

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Community Pharmacy Staffing

Section Affected: Add Title 16 California Code of Regulations (CCR) section 1714.3

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the addition of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on February 28, 2020, and ended on April 13, 2020. Due to Governor Gavin Newsom's Declaration of Emergency, on April 13, 2020, the Board extended the end of the comment period to April 30, 2020. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the comment period.

During the comment period several comments were received. On May 7, 2020, after having considered the comments in the record, the Board adopted the regulation text as noticed on February 28, 2020.

To the extent that the regulation duplicates the information from statute, such duplication is to ensure that the regulated public can readily and easily find the community pharmacy staffing requirements in one location.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the Board does not have nor does it maintain data to define if any of its licensees are a "small business" as defined in Government Code section 11342.610, the Board determined that any adverse economic impact will not be significant. This proposal does reinforce the requirement that the person designated to aid the pharmacist must qualify to have access to controlled substances (i.e. a background check has been completed).

This requirement is established by Federal regulation (21 CFR 1301.76 and 1301.90 et seq.) and is current law. It is not establishing a new requirement. The pharmacy may need to have the

person designated to aid the pharmacist complete a fingerprint background check, if one was not completed as part of the hiring process to work in the retail store.

The current processing fees associated with Live Scan fingerprinting are \$32.00 for DOJ and \$17.00 for FBI, with some Live Scan agencies charging additional fees for “rolling” fingerprints and/or administrative processing. The Board believes these costs to be minor. Additionally, the proposal establishes the requirement for policies and procedures that address specific criteria. Pharmacies are already required to have policies and procedures in place with respect to other areas of pharmacy practice. The additional policies and procedures can be incorporated into the pharmacies existing policies and procedures. These requirements will not have a significant statewide adverse economic impact on business, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Board considered the following alternatives:

1. The Board considered not establishing the specific time requirement of 5 minutes and indicate a reasonable time. The Board rejected this as the term “reasonable” is vague and will vary from person to person.
2. The Board considered not requiring the documentation of the request time and the response time for each occurrence and only require documentation of exceptions to the 5-minute response time. The Board rejected this alternative as the pharmacist may not recall the time of the request if the initial request was not documented when it was made.
3. The Board considered requiring minimal pharmacy training and not the more in-depth training required by CCR 1793.3. The Board rejected this alternative as the designated person should be able to assist with specific pharmacy operations while the pharmacist is handling a patient center care issue. If the designated person is not assisting with pharmacy operations (i.e. typing labels), that work will still need to be completed by the pharmacist and no help will have been provided to the pharmacist.
4. The Board considered increasing the required response time to an average of 10 minutes. The Board rejected this alternative as the Board determined that a response

time of 5 minutes was reasonable for designated staff to reach a safe stopping point on their current work assignment and report to the pharmacy to assist. A longer response time could impact patient safety and the clinical care being provided by the pharmacist.

The costs of each alternative is estimated to be consistent with the proposed regulations.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period from February 28, 2020 to April 30, 2020 the Board received several comments. The comments were provided in the meeting materials for the May 7, 2020 Board meeting, and were reviewed and considered by the Board.

Written Comments from Loriann DeMartini, California Society of Health-System Pharmacists

Comment 1: Commenter recommends that subdivision (a) be amended to change “pharmacy employee” to “qualified person as defined by section 1793.3.” Commenter indicates that they believe the term “pharmacy employee” implies that the person is employed by the pharmacy; however, they indicate that the individual could be working via a contracted service. Additionally, they recommend the use of the term “qualified” to enhance clarity as to the work expectations of the individual working with the pharmacist. Finally, they recommend that language with respect to the pharmacy having another person available to assist the pharmacist who is an employee of the establishment within which the pharmacy is located be stricken.

Response to Comment 1: The Board rejected this comment. While Board agrees that the pharmacy employee could be working through a contracted service, they would still be considered an employee of the pharmacy. The Board does not agree with the interpretation that the term “pharmacy employee” implies that the individual is “employed” by the pharmacy. A contracted worker is still an employee working in the pharmacy. Additionally, the Board does not agree that the term “qualified” provides clarity in this subdivision. The requirements of the designated person assigned to assist the pharmacist are identified in subdivisions (a)(2) and (a)(3). The Board also notes that the language the commenter has recommended not be used is the language of the of statute [Business and Professions Code (B&P) section 4113.5(a)].

Comment 2: Commenter recommends that the regulation require that a pharmacist have a qualified person working with them at all times when the pharmacy is open.

Response to Comment 2: The Board rejected this comment. This recommendation goes beyond the requirements of the statute. The statute requires that someone be available to assist the pharmacist at all times but does not require that the person work in the pharmacy at all times [(B&P) section 4113.5(a)].

Comment 3: Commenter recommends that the term “designate” be changed to “schedule” in subdivision (a)(1). Additionally, they recommend that language be added to ensure that an on-call person is available if the originally scheduled person is unable to work their scheduled shift. Commenter indicated that requiring a person to be “scheduled” to assist will ensure that a qualified person is always available to assist the pharmacist. They recommended that the language read as follows: “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.”

Response to Comment 3: The Board rejected this comment. The pharmacy is only required to make a person available to assist, not always have someone scheduled. The pharmacy can have multiple individuals designated to assist. The pharmacy is required to develop policies and procedures (P&P) regarding how a pharmacist identifies the person designated to assist. The pharmacy can include an on-call process within their P&P should it meet their business needs. The Board determined that having multiple designated people instead of a specific scheduled person will increase the likelihood of compliance. For example, if there are three designated persons, any of the three can report to assist based on availability.

Comment 4: Commenter recommends that the term “document” be added to section 1714.3(a)(3) to ensure that it is possible to determine who is deemed qualified to access the pharmacy.

Response to Comment 4: The Board rejected this comment. The Board determined that if a person is “designated” as being available to assist the pharmacist, that means they meet the requirements of this section, which includes a background check and that they meet the minimum training requirements. The pharmacy should not designate a person that has not successfully completed the background check or fails to meet the minimum training requirements. Additionally, the pharmacy can have a documentation process outlined in their P&P if it meets their business need.

Comment 5: Commenter recommends removing the reference to the statute within subdivision (c), as the commenter recommends that the regulation require someone to work with the pharmacist at all times when the pharmacy is open.

Response to Comment 5: The Board rejected this comment. The statute requires that someone be available to assist the pharmacist at all times but does not require that the person work in the pharmacy at all times [(B&P) section 4113.5(a)].

Comment 6: Commenter recommends that the P&P be maintained for four years.

Response to Comment 6: The Board rejected this comment. The Board determined that the P&Ps are a fluid document and must always be maintained. This regulation requires that impacted pharmacy employees and designated persons read and sign a copy of the P&P and this document be maintained in a readily retrievable format. Should the P&P required by 1714.3(b) be revised, the impacted pharmacy employees and designated persons would need to sign the revised document to document that they are aware of the revisions.

Comment 7: Commenter submitted a recommended modified text for Board consideration (see attachment B of the comment).

Response to Comment 7: The Board rejected the modified text presented by the commenter be rejected for the reasons identified above in response to comments 1 through 6.

Written Comments from Amber Baur, United Food and Commercial Workers Union

Comment 1: Commenter expressed support for the proposed regulation.

Response to Comment 1: The Board acknowledged the commenter's support of the regulation.

Written Comments from Rob Geddes, Albertsons Companies

Comment 1: Commenter recommends that subdivision (a)(1) be amended to add "or positions" following "Designate the name." Commenter indicates that staff rotate between stores and it could be a logistical challenge to maintain an accurate list. Additionally, commenter indicates that designating positions within the store would allow for persons within those positions to be trained and available to assist.

