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Business, Consumer Services and Housing Agency  
Department of Consumer Affairs  
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VIII. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

**a. Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing**

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**Summarized 45-day Comments Regarding Community Pharmacy Staffing with Board Staff Recommendations:**

**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:** Board staff recommend that this comment be rejected. While Board staff agrees that the pharmacy employee could be working through a contracted service, they would still be considered an employee of the pharmacy. Board staff 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, Board staff 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). Board staff 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:** Board staff recommend that this comment be rejected. 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:** Board staff recommend that this comment be rejected. 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. Board staff believes 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:** Board staff recommend that this comment be rejected. Board staff notes 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. Board staff further notes that 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:** Board staff recommend that this comment be rejected. 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:** Board staff recommend that this comment be rejected. Board staff notes that the P&P 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:** Board staff recommend that 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:** Board staff acknowledges 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:** Board staff recommend that this comment be rejected. As the staff need to have minimum competencies and a background check completed, Board staff 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, Board staff 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. Board staff 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:** Board staff recommend that this comment be rejected. Board staff notes 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. Board staff further note that 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:** Board staff recommend that this comment be rejected. Board staff 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.” Board staff 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. Board staff further note that 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. Finally, Board staff believes 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:** Board staff recommend that this comment be rejected. Board staff does not believe 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, Board staff 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. Board staff 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:** Board staff recommend that this comment be rejected. Board staff notes 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. Board staff 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, Board staff notes that 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:** Board staff recommend that this comment be rejected. Board staff 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. Board staff further note 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, Board staff believes 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:** Board staff recommend that this comment be rejected. As the staff need to have minimum competencies and background checks completed, Board staff does not believe it

is 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:** Board staff recommend that this comment be rejected. Board staff notes 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:** Board staff recommend that this comment be rejected. Board staff 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.” Board staff notes that 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. Board staff also notes 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:** Board staff recommend that this comment be rejected. Pharmacies are already required to maintain P&P for each location. Board staff does not believe updating the P&P will 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:** Board staff acknowledges the commenters 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:** Board staff recommend that this comment be rejected. As the staff need to have minimum competencies and background checks completed, Board staff does not believe it is 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, Board staff notes that 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:** Board staff recommend that this comment be rejected. Board staff notes 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:** Board staff recommend that this comment be rejected. 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:** Board staff recommend that this comment be rejected. Board staff 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.” 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 staff believes 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.

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**POSSIBLE MOTIONS: Should the Board agree with the staff recommended comment responses, a possible motion is as follows:**

Adopt the regulatory language as noticed on February 28, 2020, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Control agencies to complete the rulemaking file.

**Should the Board wish to modify the regulation language to address concerns expressed by stakeholders, a possible motion is as follows:**

Approve modified text and initiate a 15-day public comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to adopt the modified text and make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.



## **45-Day Comments – Community Pharmacy Staffing**

A hardcopy of the 45-day comments will be made available at the meeting or upon request. Requests may be emailed to [Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov).