



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: August 31, 2016

LOCATION: Staff Location
Department of Consumer Affairs
1625 North Market Blvd., First Floor Hearing Room
Sacramento, CA 92834

Additional Teleconference Locations
4040 Palos Verdes Drive North, Suite 206
Rolling Hills Estates, CA 90274

1418 S. San Gabriel Blvd., Suite A
San Gabriel, CA 91776

BOARD MEMBERS

PRESENT: Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Greg Lippe, Public Member
Valerie Muñoz, Public Member
Ricardo Sanchez, Public Member
Allan Schaad, RPh
Stanley Weiser, RPh

BOARD MEMBERS
NOT PRESENT: Ryan Brooks, Public Member
Lavana Butler, RPh
Albert Wong, PharmD

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Lori Martinez, Staff Manager
Debbie Damoth, Staff Manager
Laura Hendricks, Staff Analyst
Bob Dávila, Public Information Officer

Note: A webcast of this meeting may be found at:

<http://www.pharmacy.ca.gov/about/meetings.shtml>

Wednesday, August 31, 2016

Call to Order

9:02 a.m.

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 9:02 a.m. Board members present: Greg Lippe, Valerie Muñoz, Ricardo Sanchez, Allan Schaad, Amy Gutierrez, Stanley Weisser, Debbie Veale and Victor Law.

President Gutierrez asked if there were any members of the public at the teleconference locations. Ms. Veale said no members of the public were at her location in Palos Verdes Estates. Mr. Law said two members of the public were at his location in San Gabriel.

Note: This meeting was not webcast.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

President Gutierrez asked if there were any comments from the public at any of the meeting locations. There were no comments from the public at any of the meeting locations.

III. Discussion and Consideration of AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program

President Gutierrez reported that AB 1069 originally would have expanded the provisions under which a county-established repository and distribution program allows the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription. However, at the July 2016 Board Meeting, the board was advised that AB 1069 was being amended to significantly change the legislation to allow repackaging of medications in advance of the patient presenting at the pharmacy if it is a pharmacy within the county that only deals with these types of medications serving this specific population. She noted that as the amended language was not available at the July meeting, the board did not change its Oppose Unless Amended position.

President Gutierrez said that the measure has been amended twice since the July Board Meeting. In its current form, the bill will allow a pharmacy that solely operates a redistribution program to repackage a reasonable quantity of donated medication in advance of a prescription. The pharmacy must have policies and procedures in place to identify and recall medications, and the medication label must include the earliest expiration date of the medications are commingled into a single bottle.

President Gutierrez said that, as established by board policy, staff worked with the board's president and the chairperson of the Legislation and Regulation Committee to discuss the amendments and determine what (if any) changes should be made to the board's position on the measure. President Gutierrez explained that as part of the discussion, it was determined that the bill now encourages the use of a pharmacy to operate the redistribution program

which provides better safeguards for patients. As such, the position on this measure was changed to support.

President Gutierrez reported that the bill was enrolled on August 23, 2016, and is currently awaiting action by the governor.

President Gutierrez explained that at this meeting, the board would have the opportunity to discuss the amendments to AB 1069 and ratify the position taken by the board president and the chair of the Legislation and Regulation Committee. She noted that the board meeting materials included a copy of the measure as it will amend the law as well as copy of the support letter that was provided to the author's office.

Mr. Weisser noted that the bill would allow a pharmacy to repackage a "reasonable" quantity of donated medicine. He asked if this wording would pose a problem because it is not exact enough.

Ms. Freedman said the wording would be problematic for OAL – but AB 1069 is legislation, not a regulation, and the Legislature can make its own rules on wording. She also explained that if the board was charged with enforcing the statute, the board would be able to call for expert opinion from pharmacists in order to determine what would constitute a "reasonable" quantity.

President Gutierrez added that another way to determine a "reasonable" quantity of a drug would be to consider how much of that drug a pharmacy typically would have on its shelf and would dispense in a given time period. Mr. Lippe added that the term "reasonable" was not an issue for him or President Gutierrez in their discussion of AB 1069.

Mr. Schaad asked for a history of the bill to understand the type of program addressed by AB 1069. He asked how this program is currently being handled and where the dispensing it taking place.

Ms. Sodergren explained that existing provisions in the Health and Safety Code allow a county to establish a program by which it can accept donated medications from various facilities for redistribution to indigent patients. Under current law, there are various locations in the county that can provide these medications. According to the author's office, Santa Clara County is currently operating this type of program. The county receives donated medications from various sources, with skilled-nursing facilities being one of the largest donors. The current law requires the donated medication to be in a tamper-evident package, typically a bubble pack, and it must have specific information.

Ms. Sodergren explained that AB 1069 would allow a pharmacist to punch out the medication from the medication bubble cards in advance of the patient presenting. Currently, when a patient presents, the medications are stored in the bubble cards – one card may have 10 dosage units, one may have 5, another may have 12 – and the dispenser has to identify the medication prescribed, punch them out of the cards, put them in a vial and label them. This bill would allow a stand-alone pharmacy whose sole purpose is to redistribute these donated medications to repackage the medication in advance. The author's office said that patients

getting these medications at the pharmacy in Santa Clara face long waits because the repackaging is labor intensive and presents work-flow issues for the pharmacy.

Ms. Sodergren added that, besides allowing medications to be repackaged in advance, the bill would provide better patient protections because the work would be done in a pharmacy, by a pharmacist with better controls in place than.

Ms. Veale asked if counties would be controlling the program, including the pharmacist component, and whether that board would have to adopt regulations telling pharmacists what they need to do in order to participate.

Ms. Sodergren explained that current law allows redistribution to be done in various locations (i.e., clinics, doctors' offices, etc.). AB 1069 would centralize the distribution to a pharmacy, which has better controls in place. Since the pharmacy would be mixing medications with various lot numbers and expiration dates, it would be better to have this done in a pharmacy with specific policies and procedures in place for handling recalls. The bill also would ensure that the medication is repackaged with the earliest expiration date on it so that a patient does not take medication that has expired.

President Gutierrez and Ms. Sodergren noted that current law permitted someone under a physician's oversight to handle repackaging, such as in a clinic. Ms. Sodergren said that the key change in the bill would be the repackaging component and the requirement that it be done in a pharmacy.

Steve Gray of Kaiser Permanente asked if the bill would require creation of a new pharmacy license category and whether repackaging pharmacies could accept partially opened bottles of medications from pharmacies or wholesalers. Ms. Herold replied that no new license is needed. Ms. Sodergren said that a pharmacy redistributing medications would be no different from any pharmacy that specializes in an area, such as a closed-door pharmacy that focuses on skilled-nursing facilities. She added that current law requires counties to notify the board if they are operating this type of pharmacy. If a pharmacy is not handling repackaging, it is free to serve other types of patients.

Ms. Herold added that counties are required to notify the board if they are operating a repackaging pharmacy. Ms. Sodergren said repackaging pharmacies cannot accept partially opened bottles, because the law requires the medications to be in tamper-evident packaging.

Bill McGuire asked if bubble packs contain all the same drug or multiple drugs. He said that accepting bubble packs containing multiple medications, even in tamper-proof bubble packs, might conflict with USP 681. President Gutierrez said the board would review USP 681.

Motion: Affirm the decision by the board president and the chair of the Legislation and Regulation Committee to change the board's position on AB 1069 from oppose unless amended to support.

M/S: Weisser/Sanchez

Support: 8 Oppose: 0 Abstain 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong				X

IV. Consideration and Possible Adoption of Proposed Regulations to Add Title 16 CCR sections 1730, 1730.1 and 1749 related to Advanced Practice Pharmacists

President Gutierrez said that, in July 2015, staff initiated a formal rulemaking to add Title 16 CCR sections 1730, 1730.1, and amend section 1749 related to the licensing requirements for advanced practice pharmacist. At the February 2016 board meeting, the board adopted the final regulation text. The final rulemaking file was submitted to the Office of Administrative Law (OAL) for final review on June 3, 2016.

President Gutierrez said that at the July 2016 Board Meeting, DCA Staff Counsel Laura Freedman explained OAL found problems and disapproved the regulation due to a lack of clarity and ambiguity in the language. OAL’s clarity issue was with the language that prohibits experiential hours earned under a collaborative practice agreement to also be used to fulfill the criteria for the residency program, an action prohibited by the underlying statute. Ms. Freedman said that OAL wanted that provision to be memorialized in the text of the regulation itself.

