

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Duty to Consult

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1707.2

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 amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on August 16, 2019, and ended on September 30, 2019. 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 45-day comment period.

During the 45-day comment period several comments were received. On November 5, 2019, after having considered the comments in the record, the board adopted the regulation text as noticed on August 16, 2019.

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 patient consultation 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. The requirement to provide consultation was already specified within California regulation; however, this proposal ensures patients receive timely consultation. California licensed pharmacies and pharmacies that provide mail orders to California patients may hire an additional pharmacist or other staff to meet the 10-minute average requirement; however, the board does not anticipate this to be a standard practice and believes most pharmacies will meet the requirement without additional staff. As

the board concludes that impacted pharmacies will be able to meet the mandate without additional staff, the board concludes the proposed regulation will not have an adverse impact to small businesses.

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 alternative:

- The board considered not promulgating the regulation change. However, this would be contrary to the board's statutory mandate and fail to address the problem some consumers currently experience when obtaining prescription medications from mail order pharmacies.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the 45-day public comment period from August 16, 2019 to September 30, 2019, the board received several comments. The comments were provided in the meeting materials for the November 5-6, 2019 board meeting, and were reviewed and considered by the board.

Written Comments from Joe DiStefano, Pharmacist

Comment: Mr. DiStefano expressed concern about the ability to measure the "average of 10 minutes or less" to adhere to the law.

Response to Comment: The board rejected this comment. The board notes that the pharmacy can establish its process to measure response time within its policies and procedures. The adopted regulation is not directing that records must be kept. The pharmacy can determine a model that fits their business needs.

Written Comments from Marsha Cohen and B. Joseph Guglielmo, Pharm.D.

Comment: Ms. Cohen and Dr. Guglielmo expressed concern that the proposed regulation "does not go far enough to ensure consultation." They expressed concern that a written notice is not sufficient and that a pharmacist should be required to contact the patient via phone or email for mandatory consultation to increase prescription adherence and prevent medication errors.

Response to Comment: The board rejected this comment. The board notes that the recommendation is more restrictive than the adopted language. Additionally, the board notes

that requiring the pharmacist to initiate contact to the patient was previously considered; however, due to confidentiality and the possibility of Health Insurance Portability and Accountability Act (HIPAA) violations should the patient not be in an area where they could receive confidential information when the call is received, the board elected to have the patient contact the pharmacist for consultation.

Written Comments from the California Pharmacists Association (CPhA)

Comment: CPhA supports the board's regulation; however, has requested the addition of the phrase "accompanying the prescription" to sections 1707.2(b)(1)(A) - after "request consultation" and 1707.2(b)(1)(B) – after "the patient's record" to ensure that the written notices are included with the prescription and reduce the chance that the notice may get lost or misplaced.

Response to Comment: The board rejected this comment. The board notes that the proposed regulation requires that the pharmacy ensure that the patient or patient's agent receives the written notice and the triggering event is always a prescription. The board does not believe that the additional phrase provides clarity to the adopted language.

Written Comments from California Society of Health-System Pharmacists (CSHP)

Comment 1A: CSHP expressed concern that the proposed regulation is not clear with respect to the responsibilities of a hospital when medications are dispensed to a patient for use outside the hospital (i.e. "discharge", "Pass", or "Admission Preparatory" medication). CSHP recommends that section 1702.1(b)(1) be amended to add "or hospital" to ensure hospitals are included in the requirement to advise of consultation. Additionally, they recommend that 1702.1(b)(1)(C) be amended to add "unless exempted by Business and Professions Code section 4056(a) for specified small hospitals."

Response to Comment 1A: The board rejected this comment. The board notes that this recommendation goes beyond the policy considered for this proposal, which was limited to mail order or delivered prescription medication.

Comment 1B: CSHP recommended that the phrase "oral" be added to 1707.2(b)(1)(A) to ensure that patients are advised that oral consultation is available as online "chat" type consultations are also available and CSHP indicated that they believe "chat" consultations are not as effective.

Response to Comment 1B: The board rejected this comment. The board notes that the regulation specifically requires the written notice to inform the patient of the number to call to receive oral consultations in 1707.2(b)(1)(B). In addition, while the board determined that patients need to receive written notice of their right to request oral consultation, the board did not want to limit all consultations to be oral consultations. Additionally, the board notes that this is existing language that is not being amended.

Comment 2: CSHP expressed concern that the proposed regulation does not specify when the pharmacy is required to provide the consultation information and the information that must be provided. Additionally, they express concern that the phrase “patient’s agent” is vague and recommended a more descriptive phrase be used (specifically, “a patient’s agent that has been identified by the patient, or can be reasonably presumed to be, reasonably competent and responsible for providing the information to the patient whenever a pharmacist deems it warranted in the exercise of his or her professional judgment.”)

Response to Comment 2: The board rejected this comment. The board notes that the prescriptions are being delivered or shipped by mail to the patient or the patient’s agent. The agent would be any person selected by patient to receive the delivery. Additionally, sections 1702.2(b)(1) – 1702.2(b)(1)(C) identify the information to provide and when to provide the information.

