

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8614 www.pharmacy.ca.gov



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Ricardo Sanchez, Public Member, Chairperson Valerie Muñoz, Public Member, Vice Chairperson Ryan Brooks, Public Member Shirley Kim, Public Member Debbie Veale, Licensee Member

a. Call to Order and Establishment of Quorum

b. Public Comment about Items Not on the Agenda; Matters for Future Meetings

Note: The committee may not discuss or take action on any matter raised during the public comment section that is not on this agenda, except to place the matter on a future meeting agenda. [Government Code sections 11125 & 11125.7(a)]

c. <u>Approval of the May 7, 2019, Communication and Public Education Committee Meeting</u> <u>Minutes</u>

A copy of the draft minutes is in **Attachment 1**.

d. Discussion and Consideration of Policy on Subscriber Alerts

Background

At the May 7 committee meeting, staff suggested creating new types of electronic listservs for subscriber alerts for non-licensees. Additional listservs would reduce the number of subscriber alerts being sent on the main general listserv for facilities. In addition, the board would be able to communicate more effectively with consumers and other non-licensees.

The committee directed staff to report back with a plan for possible new listservs. The committee also directed staff to consider whether the board should set policy on how subscriber alerts are targeted or give staff discretion to make those decisions.

At this meeting

Staff is proposing to create a new listserv for subscriber alerts to communicate general board news and information. Subscribers who sign up would receive notifications about:

- Board and committee meetings.
- Consumer information.
- New rulemakings, laws and regulations.
- CE training opportunities.
- Publication of The Script.
- Press releases.

The main general listserv would be renamed "facilities" to accurately reflect its subscriber base. Recall notices and other important information for licensed facilities would continue to be sent to facilities subscribers.

Staff also recommends the board's executive officer have discretion to set policy for establishing listservs and determining how to target subscriber alerts. This would enable information to be communicated quickly and effectively to consumers and licensees.

Staff welcomes committee discussion and consideration of this report.

e. <u>Discussion and Consideration of Proposal to Create Online Search Tool for Pharmacies</u> <u>Providing Health Care Services</u>

Background

The committee and the board are committed to informing the public about new pharmacy services to meet their health care needs. For example, the board has created an online database that consumers can search to find pharmacies that provide drug take-back services. In addition, the board's website includes links to other agency websites that consumers can search for drug take-back locations and services.

The role of pharmacists as health care providers continues to expand in California. More pharmacies are offering new services regulated by the board pursuant to SB 493 and other legislation. These services include hormonal contraception, naloxone, and vaccinations. However, consumers may not know how or where to obtain these services.

At this meeting

Staff is proposing to provide search information on the board's website to help consumers find pharmacies offering health care services.

Staff could solicit information from pharmacies and create online databases that consumers can search for services. Alternatively – or in addition – the board's website could include links to other existing search websites. For example, <u>www.birthcontrolpharmacies.com</u> promotes awareness of access to birth control in pharmacies and connects women with pharmacies that provide this service. In addition, the Drug Policy Alliance provides search information for <u>California pharmacies furnishing naloxone</u>.

Search tools created by the board would take time to build but would give the board control over content. Existing search websites could be posted immediately, but some sites would have to be vetted and monitored for possible conflicts with board policies, and the board would have no control over their content.

Staff welcomes committee discussion and consideration of this report.

f. Discussion and Consideration of Proposed Brochure About Pharmacy Inspections

Background

At the January 2019 committee meeting, members heard a staff report on surveys performed after pharmacy inspections. Committee members discussed the need to standardize inspections and provide a way for licensees to report complaints about inspections without fear of retaliation by the board. Other board members expressed similar concerns at the January 2019 board meeting.

At the May 2019 committee meeting, staff reported working on an informational brochure about pharmacy inspections for licensees. The committee suggested the brochure could serve as a prototype for additional information brochures focusing on inspections of sterile compounding pharmacies and other specialized pharmacies.

At this meeting

For the committee's discussion and consideration, staff has created a draft brochure on inspections of community pharmacies. The brochure includes sections on:

- What licensees can expect from inspectors.
- What inspectors expect from licensees.
- Documents to have ready for an inspection.
- Additional items that inspectors will check.
- Possible administrative and disciplinary action if violations are found.
- How to report feedback to board managers or file a complaint with DCA including anonymous complaints.

The draft brochure has been submitted for legal review. A copy of the brochure is in **Attachment 2**.

g. Discussion and Consideration of the Committee's Strategic Goals

Background

The Board of Pharmacy finalized its strategic plan in 2016. The plan includes eight strategic goals for communication and public education.