Response to Comment 1: The Board rejected this comment. As the staff need to have minimum competencies and a background check completed, the Board does not believe it is appropriate to only designate job positions. Additionally, by designating only job positions, the pharmacist will not know who to contact for assistance or whether the person that arrives to assist is authorized to be in the pharmacy. If the Board permitted a list designated positions, a new staff person with only a week on the job in one of those designated positions may not have the minimum qualifications to work the pharmacy. Furthermore, the Board notes that the designated names can be updated as needed as staff transfer to the store or as frequently as needed based on the P&P identified by the specific store. The Board believes that if the pharmacy trains people within specific positions to assist, having of list of those names should be manageable.

Comment 2: Commenter recommends that subdivision (a)(2) be amended to remove the requirement for the designated person to be able to perform, at minimum, the duties of non-licensed pharmacy personnel as it can take time to become proficient in pharmacy tasks, and in most cases, the designated person will be helping infrequently. Additionally, the pharmacist may not feel comfortable with the designated person assisting with some duties. They recommend that the language be changed to “duties delegated by the supervising pharmacist.”

Response to Comment 2: The Board rejected this comment. The Board determined that the language requires that the person be able to perform the duties “at minimum” of non-licensed pharmacy personnel. The designated person needs to be able to assist the pharmacist with the duties of the pharmacy. If the designated person is not able to perform the duties, they are not aiding the pharmacist as the pharmacist would still need to perform those tasks. Further the language does not mandate that the designated person perform those duties. If the pharmacist does not feel comfortable with the designated person performing specific tasks, the pharmacist can use their professional judgement on whether the designated person performs those tasks with respect to the duties non-licensed pharmacy personnel would perform.

Comment 3: Commenter recommends that subdivision (a)(4) be amended from 5 minutes to an average of 10 minutes to allow the assigned person enough time to complete their current task, secure their cash box, and go to the pharmacy to assist. Commenter indicated that they believe that in most case the designated person will be able to immediately assist; however, commenter would like flexibility in the event of unforeseen circumstances they may prevent the arrival of the designated person in under 5 minutes.

Response to Comment 3: The Board rejected this comment. The Board determined that the statute requires that the designated person be available to assist at all times, which the Board has interpreted to mean “always physically able to respond.” The Board notes that if the pharmacist is calling for assistance, there is a need for help. Requiring the pharmacist and possibly patients to wait for “an average of 10 minutes” for a designated staff person to arrive to help could impact patient safety and the clinical care being provided by the pharmacist. Further, B&P 4113.5(d)(1) takes into considered unanticipated circumstances that may make the designated person unavailable provided that the pharmacy has taken reasonable action to make another person available to assist the pharmacist. The Board determined that 5 minutes is a reasonable amount of time for the designated person to reach a stopping point on their current task and arrive at the pharmacy to assist the pharmacist.

Written Comments from Rachel Michelin, California Retailers Association, and Steven Anderson, National Association of Chain Drug Stores

Comment 1: Commenters recommend that subdivision (a)(1) be amended to remove “one or more persons” and add “or staff positions that” following the designated name. Commenters indicate that staffing frequently fluctuates daily or by the hour, so it is necessary to allow for flexibility in naming the coverage. Commenters further explain that many pharmacies will designate certain qualified staff such as an assistant manager or shift supervisor and train them to provide coverage.

Response to Comment 1: The Board rejected this comment. The Board determined that it is appropriate to only designate job positions. A new staff person with only a week on the job in one of those designated positions may not have the minimum qualifications to work in the pharmacy. Furthermore, the Board notes that the designated names can be updated as staff transfer to the store or as frequently as needed based on the P&P identified by the specific store. The Board believes that if the pharmacy trains people within specific positions to assist, having of list of those names should be manageable.

Comment 2: Commenters recommended that subdivision (a)(2) be amended to add “if asked by the pharmacist” to the end of the subdivision. Commenters indicate that the designated person’s main responsibility is to assist the pharmacist when they need support for a great volume of patients, or they need a short break. Further, commenters indicate that the designated person may not be qualified to input data and information into the pharmacy computer.

Response to Comment 2: The Board rejected this comment. The Board determined that the language does not mandate that the designated person perform specific tasks, only that they are able to do so. The pharmacist can use their professional judgment on whether the designated person performs specific duties with respect to the duties non-licensed pharmacy personnel would complete. The Board disagrees that the designated person’s main responsibility is only to help when the pharmacist needs support for a great volume of patients, or they need a short break. The regulation and statute require that the designated person be available to assist at all times, not just when the pharmacist needs a break or has a “great volume of patients.” A pharmacist could need assistance if they are spending an extended time with one patient providing clinical care. Further, if an individual is not qualified to input data and information into the pharmacy computer, they should not be designated as a person to provide assistance to the pharmacist.

Comment 3: Commenters expressed concern that the 5-minute response time is too restrictive for pharmacies to comply with under all circumstances. Commenters recommended that subdivision (a)(4) be amended from 5 minutes to an average of 10 minutes to allow the assigned person enough time to safely complete their current task.

Response to Comment 3: The Board rejected this comment. The Board notes that the statute requires that the designated person be available to assist at all times, which the Board has interpreted to mean “always physically able to respond.” Additionally, if the pharmacist is calling for assistance, there is a need for help. Requiring the pharmacist and possibly patients to wait for “an average of 10 minutes” for a designated staff person to arrive to help could impact patient safety and the clinical care being provided by the pharmacist. The Board notes that B&P 4113.5(d)(1), takes into consideration unanticipated circumstances that may make the designated person unavailable provided that the pharmacy has taken reasonable action to make another person available to assist the pharmacist. Finally, the Board determined that 5 minutes is a reasonable amount of time for the designated person to reach a stopping point on their current task and arrive at the pharmacy to assist the pharmacist.

Written Comments from Lorri Walmsley, Walgreen Co.,

Comment 1: Commenter recommends that subdivision (a)(1) be amended to remove “persons” and add “positions” following designated name to allow companies to identify specific position codes to minimize the record-keeping burden.

Response to Comment 1: The Board rejected this comment. As the staff need to have minimum competencies and background checks completed, the Board determined that it is not appropriate to only include job positions codes. Additionally, the pharmacist will not know who to contact for assistance based on the job position code.

Comment 2: Commenter recommends that subdivision (a)(2) be amended to add “and requested by the pharmacist” to the end of the subdivision. Commenter indicates that the pharmacist should have the ability to determine what duties the designated person performs as it would be difficult for an employee to maintain competency on all duties performed by non-licensed pharmacy personnel.

Response to Comment 2: The Board rejected this comment. The Board determined that the language does not mandate the designated person perform specific tasks, only that they are able to do so. The pharmacist can use their professional judgement on whether the designated person performs specific duties with respect to the duties non-licensed pharmacy personnel would complete.

Comment 3: Commenter expressed concern about the 5-minute response time as the designated person may not be available to assist for up to 30 minutes because of meal periods and it is unreasonable to have a second employee available. Commenter recommends that subdivision (a)(4) be amended to require acknowledgement of the request for help within 5 minutes and a response time of within 30 minutes, unless the designated person is unavailable due meal periods or an unexpected absence.

Response to Comment 3: The Board rejected this comment. The Board determined that the statute requires that the designated person be available to assist at all times, which the Board has interpreted to mean “always physically able to respond.” Further, if the pharmacist is calling for assistance, there is a need for help. Requiring the pharmacist and possibly patients to wait for “for up to 30 minutes” for a designated staff person to arrive to help could impact patient safety and the clinical care being provided by the pharmacist. The Board also determined that the statute takes into consideration unanticipated circumstances of the designated person not being available as long as the pharmacy has taken steps to make another employee available [B&P 4113.5(d)(1)].

Comment 4: Commenter expressed concern that the P&P include the process for the pharmacist to request assistance and to document the response time. The commenter states that the requirement is highly impractical, creates a tremendously unnecessary administrative burden, and provides no patient benefit. They indicate that documenting the response times would be largely subjective and challenging to monitor.