President Gutierrez reported that OAL also raised two other “necessity” concerns regarding the rulemaking file. The first issue was the board’s requirement that the application be submitted under penalty of perjury. The second was the explanation of how the board chose the 1500 hours as the equivalent of one year.

President Gutierrez explained that Ms. Freedman drafted modified language to address the issue raised by OAL and reviewed the text with the board at its July 2016 meeting. The board approved the “Draft Third Modified Text” as provided at the July 2016 board meeting. The board approved board staff to initiate a 15-day comment period. The board initiated a 15-day comment period for the addition of documents to the rulemaking file and third modified text. President Gutierrez reported that the 15-day comment period began August 12, 2016, and ended on August 27, 2016.

President Gutierrez stated that, at this meeting, the board would have the opportunity to discuss the regulation and the comment(s) received and to determine what course of action it wishes to pursue. The options include:

1. Adopt the regulation as approved at the July 2016 Board Meeting after reviewing the public comments.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15 day comment period.

President Gutierrez noted that Attachment 2 of the board meeting materials contained the Draft Third Modified Text that was noticed on August 12, 2016.

Ms. Damoth reviewed the public comments that were received by the board during the most recent comment period. One comment would add “or graduate clinical emphasis degree” into subsection (b)(2) and as well as subsection (c) and in (1)(A). President Gutierrez characterized his comment as asking that the board allow an advanced degree such as an MS or Ph.D. in clinical pharmacy in lieu of pharmacy. Ms. Freedman stated that these changes were contrary to the requirements in the statute. The board did not amend the language.

Ms. Damoth reported that a comment asking how the board can justify a regulation that asks that pharmacists with a residency have better memory than pharmacists who have not completed the residency. Ms. Freedman said the comment does not appear to be related to the 15-day changes but the board could still respond.

President Gutierrez explained that the issue of requiring 1,500 hours of experience involved a desire by the board to ensure that the one year of experience was meaningful – not just doing one hour a week and for a year as a year’s worth of experience. Ms. Freedman said OAL’s issue with the 1,500 hours was that the board didn’t specifically say why that figure was chosen in the rulemaking file itself. President Gutierrez said the number of hours was based on the requirements for intern pharmacists that equate 1,500 hours to a year’s worth of experience.

The board elected not to modify the language in response to the comments received during the comment period.

There were no comments from the public.

Motion: Adopt the regulations as approved at the July 2016 Board Meeting.

Proposal to add new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

Article 3.5. Advanced Practice Pharmacist

Proposal to add §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210, subdivision (a)(2)(A).

Note: Authority cited: Sections 4005 and, 4210 and 4400, Business and Professions Code.

Reference: Section 4052.6, 4210 and 4400, Business and Professions Code.

Proposal to add §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of **Business and Professions Code section 4210**, an applicant for advanced practice pharmacist licensure must satisfy two of the following **subsections**.

~~(a)~~ (1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, **subdivision (a)(2)(A)**, ~~an applicant shall by providing~~ either:

~~(1)~~ (A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

~~(2)~~ (B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

~~(b)~~ (2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, **subdivision (a)(2)(B)**, ~~an applicant shall by providing~~ either:

~~(1)~~ (A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

~~(2)~~ (B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, **the area of specialty, and** the dates of participation and completion, ~~and area(s) of specialty. For an applicant who that cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection (2).~~

~~(c)~~ (3) Demonstrate that experience earned under a collaborative practice agreement or protocol, **as required by Business and Professions Code section 4210, subdivision (a)(2)(C)**, has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must **be composed of include** no fewer than 1,500 hours of experience providing clinical services to patients, ~~and~~

~~must be earned within four consecutive years.~~ The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, ~~modifying or and~~ discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

~~(A)~~ (A) A written statement from the applicant attesting under penalty of perjury that he or she has:

~~(A)~~ (i) Earned the clinical experience within the required time frame; ~~and~~

~~(B)~~ (ii) Completed the required number of hours of ~~experience providing~~ clinical services to patients, as specified in ~~this subdivision subsection (a)(3), and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, modifying or and discontinuing drug therapy of patients; and~~

~~(I)~~ (I) The applicant shall provide a copy of the collaborative practice agreement or protocol.

~~(II)~~ (II) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

~~(B)~~ (B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least ~~one year 1,500 hours~~ of experience providing clinical services to patients. ~~For an applicant who that cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection(2).~~

~~(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.~~

Note: Authority cited: Sections ~~4005, and 4210 and 4400~~, Business and Professions Code.
Reference: Sections ~~4052.1, 4052.2, and 4052.6, 4210 and 4400~~, Business and Professions Code.

Proposal to amend §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1749 (Fee Schedule)

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, ~~4210~~, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is **one hundred ninety-five dollars (\$195)** ~~two hundred seven dollars (\$207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

M/S: Weisser/Lippe

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz	X			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	X			
Wong				X

Motion: Delegate authority to executive officer to any make non-substantive or technical changes as may be required by the OAL to complete the rule-making.

There were no board comments or public comments on the motion.

M/S: Weisser/Sanchez

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X
Gutierrez	X			
Law	X			
Lippe	X			
Muñoz	X			
Sanchez	X			

Schaad	x			
Veale	x			
Weisser	x			
Wong				x

V. Consideration and Possible Adoption of Proposed Regulations to Amend Title 16 California Code of Regulations (CCR) section 1707.5, Related to Patient-Centered Labels

President Gutierrez said that at the January 2015 Board Meeting, the board approved proposed text to amend Section 1707.5 of Title 16 CCR related to Patient-Centered Labels. The 45-day comment period began on October 23, 2015, and ended December 7, 2015.

President Gutierrez said that at the April 2016 Board Meeting, the board approved modified text to address concerns expressed during the 45-day comment period and initiated a 15-day comment period. The 15-day comment period began on May 11, 2016, and ended on May 26, 2016.

President Gutierrez reported that at the July 2016 Board Meeting, the board approved a modified text to address concerns expressed during the 15-day comment period and initiated a second 15-day comment period. The second 15-day comment period began on August 3, 2016, and ended on August 18, 2016.

President Gutierrez said the board received several comments during the 15-day comment period.

President Gutierrez explained that at this meeting, the board would have the opportunity to discuss the regulation and the comments received and to determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2016 Board Meeting and noticed for 15-day comment on August 3, 2016.
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a third 15-day comment period.

Ms. Martinez said that four comments were received, which she reviewed for the board at the meeting. One comment stated that the regulation does not appear to require the drug manufacturer’s name, which could pose a conflict with statute. Ms. Herold noted that Business and Professions Code section 4076 already requires the manufacturer’s name be placed on the label, whether or not it is in the patient-centered area of the label.

Ms. Martinez said that a second comment recommended that the wording “may list the name of the manufacturer” be changed to “shall list ...” so that it is required. President Gutierrez said she believed that that the manufacturer’s name is not as important from a patient perspective.

Ms. Herold said that the board's intention was to give pharmacists some discretion about where to place the manufacturer's name while still meeting the statutory requirement that that the manufacturer's name be provided somewhere on the container.

Ms. Martinez said that another comment asked that "equivalent to" be used in the wording instead of "generic for" on the label because some patients do not believe that generic drugs are as good as brand drugs. Ms. Martinez said the comment reflected an issue of patient education and was outside the scope of the 15-day comment period. President Gutierrez said patients should be informed that their medication is generic.

Ms. Martinez said that the final comment was also outside the scope and requested that the board change 1707.5(a)(1)(B) to allow the purpose of the medication to be added to the label at the pharmacist's discretion.

Mr. Weisser made a motion to adopt the regulation as approved at the July 2016 Board Meeting and delegate to the executive officer the authority to make technical and non-substantive changes as may be required by OAL and DCA to complete this rule-making file. The motion was seconded by Mr. Schaad.

Mr. Law said he agreed with the two comments from the public. He said that putting the manufacturer's name in the patient-centered area is beneficial to the public, because generic companies make drugs in different sizes, shapes and colors. He said that having the abbreviation of the manufacturer's name on the label would enable patients to know the product's color, shape and size. He said putting the manufacturer's name outside the patient-centered area makes it difficult for patients to find.

In addition, Mr. Law said the board should allow pharmacists to exercise their discretion to put in parenthesis the general purpose of the drug even though the prescriber does not specify. He said that many senior citizens and others receive prescriptions for multiple medications. If the label includes in parenthesis what the medication is being prescribed for in easy-to-understand terms, which would be helpful to those patients. He recommended that these items be incorporated in the labels.

Ms. Veale said she agreed with Mr. Law that having the manufacturer's name on the label in the patient-centered area is beneficial to consumers. But she noted that the name can be either inside or outside the patient-centered portion, so as long as it is on the label as required by law, that would be acceptable. Regarding suggestions that a patient diagnosis be included on the label, Ms. Veale said that issue might be outside the scope of the rulemaking. She said the board had considered that issue previously and perhaps should revisit it, but it was beyond the current rulemaking.

President Gutierrez said that she agreed with Ms. Veale. She added that one of the issues with including a diagnosis on the label is that so many drugs are used for many different indications – so it would be difficult for pharmacists to include that information on the label unless the provider provides that information on the prescription.

Mr. Law said that he disagreed with President Gutierrez. He said that many patients complain that they have too many medications at home and that they do not know what they are for. He said that, most of the time, prescribers do not put down the purpose of the medication on the prescription. He said the board should give pharmacists, at the patient's request, to put the condition on the label so that the patient would not be confused about what the medication's purpose.

President Gutierrez said that the rulemaking is concerned with the requirements for the label – not optional items that a pharmacist, in his or her discretion, can add. Ms. Herold said that if a patient requests that the purpose be included on the label, the pharmacist could use his or her professional judgment to provide that information to the patient. She added that the issue of putting the medication purpose on the label is beyond the intended scope of the regulation and could trigger notice requirements if the board decided to address the issue here. She suggested that the board discuss the drug purpose issue at another time.

President Gutierrez suggested the Communication and Public Education committee consider the issue at its next meeting.

Mr. Law asked for clarification if pharmacists can put the drug's purpose on a label at a patient's request. Ms. Herold indicated that a pharmacist may do so at the patient's request.

Mr. Law reiterated his belief that the manufacturer's name should go in the patient-centered area. It was clarified that the word "may" in the regulation would allow a pharmacist to put it inside or outside the patient-centered area, as long as it is somewhere on the label. Ms. Veale also noted that the wording of the regulation would give the pharmacist discretion on whether to put the manufacturer's name inside or outside the patient-centered area.

Ms. Muñoz asked if including the medication purpose on the label could violate HIPAA requirements for patients who do not want their health history on the label. President Gutierrez said Ms. Muñoz raised a very good point and said the medication purpose issue raises many concerns – which is why the board should refer the matter to the Communication and Public Education Committee.

Ms. Herold noted that the drug purpose information is intended for the patient and the patient's caregiver to know how to take the medication, so it should be up to the patient to decide what information goes on the label.

Robert Stein of KGI School of Pharmacy said that the purpose of the rulemaking is to reduce public confusion – but requiring both the brand and generic name in the patient-centered portion of the label may actually cause confusion. President Gutierrez replied that one of the reasons for the requirement is situations where a patient is also taking the brand-name drug, and he or she would not understand that they are duplicating therapy by taking the brand-name and the generic drug.

Steve Gray of Kaiser Permanente expressed support for the regulation and support for Mr. Law's concerns about putting the medication's purpose on the label. He said that the issue has been pursued for 10 or 12 years and said that there was a bill to do it in the current legislative

session, but the bill died. He spoke in support of the Communication and Public Education Committee holding an in-depth discussion on providing purpose on the label.

Motion: Adopt the regulation as approved at the July 2016 Board Meeting and delegate to the executive officer the authority to make technical and non-substantive changes as may be required by OAL and DCA to complete this rule-making file.

To Amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted ~~into the parentheses. If, it has been at least five years since the expiration of the brand name's patent or, if~~ in the professional judgment of the pharmacist, the brand name is no longer widely used, the label may list only the generic name of the drug and outside of the patient centered area, may list the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

- (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
- (P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

~~(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.~~

~~(f)~~ (e) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

M/S: Weisser/Schaad

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Butler				X

Gutierrez	x			
Law	x			
Lippe	x			
Muñoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong				x

President Gutierrez adjourned the meeting at 9:59 a.m.