At this meeting

Staff is presenting a brief status report for the committee's information. Staff recommends the committee review the status of each of the goals, which are listed below.

4.1: Develop and implement a communication plan for licensees and consumers to improve communication and keep stakeholders better informed.

<u>Status</u>: Although the board has expanded its communications to both consumers and licensees, these efforts do not follow a written communication plan.

4.2: Identify and use additional resources for public and licensee outreach services to implement the communication plan.

<u>Status</u>: The board has expanded into social media to communicate with the public and licensees, in addition to relying on its website, newsletter and subscriber alerts. The board has hosted live CE training events throughout the state and produced three online CE webinars for licensees. The board has moved its meeting locations throughout the state, increasing public exposure and awareness of the board's activities.

4.3: Establish a process to collect email addresses and mobile numbers for text messaging from all licensees for better ability to improve communication.

<u>Status</u>: The board has implemented regulations requiring pharmacists, intern pharmacists, pharmacy technicians and designated representatives to register their email addresses to receive subscriber alerts.

4.4: Provide implementation guidance on newly enacted changes to pharmacy law by publishing summaries and explaining implementation tactics.

<u>Status</u>: The board maintains a pharmacy lawbook online and publishes annual summaries of new laws online and in The Script. The board also issues subscriber alerts and publishes FAQs and guidance information on major laws and policies, including inventory reconciliation, compounding matters and changes to security prescription forms.

4.5: Inspect pharmacies at least once every four years to provide a forum for licenseeinspector communication and education in practice settings.

<u>Status</u>: The board is creating an informational brochure and provides information in The Script to improve communication between inspectors and licensees during inspections.

4.6: Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.

<u>Status</u>: The board has created an online search tool to help consumers find drug take-back locations. In addition, staff is recommending providing search tools to help consumers find pharmacies providing special health care services.

4.7: Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.

<u>Status</u>: The board has updated a consumer brochure about the risks of buying drugs online. Staff is working to review and update additional consumer materials as needed.

4.8: Promote board initiatives to improve patient knowledge, medication adherence, and medication safety.

<u>Status</u>: Board staff is working to attend more outreach events targeting consumers as well as licensees. Recently staff worked with DCA to publish <u>an online article</u> with consumer tips on filling opioid prescriptions and talking to their pharmacist.

h. Update on Communication and Public Education Activities by Board Staff

1. The Script

Work is underway on the next issue of the newsletter. Publication is expected this summer.

2. Projects Update

Staff has submitted for legal review a consumer tip sheet on disaster planning. The draft document includes committee suggestions from the May 7 meeting, such as reminding consumers to ensure medications in their emergency planning kit do not expire.

3. News Media

The board's public information officer provided background information to news reporters in response to media inquiries listed in **Attachment 3**.

4. Public Outreach

Inspectors and staff were scheduled to provide training for pharmacists at the board's CE training on drug abuse and drug diversion July 20 at Marin County Office of Education in San Rafael. The board cohosted the training with Rx Safe Marin. To date the board has hosted 12 CE training events throughout the state since March 2017.

In addition, the board provides free CE webinars on pharmacy law, ethics and naloxone training. As of the end of the fiscal year on June 30, pharmacist participation for the webinars totaled:

- Law: 13,754 since 8/8/2018.
- Naloxone: 2,023 since 10/25/2018.
- Ethics: 3,359 since 5/17/2019.

Additional recent outreach activities by inspectors and staff are in Attachment 4.

i. Future Meeting Dates

The final committee meeting date this year is scheduled for Wednesday, Oct. 9, 2019.

May 7, 2019 Meeting Minutes

California State Board of Pharmacy 1625 N. Market Blvd, N219 Sacramento, CA 95834 Phone: (916) 574-7900 Fax: (916) 574-8618 www.pharmacy.ca.gov



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Date:	May 7, 2019
Location:	Department of Consumer Affairs DCA Headquarters Building 1625 N. Market Blvd., First Floor Hearing Room Sacramento, CA 95834
Committee Members Present:	Ricardo Sanchez, Public Member, Chairperson Valerie Muñoz, Public Member Deborah Veale, Licensee Member
Committee Members	Ryan Brooks, Public Member
Not Present:	Shirley Kim, Public Member
Staff Present:	Anne Sodergren, Interim Executive Officer Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Debbie Damoth, Administrative Manager Laura Hendricks, Staff Analyst Bob Dávila, Public Information Officer

a. Call to Order and Establishment of Quorum

Chairperson Sanchez called the meeting to order at 10:41 a.m. A quorum was established.

