



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

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

a. Proposed Amendments to Title 16 CCR Section 1707.2 Related to Mail Order Pharmacy Consultation

Background:

At the May 2018 Board meeting, the board approved proposed text to amend Section 1707.2 of Title 16, CCR, related to mail order pharmacy consultation. This proposal clarifies and makes specific the standards that apply to all pharmacies, including mail order pharmacies or pharmacies that deliver medications, to fulfill their patient consultation requirements.

As required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on August 16, 2019, which ended on September 30, 2019. The proposed text, comments, and staff recommended modified text are attached following this memo.

Summarized 45-day Comments Regarding Fees with Board Staff Recommendations:

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.

Board Staff Response to Comment: The board staff recommend that this comment be rejected. Board staff notes that the pharmacy can establish its process to measure response time within its policies and procedures. The proposed 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 staff recommend that this comment be rejected. Board staff notes the policy decision for the board is reflected in the proposed language and that the

recommendation is more restrictive. Additionally, board staff notes that requiring the pharmacist to contact the patient was previously considered; however, due to privacy concerns, 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 staff recommend that this comment be rejected. Board staff 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. Board staff does not believe that the additional phrase provides clarity to the proposed 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 staff recommend that this comment be rejected. Board staff 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: Board staff recommend that this comment be rejected. Board staff notes that the regulation is specific to oral consultations as specified in 1707.2(b)(1)(B) and 1707.2(b)(1)(C). Board staff does not believe adding "ORAL" to 1707.2(b)(1)(A) is necessary for clarity to the proposed language. Additionally, Board staff notes that the proposed language does not address "chat" type consultations. The option for non-oral consultations via "real-time assistance" is a policy decision for the board.

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: Board staff recommend that this comment be rejected. Board staff 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, section 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, nonresident pharmacies must provide a toll-free number. They indicated that patients who use nonresident 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: Board staff believes this is a policy decision for Board. Board staff notes that the requirement of a toll-free number for in-state pharmacies may result in a fiscal impact.

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: Board staff recommend that this comment be rejected. For nonresident 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 nonresident 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. Board staff notes that the language recommend by CSHP could conflict with statute if the pharmacy is not open 6 days a week.

Board staff does recommend that the language in 1702.2(b)(1)(B) be amended to change “hours of availability” to “regular hours of operation” for clarity as the pharmacist must be available during any regular hours of operation.

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: Board staff recommend that this comment be rejected. For nonresident 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 nonresident 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: Board staff notes that this is existing language and it is also duplicated language from B&P section 4112(f). However, board staff does recommend that the language in 1702.2(b)(1)(B) be amended to add “drug therapy and medication” before record for consistency with the terms used in 16 CCR section 1707.1 and 1707.3.

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 nonresident pharmacies to employ a CA licensed pharmacist to provide consultation.

Response to Comment 6: Board staff recommend that this comment be rejected. B&P section 4112(c) requires that a nonresident pharmacy provide the board with the names of the pharmacists working at the nonresident pharmacy that dispense medication to CA residents. Additionally, B&P section 4112(d) requires that nonresident 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.” Board staff 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” 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: Board staff recommend that this comment be rejected. B&P section 4112(c) requires that a nonresident pharmacy provide the board with the names of the pharmacists working at the nonresident pharmacy that dispense medication to CA residents. Additionally, B&P section 4112(d) requires that nonresident 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.” Board staff believes that the language is clear that the pharmacist must be employed by the pharmacy and have access to the patient’s records.

POSSIBLE MOTIONS: Should the Board agree with the staff recommended modified text, a possible motion is as follows:

Adopt the staff recommended modified text, dated October 25, 2019, and notice the language for a 15-day comment period. Additionally, should no negative comments be received, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Should the Board determine that all the comments be rejected, a possible motion is as follows:

Adopt the regulation language as noticed on August 16, 2019, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by a Control agency to complete the rulemaking file.

Attachments

- Board approved proposed regulation text as noticed on August 16, 2019
- Comments received during the 45-day comment period
- Staff recommended modified text for Board consideration

Title 16. Board of Pharmacy

Amend section 1707.2 in Article 2 of Division 17 of Title 16 California Code of Regulations to read as follows:

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment; ~~or~~

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:~~

~~(3A) whenever the prescription drug has not previously been dispensed to a patient; or~~

~~(4B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.~~

~~(b)(12) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that ~~the patient receives written notice:~~~~

~~(A) the patient receives written notice of his or her right to request consultation; ~~and~~~~

~~(B) the patient receives written notice of a the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record; ~~and~~~~

~~(C) a pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.~~

~~(23) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.~~

(c) When oral consultation is provided, it shall include at least the following:

- (1) directions for use and storage and the importance of compliance with directions; and
- (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- (1) the name and description of the medication;
- (2) the route of administration, dosage form, dosage, and duration of drug therapy;
- (3) any special directions for use and storage;
- (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- (5) prescription refill information;
- (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
- (7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Note: Authority cited: Sections 4005, 4076 and ~~4122~~4112, Business and Professions Code.
Reference: Sections 4005, 4076 and ~~4122~~4112, Business and Professions Code.

