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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

LICENSING COMMITTEE REPORT
April 19, 2018

Stan Weisser, Licensee Member, Chairperson
Lavanza Butler, Licensee Member, Vice-Chairperson
Ryan Books, Public Member
Ricardo Sanchez, Public Member
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a. Discussion and Consideration of Patient Consultation Requirements for Mail Order Pharmacies or Nonresident Pharmacies – Recommendations to Amend Regulations

Attachment 1

Background

At prior meetings of the Licensing Committee and of the board, there has been discussion on consultation that is provided to patients who receive medication via mail order or delivery. While acknowledging the benefits of convenience, the board's discussions have included:

- Whether patients are receiving essential information about how to take medications appropriately.
- Whether the current requirements for mail order and nonresident pharmacies are sufficient to ensure patients have access to a pharmacist for consultation.
- Whether a pharmacist is available to assist patients and the pharmacist can be reached upon patient request.
- Whether translation services are available when needed and how patients are advised about such services.
- Whether patients know where to go with complaints.

According to data available to the board, about 25 percent of pharmaceutical sales goes to mail order pharmacies.

An excerpt from the February 2018 board minutes where the board discussed this topic is provided in **Attachment 1**. This discussion included the following recommendations from the January 16, 2018, Licensing Committee.

Direct board staff to:

1. Modify 16 CCR section 1707.2 as provided below with changes to subdivisions (b)(1) and 1707.2(b)(2)(B):

1707.2(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~~:

1707.2 (b)(2)(B) A telephone number shall be provided to the patient from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record. The pharmacists shall be available to speak to the patient no less than six days per week, and for a minimum of 40 hours per week and the call shall be answered by a pharmacist within two minutes.

2. Draft proposed language requiring patient notification of the availability of translation services and patient notification of how to file a complaint with the Board of Pharmacy.

Committee Discussion and Action

During the April 19, 2018, committee meeting the board's Chief of Enforcement provided a presentation on complaints received by the board concerning mail order pharmacies. A copy of this presentation has been provided in **Attachment 1**. The committee noted that while the data sample used in the presentation was limited, it did illustrate that there are problems with patient interactions and mail order pharmacies, especially regarding how difficult it can be to speak with a pharmacist.

The committee discussed the need to balance overregulation with the board's mandate to ensure that patients, who are often required by their insurance to use mail order pharmacies, receive appropriate care.

As part of its deliberations, the committee reviewed 16 CCR section 1707.2 (a copy is provided in **Attachment 1**). The committee reconsidered if it is realistic to require phone calls in a mail order pharmacy to be answered by a pharmacist within two minutes. The committee also considered if a retail pharmacy that provides delivery services should also be required to have a pharmacist available to answer the phone within two minutes of a patient calling. Members of the public commented that two minutes is an unrealistic timeframe, especially considering there is often only one pharmacist on duty in a retail setting and it usually takes the patient a few minutes to ask a question.

After further discussion and additional input from the public, the committee determined that a patient of a mail order pharmacy or a patient who has his or her medications delivered should be able to speak to a pharmacist on the phone within an average of 10 minutes. If the pharmacist will be unable to speak to the patient within 10 minutes, then a return call must be scheduled to occur within one hour. The committee also clarified that customer service representatives, clerks or other ancillary pharmacy staff can still triage calls to determine if patients need help with non-pharmacy related questions (billing, insurance, delivery, etc.).

Committee Recommendation (Motion): Direct staff to develop draft regulation language to modify 16 CCR section 1707.2 to require that a pharmacist shall be available to speak with a

patient within an average of 10 minutes or less or shall schedule a return phone call within one hour, and present it at the May 2018 board meeting for consideration.

Recent Update
Following the committee meeting, board staffed work with legal counsel to draft language for the board's consideration. Should the board agree with committee's recommendation and the proposed language provided below, the following motion could be used to initiate the rulemaking process.

Motion: Approve the proposed amendment to Title 16 CCR Section 1707.2 (as provided below) and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

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

(4~~B~~) 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)(1~~2~~) 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.

(C) ~~-A~~ pharmacists~~s~~ 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.

(2~~3~~) 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.

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b. Discussion and Consideration of Proposed Requirement for Mail Order Pharmacies or Nonresident Pharmacies to Notify Patients of the Availability of Translation Services and to Notify Patients of How to File a Complaint with the Board

Background

During the January 16, 2018, Licensing Committee meeting, members discussed concerns regarding mail order patients not receiving translation information as well as notification on how to file a complaint with the board.

Committee Discussion and Action

During the meeting committee members heard testimony from representatives of mail order pharmacies regarding what information is currently provided to patients on the availability of translation services and the number of patients who use the translations services.

After hearing the testimony from the public, the committee determined that more information should be gathered to determine if there is actually a problem with patients not receiving information on translation services. The committee directed board staff to work with some of the large mail order pharmacies to determine how many patients use translation services, what information is currently provided to patients when they receive their medication and how patients are provided the information (paper handouts, emails, website, text, etc.). The committee asked that this information be provided at the June Licensing Committee meeting for discussion and consideration.

c. Update on Implementation of Board-Provided Law and Ethics Continuing Education Courses

Attachment 2

Background

A new requirement for pharmacist license renewal is that two of the 30 units of continuing education credit required must be earned by completing a board-provided CE program in law and ethics. This requirement becomes effective for all pharmacist renewals after July 1, 2019. The specific requirement is highlighted below:

1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.

(c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Board staff has developed a program that covers 2018 new pharmacy laws. This program has been presented live several times and has been taped for placement on the board's website. However, this program does not contain an ethics component.

When the requirements for the CE program were developed, the board did not discuss in depth what it intended to include in an ethics course.

Provided in **Attachment 2** are the three items listed below containing information on pharmacy ethics that was gathered by board staff.

- An article published in the January-February 2018 California Journal of Health System Pharmacy titled "Ethics: A Problem in Pharmacy?" This article was written by Keith Yoshizuka, who is a professor at Touro University's School of Pharmacy. Dr. Yoshizuka is willing to assist the board in development of an ethics component.
- Information gathered by the executive officer from discussions with Lorie Rice, former board executive officer and UCSF School of Pharmacy professor, who instructed UCSF students in pharmacy ethics.
- A copy of board regulations (CFR title 16, section 1773.5) establishing a specific ethics program developed by the board that used to refer pharmacists in disciplinary cases or citation cases.

Committee Discussion and Action

During the committee meeting board staff reported that the "2018 New Pharmacy Law" webinar is in the final stages of development. The webinar will be available on the board's website and will contain quiz questions to ensure that pharmacists are participating in the webinar. Board staff stated that an ethics webinar could be created in a similar format.

Members of the public asked whether the law and ethics courses must be provided by the board or if courses could be created and provided by an outside entity. Board staff explained that when the board created the requirement in 1732.5, they specifically drafted it so that the two hours of CE on law and ethics must be provided by the board. This ensures that the CE is free to all pharmacists and that the content of the CE comes from the board. Board staff further clarified that subject matter experts could be used to assist the board with creating content for a CE course; however, the course would still be provided by the board at no cost to licensees via the board's website and at live events.

As part of its deliberations the committee reviewed the materials from Dr. Yoshizuka and Dr. Rice and recommended that board staff use them as subject matter experts when

creating an ethics CE course.

The committee directed board staff to work with subject matter experts to develop a CE course that focuses on ethical issues that arise in practice and uses board investigations and enforcement actions as examples of what a pharmacist "could/should/would do" when an ethical issue occurs. The committee will continue to receive updates on the status of this project.

d. Update on Implementing Pharmacist Licenses with Photo Identification – Recommendations to Amend Law and Regulations

Background

The board has encountered individuals posing as pharmacists and providing fake licenses for employment purposes. This is a threat to the health, safety and welfare of Californian consumers. An unlicensed person posing as a pharmacist does not meet the educational and experiential minimum qualifications for licensure and may cause patient harm.

At the July 2017 Licensing Committee meeting, board staff proposed implementing photo identifications for pharmacists. Board staff recommended a phased approach starting with new licensees and gradually adding current licensees based on the licensees' renewal. The committee sent a motion to the board to proceed with photo licenses for pharmacists.

At the July 2017 board meeting, the board affirmed the committee's recommendation to proceed with implementing photo identifications for pharmacists by July 2018. The board directed staff to use a phased approach, beginning with newly licensed pharmacists and adding current pharmacists based on their renewal. The board also discussed the need to have the photos updated periodically and have licensees pay the vendor directly for the photo identification.

Following the July 2017 board meeting staff determined that while the current pharmacist pocket license states, "Please sign and carry the Pocket License with you" there is no authority to require pharmacists to carry their pocket license on their person. Additionally, the board does not have the authority to require a pharmacist, upon initial licensure or renewal, to pay an additional fee to a vendor for a photo identification without a change in regulation or statute. In light of this information, board staff bought this item back to the committee and recommends implementing a voluntary pharmacist photo identification program while simultaneously pursuing a regulation to make the pharmacist photo identification a requirement in regulation.

Voluntary Phase with Tracking

The board may begin offering the option for pharmacist photo identification as soon as the contract with the current exam vendor PSI can be amended and the programming and/or manual tracking can be implemented. PSI currently administers the CPJE and will provide for an easy transition. While PSI does not offer biometrics, safeguard measures will be added that will serve a similar purpose for unique identification and verification. PSI offers

locations in California and throughout the US for current licensees to take their photograph. Exam candidates would be notified through exam instructions, exam candidate handbooks and the board website. Current pharmacists would be notified through subscriber alerts, the website, and newsletter articles. The board would track when new and current licensed pharmacists obtain photo identification.

Mandatory Phase with Continued Tracking

Upon promulgation of the regulation, the board would require all active pharmacists to maintain a photo identification and to update the photo every 10 years.

Proposed Implementation Timeline*	
April 2018	Recommendation to the Licensing Committee.
May 2018	Licensing Committee's recommendations to the board meeting for approval.
May 2018	Begin regulation promulgation with DCA Pre-Review Process.
May 2018	Amend the contract with PSI to add photo identification cards.
May-July 2018	Work with PSI and DCA to implement and develop voluntary option for new/current licensees while simultaneously laying the groundwork for mandatory implementation date of 7/1/19.
July 2019	Regulation effective date requiring new/current licenses to obtain and maintain photo identification card.
July 2019-June 2021	Phased in approach to add all current licensees by June 30, 2021.

***Note:** This timeline assumes that DCA will meet timeline requirements for contract amendments, computer programing and complete the regulation process to make it effective July 1, 2019.

Committee Discussion and Action

During the meeting, the committee reviewed the staff recommendation and timeline to begin a voluntary photo ID program while simultaneously working to implement a mandatory requirement for photo IDs for all pharmacists.

The committee members noted that the photo IDs could still be counterfeited; however, they agreed that mandating a photo ID would add an additional barrier for someone who is attempting to pose as a pharmacist and will provide employers an additional way to verify an applicant's identity.

Members of the public expressed support of mandating photo IDs and stated that the current pharmacist pocket license is easily destroyed/counterfeited and does not provide any information to help an employer verify the identity of the pharmacist.

The committee directed board staff to implement a voluntary pharmacist photo identification program while simultaneously working with legal counsel to draft language to make the pharmacist photo identification a requirement.

The committee further asked that board staff provide a sample of the photo ID at the next

committee meeting. The committee also asked staff to provide an overview of the process for pharmacists to obtain the photo ID including: locations for taking the photo, price for the photo ID, payment options and the timeframe for receiving the photo ID from the vendor.

Recent Update

Following the committee meeting board staff has begun the process of implementing the voluntary photo ID program. Board staff is also working with legal counsel to draft language to make photo IDs mandatory for all pharmacists by July 1, 2019. This language as well as the additional information requested by the committee will be provided at the June 2018 committee meeting.

e. Discussion and Consideration to Amend Business and Professions Code Section 4200(a)(6) relating to the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Attachment 3

Relevant Law

Business and Professions Code (BPC) section 4200 establishes the licensing requirements for a pharmacist. BPC section 4200 (a)(6) requires the board to accept a passing examination score on the NAPLEX and the CPJE on or after January 1, 2004.

BPC section 4200.3 requires the examination process shall be regularly reviewed pursuant to BPC section 139 and meet established standards and guidelines.

BPC section 139 establishes occupational analyses and examination validation studies are fundamental components of licensure programs. BPC section 139 requires the Department of Consumer Affairs (DCA) to develop policy regarding examination development and validation, and occupational analysis for all boards, programs, bureaus and divisions under its jurisdiction.

Attachment 3 contains copies of BPC section 4200, BPC section 4200.3 and BPC section 139.

Background

As required by BPC section 139, DCA developed a Licensure Examination Validation Policy (policy). The policy requires boards offering licensure examinations to conduct an occupational analysis every five years so that a detailed content outline (DCO) may be developed based on current professional practice. From the DCO, the licensure examination is developed. The policy also outlines requirements for ensuring validation of the licensing examination.

The board currently administers the CPJE as one of the required examinations for licensure in California as a pharmacist. Pharmacist licensure candidates must obtain a passing score on both the CPJE and NAPLEX prior to being licensed as a pharmacist. The board adheres to the requirements outlined by BCP 139 and the policy set forth by DCA.