b. Public Comment for Items Not on the Agenda; Matters for Future Meetings

Steve Gray asked the committee to consider public education regarding a patient's right to request prescribers put the purpose of a medication on the prescription. He said the public is unaware current law allows patients to request this information. Ms. Sodergren noted the Legislation and Regulation Committee is recommending the board support legislation to require prescribers to include the purpose of a drug on the prescription.

c. <u>Approval of January 8, 2019, Communication and Public Education Committee Meeting</u> <u>Minutes</u>

M/S: Muñoz/Veale

- Support: Sanchez, Muñoz, Veale.
- Oppose: None.
- Abstain: None.
- Not present: Brooks, Kim.

d. Discussion and Consideration of Policy on Subscriber Alerts

Chairperson Sanchez noted the board uses listservs to send information for facilities, pharmacists, intern pharmacists, pharmacy technicians and designated representatives via subscriber alerts. The facilities listserv is also used for alerts about general topics.

Chairperson Sanchez said some facilities feel they receive too many subscriber alerts. Meanwhile, individual licensees do not receive alerts sent to facilities. Also, the board does not have listservs to send alerts to non-licensee audiences. He noted that other DCA boards and bureaus use a variety of listservs to target alerts to the public as well as licensees.

Staff suggested creating new listservs to reach non-licensee groups. Staff also suggested creating listservs for specific types of messages such board announcements, new laws, etc. Staff said these options could help efforts to reach and communicate with non-licensees, including consumers and stakeholders.

The committee directed staff to report back with a plan including possible new listservs. The committee also directed staff to consider whether the board should set policy on how subscriber alerts are targeted or give staff discretion to make those decisions.

Public comment: Steve Gray urged the board to make clear which alerts are mandatory for licensees to receive and which are optional. He also suggested the board develop a system that would enable users to receive selective alerts about preferred topics, such as updates on specific regulations or committee activities.

Danny Martinez of CPhA expressed support for new listservs to reach consumers. He also urged that alerts to consumers be written in a less technical style and provide more explanatory detail than alerts sent to licensees.

e. Staff Report on the "Ask and Inspector" Program

Chairperson Sanchez said committee member directed staff at the January 8 committee meeting to report back on the possibly expanding the "Ask an Inspector" program hours. The committee also discussed publishing FAQs based on common "Ask and Inspector" questions. Chairperson Sanchez added that at the January board meeting, the board directed the Enforcement Committee to review the FAQs before publication.

Staff reported inspectors are now assigned to "Ask an Inspector" duty Monday through

Thursday from 9 a.m. to 1 p.m. This change took effect April 1. In addition, staff has drafted FAQs about controlled substances, the most common type of "Ask an Inspector" question. The FAQs are undergoing legal review and expected to be presented at the Enforcement Committee meeting in July.

The committee asked staff to report back on whether the number of "Ask an Inspector" calls has changed since the expanded hours began.

f. <u>Discussion and Consideration of Educational Materials for Consumers and Licensees</u> <u>during Declared Disasters</u>

Chairperson Sanchez said at the January 8 committee meeting, members discussed ways to provide better information to pharmacy patients before and during declared disasters. The committee directed staff to report back with recommendations to improve communications with licensees and the public during disasters. Chairperson Sanchez added that at the January board meeting, the board asked staff to explore awarding CE credit to pharmacists who volunteer services during disasters.

Staff reported the board has established a social media account on Twitter, which is widely used to provide information to the public during disasters. Staff also is drafting a consumer tip sheet on how to prepare for a disaster.

Staff reported finding no other states that offer CE to pharmacists who volunteer during disasters. However, Florida, Virginia, Michigan, and West Virginia do offer CE credit or other incentives for pharmacists who volunteer in <u>indigent or medically underserved</u> <u>communities</u>.

The committee recommended advising consumers to review their disaster preparation kits once a year to ensure supplies are up to date. The committee also suggested creating information sheets for licensees on what to do during a disaster and directed staff to report back on the possibility of providing disaster CE training for pharmacists.

g. Update on Communication and Public Education Activities by Board Staff

a. The Script

Staff reported the current issue of the newsletter was published in March. Work is underway on the next issue, which is expected to be published in the summer.

b. Projects Update

Pharmacy inspections

Staff reported plans to create a brochure about pharmacy inspections for licensees. The brochure will provide information about the inspection process – including what licensees can expect to happen during the inspection, what inspectors expect from licensees, and how licensees can contact the board with feedback or complaints

Communication and Public Education Committee Meeting Minutes – May 7, 2019 Page 3 of 5 after the inspection. Inspectors will hand out brochures to licensees during inspections. The brochures also would be posted on the board's website and published in The Script.