Response to Comment 4: The Board rejected this comment. Pharmacies are already required to maintain P&P for each location. The Board determined that updating the P&P will not create an administrative burden as the update could be a simple one time edit to existing P&P, unless the pharmacy routinely changes their P&P. Additionally, it is important for the pharmacy, pharmacist, and all impacted staff to understand the request for assistance process to ensure that the appropriate staff are aware of the process and expectations. Further, documenting when the request for assistance was made and when the designated person arrived will help the pharmacy, the pharmacist, and the Board ensure that the pharmacy is operating in compliance with pharmacy law. Upon review of the response times, the pharmacy can take corrective measures if necessary to address any issues without Board intervention, which will benefit patients.

Written Comments from Senator Scott Wiener, California State Senate

Comment 1: Commenter expressed support for the proposed regulation, particularly the requirement of assistance within 5 minutes. Commenter expressed support that the Board's regulations are faithful interpretation of both the letter and spirit of the statute.

Response to Comment 1: The Board acknowledges the commenter's support of the regulation.

Written Comments from Mark Johnston, CVS Health

Comment 1: Commenter recommends that subdivision (a)(1) be removed from the regulation. Commenter states that the name of the person is not relevant and that the job title can be identified in the policies and procedures as this would allow flexibility in scheduling.

Response to Comment 1: The Board rejected this comment. As the staff need to have minimum competencies and background checks completed, Board determined that it is not appropriate to only include job titles in the policies and procedures. Additionally, the pharmacist will not know who to contact for assistance or whether the person is authorized and trained to be in the pharmacy. Furthermore, the designated names can be updated daily or as frequently as needed based on the P&P identified by the specific store.

Comment 2: Commenter opposes the requirement for the designated staff person to have the minimum training as required by CCR section 1793.3 within subdivision (a)(2). Commenter indicated that the designated person will likely not perform the duties enough to continue to safely perform them. Further, they indicated that subdivision (b)(1) provides the appropriate training requirements.

Response to Comment 2: The Board rejected this comment. The Board determined that the language does not mandate that the designated person perform specific tasks, only that they are able to do so. The designated person is to assist the pharmacist with the duties of the pharmacy. If the designated person is not able to perform the duties, they are not aiding the pharmacist as the pharmacist will still need to complete the work. However, the pharmacist can use their professional judgment on the tasks the designated person performs with respect to the duties non-licensed pharmacy personnel would complete.

Comment 3: Commenter recommends that "which shall be consistent with subdivision (a)" be removed from subdivision (b)(1) to be consistent with removing the minimum training requirement of 1793.3 (referenced in comment 2).

Response to Comment 3: The Board rejected this comment. See response to above comment 2.

Comment 4: Commenter expressed concern that the 5-minute response time does not allow time for employees to complete their current task before assisting the pharmacist. Commenter recommended that subdivision (a)(4) be amended from 5 minutes to an average of 10 minutes to allow the assigned person enough time to safely complete their current task, secure their cash box, or eliminate safety hazards. Additionally, commenter indicates that the average of 10-minute response time would be parallel to the Board’s currently pending Duty to Consult regulation which requires a response within an average of 10 minutes.

Response to Comment 4: The Board rejected this comment. The Board determined that the statute requires that the designated person be available to assist at all times, which the Board has interpreted to mean “always physically able to respond.” If the pharmacist is calling for assistance, there is a need for help. Requiring the pharmacist and possibly patients to wait for “an average of 10 minutes” for a designated staff person to arrive to help could impact patient safety and the clinical care being provided by the pharmacist. Additionally, the 10-minute response time related to consultation as mentioned in the Duty to Consult regulation is service being provided via telephone and is not related to the availability of a pharmacist to provide clinical care to patients directly in front of them in the pharmacy. Finally, Board determined that 5 minutes is a reasonable amount of time for the designated person to reach a stopping point on their current task and arrive at the pharmacy to assist the pharmacist.

At its May 7, 2020 meeting, the Board considered the comments received and voted to adopt the regulation text as it was noticed on February 28, 2020.