Every five years, as part of the occupational analysis, the profession of pharmacy in California is reassessed. The analysis includes a review of job-related critical tasks and the knowledge, skills and abilities necessary to practice pharmacy in California. Based on the reassessment of the profession, the DCO is updated to ensure the licensure examination reflects current pharmacy practice in California.

Recently, board staff has noticed a trend of pharmacist applicants having passed the NAPLEX and/or the CPJE more than five years ago. Because the occupational analysis is conducted every five years, a passing score from more than five years ago does not demonstrate that the applicant has met the minimum qualifications based on current practice standards. For example, the most recent occupation analysis of the CPJE was completed in 2014; therefore, if a candidate passed the CPJE in 2012, the passing score no longer represents a demonstration of minimum competency in 2018.

The intent of BPC sections 4200, 4200.3 and 139 is to ensure that an applicant is issued a pharmacist license relatively soon after receiving a passing score on both the CPJE and NAPLEX. However, pursuant to BPC section 4200, the board may license a pharmacist licensure candidate who has passed the NAPLEX and CPJE on or after January 1, 2004. As currently written, BPC section 4200 is not aligned with the intent of BPC section 139 and DCA's Licensure Examination Validation Policy, as passing scores are being accepted in accordance with statute without regard to when the most recent occupational analysis was conducted. Board staff reached out to the DCA's Office of Professional Examination Services (OPES) regarding this issue. OPES advised board staff that an examination score is only valid during the current occupational analysis and examination content.

To ensure that an applicant has met the minimum competency at the time of licensure, the committee may wish to consider amending its regulations to only accept a CPJE passing score during the current occupational analysis and exam content. Additionally, the committee may also wish to consider only accepting a NAPLEX passing score from the current occupational analysis *unless* the applicant is currently licensed as a pharmacist in another state. Note: Even if an applicant is licensed in another state, he or she must still pass the CPJE during the current occupational analysis prior to being issued a California pharmacist license.

Currently, the board has 44 applicants who passed the CPJE over five years ago. Additionally, the board has 256 applicants who passed the NAPLEX over five years ago and do not hold a pharmacist license in another state. If the board amends the regulations, it would result in these applicants having to retake the CPJE and/or NAPLEX.

<u>Committee Discussion and Action</u>
During the committee meeting members discussed the importance of having an applicant demonstrate that they have met the minimum competency requirements to practice pharmacy in California at the time of application for licensure. The committee noted that the practice of pharmacy has changed drastically in the past few years and an exam from

2004 would not reflect the current practice standards in 2018.

The executive officer explained the process of conducting an occupational analysis every five years, including a review of job-related critical tasks and the knowledge, skills and abilities necessary to practice pharmacy. It was explained that based on the reassessment of the profession, the content outline of the exam is updated to ensure the licensure examination reflects current pharmacy practice in California.

The committee heard testimony from faculty of Chapman University School of Pharmacy stating that the only way to ensure that applicants have the appropriate knowledge to practice pharmacy is to have them pass the CPJE and NAPLEX during the current content outline.

As part of its deliberation the committee also discussed the need to allow a grace period after a content outline expires to give an applicant who passed the exam at the very end of the current content outline time to complete the application process with the board.

Committee Recommendation (Motion): Direct staff to draft language to amend its regulations to only accept a CPJE passing score during the current occupational analysis and exam content. Additionally, direct staff to draft language to amends its regulations to only accept a NAPLEX passing score from the current occupational analysis *unless* the applicant is currently licensed as a pharmacist in another state.

Recent Update

Following the committee meeting, board staffed work with legal counsel to draft language based on the committee's direction. The language will be provided at the board meeting for discussion and consideration.

f. Discussion and Consideration of Renewal Requirements for Individual Licenses and Facility Licenses – Recommendation to Amend Regulations

Background

Currently the board's regulations outline specific renewal requirements for pharmacists, pharmacy technicians, designated representatives, pharmacies, nonresident wholesalers and nonresident pharmacies. Specifically, these licensees are required to indicate if they have been disciplined by any governmental agency since their last renewal. For example, pharmacists must answer the following question on their renewal application.

> "Since you last renewed your license, have you had any license disciplined by a government agency or other disciplinary body; or, have you been convicted of any crime in any state, the USA and its territories, military court of foreign country?"

As the board's regulatory jurisdiction continues to grow, the renewal requirements for the new license types listed below were not drafted to include the same discipline disclosure.

- designated representative-3PL
- designated representative-vet
- designated representative-reverse distributor
- designated paramedics
- nonresident third-party logistics provider
- nonresident outsourcing

Board staff is recommending simplifying its regulations to consolidate the renewal requirements for licenses issued to a premise as well as the licenses issued to individuals. This approach would allow for the incorporation of new licenses that will be implemented in the future and follows the same format as the approach the board approved for the abandonment of applications at the February 2018 board meeting.

Committee Discussion and Action
The committee agreed with the staff's recommendation to consolidate the renewal requirements for licenses into two categories: licenses issued to individuals and licenses issued to a premise.

As part of its deliberation the committee noted that using this approach will ensure that any future licensing types will have the same renewal requirements without having to modify any regulations.

The committee also heard testimony from the public supporting the proposal.

Committee Recommendation (Motion): Direct staff to draft language to consolidate the renewal requirements for licenses issued to a premise as well as the licenses issued to individuals and present it at the May 2018, board meeting for consideration.

Recent Update
Following the committee meeting, board staffed work with legal counsel to draft language based on the committee's direction. The language will be provided at the board meeting for discussion and consideration.

g. Discussion and Consideration of Continuing Education Requirements for an Advanced Practice Pharmacist – Recommendation to Amend Regulations

Relevant Law
BPC section 4210 establishes the licensing requirements for an advanced practice pharmacist.

BPC section 4233 establishes the continuing education requirements for an advanced practice pharmacist.

BPC section 4231 establishes the pharmacist renewal requirements, which includes the

required 30 hours of continuing education as well as language to place a pharmacist license on inactive status for failing to comply with the renewal requirements.

Background

As of December 13, 2016, the board began accepting applications for advanced practice pharmacists and shortly thereafter in 2017 began issuing advanced practice pharmacist licenses to those that met the licensure requirements.

An advanced practice pharmacist is required to complete an additional 10 hours of continuing education each renewal cycle in addition to the 30 hours required by BPC 4231.

Currently, BPC 4233 does not include the same renewal requirements for advanced practice pharmacists as required for pharmacists pursuant to BPC 4231. Specifically, pursuant to BPC 4231, if a pharmacist submits the renewal application and renewal fee but does not certify on the renewal application that he or she has completed 30 hours of continuing education, the board has the authority to place the pharmacist on inactive status. BPC 4233 was not written in this manner. As a result, the board is unable to place an advanced practice pharmacist who does not certify that he or she has completed the required continuing education on inactive status.

Board staff recommends amending the board's regulations to specify that at the time of renewal, the advanced practice pharmacist must provide to the board the renewal application, renewal fee and certify that he or she has completed 10 additional hours of continuing education. Additionally, staff recommends that if an advanced practice pharmacist is unable to provide proof of completing 10 hours of continuing education when audited, his or her license should be placed on inactive status.

Committee Discussion and Action

During the meeting committee members discussed the continuing education requirements for an advanced practice pharmacist at the time of renewal.

The committee agreed with staff's recommendation to require that at the time of renewal, an advanced practice pharmacist must provide to the board the renewal application, renewal fee and certification that he or she has completed 10 additional hours of continuing education.

The committee also determined that if an advanced practice pharmacist is unable to provide proof of completing 10 hours of continuing education when audited, his or her license should be placed on inactive status.

Committee Recommendation (Motion): Direct staff to draft language to require that at the time of renewal, an advanced practice pharmacist must provide to the board the renewal application, renewal fee and certification that he or she has completed 10 additional hours of continuing education. Additionally, staff recommends that if an advanced practice

pharmacist is unable to provide proof of completing 10 hours of continuing education when audited, his or her license should be placed on inactive status.

Recent Update
Following the committee meeting, board staffed work with legal counsel to draft language based on the committee's direction. The language will be provided at the board meeting for discussion and consideration.

h. Licensing Statistics

Attachment 4

The board is currently processing all licensing applications in under 30 days. In addition, the average processing time for evaluating deficiency mail is within 18 days.

Licensing Statistics for July 1, 2017 – March 31, 2018

In fiscal year 2017/2018, the board has received 10,584 initial applications, including:

- 2,024 intern pharmacists.
- 1,450 pharmacist exam applications.
- 192 advanced practice pharmacists.
- 3,850 pharmacy technicians.
- 1 outsourcing facility.
- 6 nonresident outsourcing facilities.

As of March 31, 2018, the board has issued 8,834 licenses, renewed 48,664 licenses and has 139,934 active licenses, including:

- 7,008 intern pharmacists.
- 45,931 pharmacists.
- 279 advanced practice pharmacists.
- 71,589 pharmacy technicians.
- 6,644 pharmacies.
- 503 hospitals and exempt hospitals.
- 15 nonresident outsourcing facilities.
- 2 outsourcing facilities

i. Future Committee Meeting Dates

Provided below are Licensing Committee meeting dates through the remainder of 2018:

- June 26, 2018
- September 26, 2018

Attachment 1

California State Board of Pharmacy Licensing Committee Meeting April 19, 2018

MAIL ORDER PHARMACIES Consumer Surveys

Thomas Lenox

Chief of Enforcement

CALIFORNIA STATE BOARD OF PHARMACY

Presentation Topics

- Patient Consultation
- Translation Services

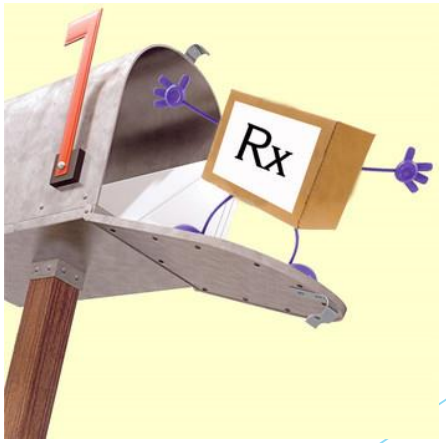
Mail Order Pharmacies Random Consumer Surveys

- 27 Total Consumers complaints involving Mail Order Pharmacies reviewed by staff
- **13 Consumers were directly contacted by staff**
- 5 cases were already completed and inspector had no immediate access to consumer contact info – reviewed reports
- 4 Cases contact attempted but no response or anonymous with no contact information available
- 4 were non-medication related
  - Billing, prescriber issues,
- 1 Case was from a prescriber (recently received pending assignment)

Mail Order Pharmacies

Three national Mail Order Pharmacies were identified during the survey

- Pharmacy 1 = 13 complaints
- Pharmacy 2 = 7 complaints
- Pharmacy 3 = 7 complaints



Survey Question

1. How often had the consumer (complainant) contacted the mail order pharmacy for follow up information/questions on a prescription already received?

2. How did they make contact; via phone, email?

3. When they called, who did they typically speak with?
   a. A Pharmacist? A service rep, a pharmacy tech?

4. Did they called to speak to a pharmacist?

5. If they needed/asked to speak with a pharmacist, on average how long did it take for them to speak with a pharmacists?

6. Did they speak with a Pharmacist during the call or did they have to wait for a return call?

Survey Questions
Translation Service

- Was there any difficulty in communicating with the company?
- Had they ever requested to speak with someone in a language other than English?
- Was it (translation services) ever offered to them?

Responses

1. ***How often had the consumer(complainant) contacted the mail order pharmacy for follow up information/questions on a prescription already received?***

Case 1: Consumer contacted them several times when the meds were not received on promised date. This was the first complaint, had no issues prior to this complaint.

Case 2: Consumer contacted them 4-5 times when the meds were not received on promised date. Seems to be the problem with only one medication.

Case 3: Consumer contacted them when the meds were not received. This was the second complaint, previous complaint related to pharmacy auto refilling her husband's medication.

Case 4: Consumer said that for non-specialty medication - only a few times. But with regard to my immune suppressant prescriptions that were sent in on about January of 2018 - I contacted them maybe 10 times in an effort to get those vital prescriptions sent to me in a timey fashion.

Case 5: Consumer stated she made hundreds of call to pharmacy and emphasized she was not exaggerating. She said the mail order pharmacy caused her a lot of stress and anxiety. She was so frustrated with them and in tears after the call. She felt invisible as if she wasn't speaking or getting through to anyone.

Responses

1. ***How often had the consumer (complainant) contacted the mail order pharmacy for follow up information/questions on a prescription already received?***

Case 6: Consumer contacted them 5-8 times in the last 2 and half months.

Case 7: Consumer has never contacted for information or question regarding a prescription already received.

Case 8: Two times. Once I called them and once they called me.

Case 9: On one incident about 50 plus times!

2. How did the consumer make contact, via phone, email?

Phone: 8

Email/Website/Account: 3

Both Email/Phone: 2

Responses

3. When the consumer called, who did they typically speak with?

Pharmacy Technician: 1 Service Representative: 10 Pharmacist: 2

Do Not Who they are speaking with: 2 (1– online/ 1 on phone)

<u>Related Comments:</u>

Service representative until she was able to get the direct line to the pharmacist.