Ms. Veale recommended that additional brochures be created targeting specific issues related to inspections of compounding pharmacies and other specialized types of pharmacies.

In addition, staff reported plans to create an educational video by Inspector Steven Kyle on "How to Prepare for Pharmacy Inspections by the Board of Pharmacy." The video will be posted on the board's website.

Danny Martinez of CPhA expressed support for the informational brochure and said CPhA would be willing to help disseminate the information to members.

<u>Billboards</u>

Staff reported waiting for information from Outfront Media regarding the creation of five billboards being donated to the board to promote awareness of prescription drug abuse.

• <u>CE webinars</u>

Staff reported completion of a free CE webinar on ethics that has been posted on the board's website. In addition, staff said the board's current CE webinar on law also was being updated

c. News Media

Staff provided a list of news media organizations that contacted the board's executive officer and public information officer for interviews or background information.

d. Public Outreach

Inspectors and staff provided training at CE events hosted by the board on February 23 at California Health Sciences University in Clovis and April 6 at UC San Diego in La Jolla. A total of 298 pharmacists attended and received up to seven hours of CE at the events. The next board CE training event is planned for July in Marin County.

Staff also reported the board has hosted a total of 11 CE training events throughout the state on prescription drug abuse and drug diversion since March 2017. A total of 1,531 pharmacists have received CE credit at these events, including 1,237 who also received specific training to furnish naloxone.

h. Review and Discussion of News or Journal Articles

Staff provided a list of news articles on pharmacy issues of possible interest to the board.

i. Future Meeting Dates

The committee agreed to reschedule its June 25, 2019, meeting to July 24, 2019; the committee will meet in advance of the board meeting also scheduled that day. The final committee meeting of 2019 will be Oct. 9.

The meeting adjourned at 12:21 p.m.

Draft Brochure on Pharmacy Inspections

After the inspection

If the inspector orders a correction, you will be instructed how to submit a plan or proof of correction to the board within a specified period. Keep all documentation related to completing the correction order with the inspection report.

If the inspector suspects a violation of pharmacy law has occurred, you may receive a written notice. Depending on the type of violation, the board may:

- Issue a letter of admonishment.
- Issue a citation (with or without a fine).
- Refer the case for disciplinary action against the pharmacy and/or individual licensee.

Letters of admonishment and citations are considered administrative actions. You may contest a letter of admonishment or citation by requesting an informal office conference, a formal hearing before an administrative law judge, or both. You will receive a letter from the board about the administrative action process, and you must reply by the specified due date.

Let us know how we performed.

The board welcomes your feedback about the inspection experience. Contact any manager listed on the back of this brochure with questions, comments or complaints.

You also may file a comment or complaint with the board's parent agency, the Department of Consumer Affairs (DCA). Visit the DCA website at <u>www.dca.ca.gov</u>, go to the Consumer tab, and click on "File a Complaint." You may provide your contact information to DCA or file a comment or complaint anonymously.

Board of Pharmacy Managers

Anne Sodergren, Interim Executive Officer (916) 518-3110 <u>Anne.Sodergren@dca.ca.gov</u>

Julia Ansel, Chief of Enforcement (916) 518-3077 Julia.Ansel@dca.ca.gov

Tom Lenox, Chief of Enforcement (916) 518-3109 <u>Tom.Lenox@dca.ca.gov</u>.

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Pharmacy Inspections By the California State Board Board of Pharmacy



What You Can Expect from an Inspection – What the Board Expects from You

The Board of Pharmacy appreciates your cooperation during this inspection. The goal of an inspection is to safeguard the health and safety of consumers. This is also an opportunity for you to receive guidance and answers to your questions about pharmacy laws and regulations from a board inspector. After the inspection is complete, we welcome feedback about your experience and any questions or comments about the inspector and the inspection process.



California State Board of Pharmacy www.pharmacy.ca.gov

What you can expect

An inspector will:

- Identify himself/herself with a boardissued badge and provide a business card.
- Be professional and courteous.
- Provide a receipt for any records taken into possession.
- Review and leave a copy of the inspection report with the pharmacist on duty and/or pharmacist-in-charge.
- Provide information and answer questions about pharmacy laws and regulations.

What is expected of you

Pharmacy staff will:

- Provide access to the inspector during regular business hours.
- Provide access to review all stocks of dangerous drugs and devices.
- Provide access to review all records of manufacture, sale, acquisition, receipt, shipment and disposition.
- Allow the inspector to secure samples or specimens.