A hardcopy of the comments received during the 45-day comment period will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov.

**Title 16. Board of Pharmacy
Modified Text**

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Amend section 1707.2 in Article 2 of Division 17 of Title 16 California Code of Regulations to read as follows:

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;~~;~~

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:~~

~~(3A)~~ whenever the prescription drug has not previously been dispensed to a patient; or

~~(4B)~~ whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.

~~(b)(12)~~ When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that ~~the patient receives written notice:~~

(A) the patient receives written notice of his or her right to request consultation; ~~and~~

(B) the patient receives written notice of a the hours of availability, regular hours of operation and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's drug therapy and medication record; ~~and~~

(C) a pharmacist shall be available (i) to speak to the patient or patient's agent during any

regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(23) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

- (1) directions for use and storage and the importance of compliance with directions; and
- (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- (1) the name and description of the medication;
- (2) the route of administration, dosage form, dosage, and duration of drug therapy;
- (3) any special directions for use and storage;
- (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- (5) prescription refill information;
- (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
- (7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Note: Authority cited: Sections 4005, 4076 and ~~4122~~4112, Business and Professions Code.
Reference: Sections 4005, 4076 and ~~4122~~4112, Business and Professions Code.



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To: Board Members

Subject: Agenda Item IX. Discussion and Consideration of Board Approved Regulations,
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b. Proposed Amendments to Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Background:

At the February 2018 Board meeting, the board approved proposed text to amend Section 1706.2 of Title 16, CCR, related to abandonment of applications. This proposal updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

As required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on August 30, 2019, which ended on October 14, 2019. No comments were received during the comment period. The proposed text is attached following this memo.

STAFF RECOMMENDED MOTION:

Adopt the regulation language as noticed on August 30, 2019, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by a Control agency to complete the rulemaking file.

**Title 16. Board of Pharmacy
Proposed Text**

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

Amend section 1706.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1706.2. Abandonment of Application Files.

- (a) An applicant for a premises license ~~to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.
- (b) An applicant for a ~~pharmacy technician license or a designated representative license~~ an individual license not included in subdivision (c), (d), or (e), who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
- (c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f)(1) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
- (d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.
- (e) An applicant for an an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, ~~4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, and 4208, and 4210~~, Business and Professions Code.



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**c. Proposed Amendments to Title 16 CCR Section 1793.9 Related to Remote Dispensing
Pharmacy Technicians**

Background:

At the July 2017 Board meeting, the board approved proposed text to add Section 1793.9 of Title 16, CCR, related to Remote Dispensing Pharmacy Technicians. This proposal established minimum qualifications for pharmacy technicians working at a Remote Dispensing Site Pharmacy.

As required by the Administrative Procedure Act, board staff released the proposed text for the 45-day comment period on April 12, 2019, which ended on May 28, 2019. At the June 2019 Board meeting, the Board voted to defer action on the regulation due to pending legislation in this area (Assembly Bill 690). AB 690 was Chaptered on October 9, 2019. The measure establishes the requirements for a pharmacy technician working in this environment. The requirements established in the statute go beyond those in the board's proposed regulation. Given this subsequent action, withdrawal of the proposed regulation is appropriate. The proposed regulation text and the Chaptered legislation is attached following this memo.

STAFF RECOMMENDED MOTION:

Withdraw the proposed regulation as noticed on April 12, 2019.

**Title 16. Board of Pharmacy
Proposed Text**

Add section 1793.9 in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.9. Pharmacy Technician in a Remote Dispensing Site Pharmacy.

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

- (a) Possess a pharmacy technician license that is in good standing.
- (b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
- (c) (1) Possess a minimum of an associate degree in pharmacy technology;
(2) Possess a minimum of a bachelor's degree in any subject; or
(3) Complete a course of training specified by the board as provided in section 1793.6.
- (d) Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.

Note: Authority cited: Sections 4005 and 4132, Business and Professions Code.

Reference: Sections 4005, 4026.5, 4044.3, 4052, 4115, 4132 and 4202, Business and Professions Code.

Chaptered language for AB 690 may be accessed at www.leginfo.ca.gov.

A copy of these documents will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov.