113.5. Additionally, the findings of these inspections, to ascertain compliance with BPC 4113.5, shall be presented to the public via a Board of Pharmacy meeting.

Your attention to this matter is greatly appreciated by our members and the public they serve.

Sincerely,



Lisa Gunther Lum, PharmD, FASHP, FCSHP
President
California Society of Health Systems Pharmacists



Loriann DeMartini, PharmD, MPH, BCGP
Chief Executive Officer
California Society of Health System Pharmacists

CC:

Mr. Gregory N. Lippe
President, California State Board of Pharmacy
2720 Gateway Oaks Dr., Suite 100, Sacramento, CA 95833

Attachment B

§ 1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

(a) ~~When a~~ pharmacy that is open to the public ~~and shall not have~~ a pharmacist ~~is~~ working without another pharmacy ~~employee-qualified person, as specified in section 1793.3 in the pharmacy assigned currently working, the pharmacy shall make another person who is an employee of the establishment within which the pharmacy is located available~~ to assist the pharmacist. The pharmacy ~~shall~~must:

(1) ~~Designate-Schedule~~ the name(s) of one or more persons who will ~~be available to~~ assist the pharmacist including on-call persons to be available if an originally scheduled person is unable to work the scheduled shift;

(2) ~~Determine-Ensure~~ that each scheduled or on call designated person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3;

(3) ~~Determine and document-Ensure~~ that each scheduled or on-call designated person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;

(4) Ensure that a the designated on-call qualified person responds and is able to assist the pharmacist within five minutes after the pharmacist's request if the originally scheduled person does not arrive ready to assist the pharmacist or has to stop assisting the pharmacist;

(b) A pharmacy must ~~shall~~ have and maintain policies and procedures that address the following:

(1) ~~How a pharmacist on-duty will be able to identify the person(s) designated as available to assist them, and~~ The required criteria and training for a scheduled or those designated on-call person(s), which shall be consistent with subdivision (a).

(2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the scheduled or designated on-call person to at the pharmacy.

(c) All ~~impacted~~ pharmacy employees and scheduled or designated on-call persons must read and sign a copy of the policies and procedures required by this section. ~~For purposes of this section, "impacted pharmacy employees" means any employee of the pharmacy, whether the person works within or for the pharmacy owner, who has any duties to prepare for or to execute how or when a pharmacist may seek or obtain assistance pursuant to Business and Professions Code section 4113.5, including any pharmacist, any person who creates or approves pharmacy employees' work schedules, or who designates persons who may assist the pharmacist pursuant to this section.~~

(d) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format: for a minimum of four years from the end of the applicable payroll period of the pharmacy.

Attachment C

§ 1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

(a) A pharmacy that is open to the public shall not have a pharmacist working without another pharmacy qualified person, as specified in section 1793.3 in the pharmacy assigned to assist the pharmacist. The pharmacy must:

- (1) Schedule the name(s) of one or more persons who will assist the pharmacist including on-call persons to be available if an originally scheduled person is unable to work the scheduled shift;
 - (2) Determine that each scheduled or on call person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3;
 - (3) Determine and document that each scheduled or on-call person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;
 - (4) Ensure that the designated on-call qualified person responds and is able to assist the pharmacist within five minutes after the pharmacist's request if the originally scheduled person does not arrive ready to assist the pharmacist or has to stop assisting the pharmacist
- (b) A pharmacy must have and maintain policies and procedures that address the following:
- (1) The required criteria and training for a scheduled or designated on-call person(s), which shall be consistent with subdivision (a).
 - (2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the scheduled or designated on-call person to the pharmacy.
 - (c) All pharmacy employees and scheduled or designated on-call persons must read and sign a copy of the policies and procedures required by this section.
 - (d) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format for a minimum of four years from the end of the applicable payroll period of the pharmacy.