Documents for inspection

Pharmacies are required to have certain documents readily available for inspectors to review. Hard and electronic copies of records must be available during business hours.

Documents to have available include:

- Past inspection reports.
- Pharmacy self-assessments.
- Copies of staff licenses.
- Master list of pharmacist and technician initials.

- DEA 222 forms.
- Power of attorney to execute DEA 222 forms.
- DEA biennial inventory.
- Drug take-back records.
- Wholesaler invoices.
- Records of drug returns.
- Records of destruction.
- Off-site records waiver.
- Pedigrees for drugs purchased.
- Inventory reconciliation reports.
- Controlled substances refill reports.
- Policies:
 - Quality assurance reports.
 - QA for medication errors.
 - Theft and impaired licensees.
 - Pharmacy technician job description.
 - Pharmacist absence for meals.
 - After hours deliveries.
 - Interpretive services.
 - Repackaging previously dispensed drugs.
 - Automated Drug Delivery Systems.
 - Common electronic files to prevent unauthorized release of patient information.
- Protocols:
 - Refusing to dispense on ethical, moral, religious grounds.
 - o Immunizations.
 - Emergency contraception.
 - Nicotine replacement.
 - Advanced practice pharmacist.
 - Procedures performed pursuant to BPC section 4052.2.

Additional items

The inspector also will check:

- DEA registration.
- Drug expiration dates.
- Drug take-back receptacles.
- Hot/cold running water (separate from restroom).
- Confidential waste disposal.
- Interpretive services poster.
- Notice to consumers poster.
- Restroom location.
- Patient consultation.
- Posted pharmacy license and renewal.
- Out-of-state licenses.
- Prescription labeling.
- Prescription records.
- Quarantine area for expired and recalled drugs.
- Refrigerator/freezer temperature.
- Security features.
- Staffing ratio.
- Transmission of CURES data.
- Wearing identification or name tag printed in at least 18-point type.
- Possession of keys to the pharmacy.

You may provide your contact information to DCA or file a comment or complaint anonymously.

Board of Pharmacy Managers

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News Media Inquiries

News Media Activity

The board's public information officer provided background information in response to following media inquiries:

- May 6: Ed Silverman, STAT Pharmalot blog, re disciplinary case against Cardinal for shipping drug products to a pharmacy where the pharmacist was deceased.
- May 17: Jim Alfaro, CBD Follow, re CBD products in California pharmacies.
- May 20: Julia Avera, KRCR, re disciplinary action against Ferry's Pharmacy in Anderson.
- May 20: David Benda, Redding Record Searchlight, re disciplinary action against Ferry's Pharmacy in Anderson
- May 21: Devon Miller, KHTS, re disciplinary action against Newhall Pharmacy in Newhall.
- June 13: Kevin Nious, NBC San Francisco, PRA request re drug loss/theft reports submitted to board from 1/1/2018 to present.
- June 18: Ethan Stein, NBC News, re licenses issued to Solara Medical Supply.
- June 27: Emily Baumgaertner, Los Angeles Times, PRA request re complaints against CVS pharmacies between Jan. 1, 2017, and June 1, 2019.

Public Outreach Activities

Public Outreach Activities

Board staff reported the following activities:

- April 3: Interim Executive Officer Anne Sodergren and Supervising Inspector Steven Kyle gave a presentation on new 2019 pharmacy laws to the California Pharmacists Association.
- April 6: Supervising Inspector Anne Hunt provided a legal update at the board's CE program on prescription drug abuse and diversion at UC San Diego, Skaggs School of Pharmacy.
- May 22: Supervising Inspector Janice Dang on fraud trends and red flags in pharmacy investigations at the Riverside County District Attorney's office and investigators from various insurance companies.
- June 25: Supervising Inspector Manisha Shafir presented a 2019 pharmacy law update to the Alameda Pharmacist Association and Indian Pharmacist Association.
- June 26: Supervising Inspectors Manisha Shafir and Anne Hunt presented a 2019 pharmacy law update at California Northstate University in Elk Grove.
- July 20: Enforcement Chief Tom Lenox, Supervising Inspectors Manisha Shafir and Janice Dang, and Inspectors Steven Kyle and Trang Song are scheduled to present training at the board's Drug Abuse/Drug Diversion CE event in Marin County.
- October 23: Inspector Ben Rustia is scheduled to present training on prescription requirements for the Department of Health Care Services in Mission Valley.