Comment 3: CSHP expressed concern that the proposed regulation requires “a telephone number” be provided for consultation; however, non-resident pharmacies must provide a toll-free number. They indicated that patients who use non-resident pharmacies would have a lower phone bill because of the toll-free phone number. They recommend requiring in-state pharmacies to provide a toll-free number as well.

Response to Comment 3: The board rejected this comment. The adopted regulation does not prohibit an in-state pharmacy from providing a toll-free number. Additionally, the board notes that reference to the telephone number is existing language and the pharmacy should already be providing its patients with a telephone number to contact for consultation.

Comment 4A: CSHP expressed concern that the proposed regulation states that consultation must be available during the pharmacies normal business hours, but that it does not specify that consultation does not need to be available outside of normal business hours. They recommended the addition of the phrase “required to be” and “only” during any regular hours of operation.

Response to Comment 4A: The board rejected this comment. For non-resident pharmacies, B&P section 4112(f) requires that a pharmacist be available to provide consultation during regular business hours and a minimum of 6 days a week, for a minimum of 40 hours a week. Additionally, B&P section 4112(h) specifies that the same requirements or standards that apply for consultation to a non-resident pharmacy shall be the same as the requirements that apply to in-state pharmacies. As such, a statutory change would be needed to require a change from the 6 days a week and 40 hours a week minimum. The board notes that the language recommended by CSHP could conflict with statute.

Comment 4B: CSHP expressed concern that the proposed regulation in section 1702.2(b)(1)(C) requires a pharmacist be available a minimum of 6 days week for a minimum of 40 hours a week; however, they note that some pharmacies are not open 6 days a week or for 40 hours a week (i.e. closed-door pharmacies). They recommend that language be added that specifies that pharmacies that are not open for 40 hours a week or 6 days a week are only required to provide consultation during normal business hours.

Response to Comment 4B: The board rejected this comment. For non-resident pharmacies, B&P section 4112(f) requires that a pharmacist be available to provide consultation during regular business hours and a minimum of 6 days a week, for a minimum of 40 hours a week. Additionally, B&P section 4112(h) specifies that the same requirements or standards that apply for consultation to a non-resident pharmacy shall be the same as the requirements that apply to in-state pharmacies. As such, a statutory change would be needed to require a change from the 6 days a week and 40 hours a week minimum.

Comment 5: CSHP expressed concern that the proposed regulation in section 1702.2(b)(1)(B) is not clear with respect to the phrase “ready access to patient’s record” and recommended that the language should be amended to read “patient medication records” for clarity and to be consistent with 16 CCR section 1707.1. Additionally, CSHP expressed concern that access to a patient’s profile may not be sufficient to provide consultation. They recommend that the regulation require the pharmacist performing the consultation have access to “other relevant medical information necessary for patient and clinical consultation”.

Response to Comment 5: The board rejected this comment. The board notes that this is existing language and it is also duplicated language from B&P section 4112(f). Additionally, the board notes that there are have not been any complaints filed with board by consumers where the pharmacist did not have access to the patient’s profile and was not aware of what medication the patient was taking, which would have impacted the consultation provided.

Comment 6: CSHP expressed concern that the use of the term “pharmacist” is vague and confusing as it is presumed to mean a person licensed by the board as defined by B&P section 4036. CSHP is requesting clarification if the board is requiring non-resident pharmacies to employ a CA licensed pharmacist to provide consultation.

Response to Comment 6: The board rejected this comment. B&P section 4112(c) requires that a non-resident pharmacy provide the board with the names of the pharmacists working at the non-resident pharmacy that dispense medication to CA residents. Additionally, B&P section 4112(d) requires that non-resident pharmacies comply with the laws of the regulatory or licensing agencies in which they are licensed. Finally, B&P section 4112(f) requires that the pharmacist providing consultation must be “a pharmacist at the pharmacy who has access to

the patient's records." The board believes that the use of the term "pharmacist," which is existing language, is clear that the person must be licensed as a pharmacist. The term "pharmacist" is industry standard in all states.

Comment 7: CSHP expressed concern that the proposed regulation is not clear with respect to whether a pharmacist must be licensed in California, in the state in which the prescription was dispensed, or by a state board of pharmacy. They recommend that the language specifically identify where the pharmacist must be licensed.

Response to Comment 7: The board rejected this comment. B&P section 4112(c) requires that a non-resident pharmacy provide the board with the names of the pharmacists working at the non-resident pharmacy that dispense medication to CA residents. Additionally, B&P section 4112(d) requires that non-resident pharmacies comply with the laws of the regulatory or licensing agencies in which they are licensed. Finally, B&P section 4112(f) requires that the pharmacist providing consultation must be "a pharmacist at the pharmacy who has access to the patient's records." The board determined that the language is clear that the pharmacist must be employed by the pharmacy and have access to the patient's records.

At its November 5-6, 2019 meeting, the board considered the comments received and voted to adopt the regulation text as it was noticed on August 16, 2019.