"*I finally pushed my way through to get to a pharmacist. Once I talked to the pharmacist, she immediately understood what I was talking about regarding the number of vials of Insulin they were sending and how the vial was expiring at 28 days, but they were calculating the days' supply as to how much volume was in the vials."*

Consumer explained the customer service rep would shove her around everywhere and transfer her calls to Texas, Florida, Las Vegas.

From an Inspector: There were cases I worked where the pharmacist in charge (PIC) or director got personally involved and contacted the complainant when I started the investigation. In those cases the PIC became aware for the first time, since often these issues seem to stop at the customer service level.

Responses

4. Had they called to speak to a pharmacist?

No – 9
Yes – 4

5. If the consumer needed/asked to speak with a pharmacist, on average how long did it take for them to speak with a pharmacists?

Usually the call is routed to a customer service representative until she got the direct line.

Called to speak with someone about his complaint and was on hold for 15-20 min before deciding to hang up

It feels like there are a number of bureaucratic levels to get through to get a pharmacist.

Hours – days

Responses

6. Did the consumer speak with a Pharmacist during the call or did they have to wait for a return call?

Initially yes, unit she got the direct line to the pharmacist.

The complainant stated she had so many problems that she does not remember who called or when. She stated she never wants to deal with them and had suffered a lot because of them.

Most often a return call.

When he finally spoke with the pharmacist, the problem was understood and was fixed without a problem. However, by the time he talked to the pharmacist, he had had enough and registered his complaint with us.

Translation Questions

- Was there any difficulty in communicating with the company? NO
- Had the consumer ever requested to speak with someone in a language other than English? NO
- Had it (translation service) ever been offered to them? NO

Additional Consumer Comments

1. The individual I spoke with each time promised expedited delivery which did not subsequently occur on all but one of those occasions - which I finally received the medication.
2. She felt invisible as if she wasn't speaking or getting through to anyone. She stated, "they were negligent, uncaring, lie all the time and ruined her health." She believes the stress from interacting with them caused her heart attack.
3. He stated it is difficult to get a response from his online communications, but that is the method the pharmacy prefers.
4. Some insurance companies do not give patients a choice of mail order services. If they want to have $0 co-pay, they must use the one specified mail order service.
5. Complainant has cancelled his prescriptions with the Mail Order Pharmacy on two different occasions, but still had auto-refills mailed to him. Complainant was asked to mail back the prescriptions at his own expense (he refused). He was not able to use another pharmacy to fill his prescriptions until the Mail Order Pharmacy received the prescriptions they mailed him in error AND credited them back.
6. The people that answer the 800 number are never helpful or knowledgeable. Consumer always has to ask for a supervisor or manager, and then sometimes still has to escalate the issue higher.
7. ***From a prescriber***: Mail Order pharmacy provides the wrong medication, when he does speak with a Pharmacist, they will not provide their name or license number and have hung up on him. They are not helping him to care for his patients who must use the Mail Order pharmacy

QUESTIONS?

CALIFORNIA STATE
BOARD OF PHARMACY

THANK YOU

§ 1707.2. Duty to Consult.
16 CA ADC § 1707.2
BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations Currentness
Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 2. Pharmacies (Refs & Annos)
16 CCR § 1707.2

§ 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:

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

(B) 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.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) 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, Business and Professions Code. Reference: Sections 4005, 4076 and 4122, Business and Professions Code.

HISTORY

1. Renumbering and amendment of former section 1707.1 to section 1707.2 filed 8-10-90; operative 3-1-91 (Register 90, No. 39).
2. Request for change in operative date to 1-1-92 pursuant to Government Code section 11346.2 filed 1-11-91; operative 1-11-91 (Register 91, No. 6).
3. Request for change in operative date to 11-1-92 filed 12-23-91 as an emergency; operative 12-23-91 (Register 92, No. 11). A Certificate of Compliance must be transmitted to OAL 4-21-92 or emergency language will be repealed by operation of law on the following day.
4. Certificate of Compliance as to 12-23-91 order transmitted to OAL 4-21-92 and filed 5-28-92 (Register 92, No. 22).
5. Amendment filed 3-12-93; operative 4-12-93 (Register 93, No. 11).
6. Editorial correction of subsections (b)(1)(A) and (f) (Register 95, No. 16).
7. Amendment of subsections (b)(3)-(c) and (f) and amendment of Note filed 8-8-2002; operative 9-7-2002 (Register 2002, No. 32).
8. New subsection (g) and amendment of Note filed 10-31-2007 as an emergency; operative 11-30-2007 (Register 2007, No. 44).
9. Amendment of section heading, repealer of subsections (f) and (g) and amendment of Note filed 1-17-2012; operative 2-16-2012 (Register 2012, No. 3).

This database is current through 11/24/17 Register 2017, No. 47
16 CCR § 1707.2, 16 CA ADC § 1707.2

Excerpt from the February 2018 Draft Board Meeting Minutes

Discussion and Consideration of Patient Consultation Requirements for Mail Order Pharmacies or Nonresident Pharmacies

Chairperson Weisser explained that BPC Section 4112 establishes the licensing requirements for a nonresident pharmacy. Further, as part of this section, Subdivision (h) requires the board adopt regulations that apply the same requirements for oral consultation for medications dispensed for such pharmacies.

Chairperson Weisser noted that CCR Section 1707.2 establishes the duty of a pharmacist to provide oral consultations to his or her patient in all care settings under specified conditions.

Chairperson Weisser reported that at the January 16 meeting committee discuss consultation requirements for nonresident pharmacies and other mail order pharmacies. As part of its discussion the committee considered:

- Are the current requirements for mail order and nonresident pharmacies sufficient to ensure patients have access to a pharmacist for consultation?
- How can mail order and nonresident patients be advised that they have the right to translation services? Are existing requirements sufficient?
- Are patients of mail order and nonresident pharmacies receiving appropriate consultation?
- Does the board need to treat mail order pharmacies and nonresident pharmacies differently if they both ship medication to patients?
- Should the board promulgate regulations for nonresident pharmacies consistent with the provisions of Business and Professions Code section 4112(h)?

Chairperson Weisser stated that the committee discussed the number of complaints the board receives each year involving mail order pharmacies and how patients are advised of their right to have translation services available. The committee also heard from representatives of mail order pharmacies that detailed their business models and how their respective companies provide oral consultation.

Chairperson Weisser reported that the committee made the following motion.

Committee Recommendation (Motion): Direct staff to amend CCR Section 1707.2(b)(1) and 1707.2(b)(2)(B) as follows:

…

1707.2(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:

…

1707.2 (b)(2)(B) a telephone number shall be provided to the patient from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record. The pharmacists shall be available to speak to the patient no less than six days per week, and for a minimum of 40 hours per week and the call shall be answered by a pharmacist within two minutes.;

Chairperson Weisser stated that the committee also directed staff to draft proposed language requirement patient notification of the availability of translation services and patient notification of how to file a complaint with the board of pharmacy.

President Gutierrez asked where the committee determined that calls shall be answered by a pharmacist within two minutes. Mr. Weisser stated that the committee wanted to ensure that patients are able to reach a pharmacist quickly. President Gutierrez stated that even when a patient calls a regular pharmacy they experience

a long wait time and recommended removing a time frame.

Ms. Veale stated that as written the language would apply not only to mail order pharmacies, it would apply to *all* pharmacy settings.

The board discussed modifying the language to say that a pharmacist must be available during normal business hours.

Mr. Weisser asked if the board wants to address the fact that patients are on hold for long periods of time without being able to speak to a pharmacist. President Gutierrez stated that consumers can file a complaint with the board.

Mr. Herold explained that she recently called a mail order pharmacy and was unable to speak to a pharmacist. She added that the board received complaints from patients whose therapy was delayed because they could not speak to a pharmacist.

President Gutierrez recommended that the board require that mail order pharmacies provide notice to patients that a pharmacist is available during normal business hours.

Ms. Freedman read Business and Professions Code section 4112(f) as follows and explained that the requirements in the section only apply to pharmacies located outside of California.

4112(f): Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

Mr. Brooks asked if the board had any authority to discipline a mail order pharmacy for keeping a patient on hold too long before they can talk to a pharmacist. Mr. Herold responded that currently there is no law that the board could use to discipline a mail order pharmacy for having a patient on hold for too long.

Ms. Veale stated that she has seen reports that show that mail order pharmacy enrollment is not increasing, rather it is remaining flat. She added that the quality of patient care provided by mail order pharmacies has improved over the years.

Dr. Wong stated that he would like there to be a direct phone number for patients to reach a pharmacist immediately.

Ms. Veale stated that the committee needs to be mindful that these new requirements could also apply to other pharmacy settings.

President Gutierrez recommended that the committee discuss the issue again and look at how other states regulate mail order pharmacies.

The board asked the committee to discuss how long a patient should have to wait to talk to a pharmacist and how the board could enforce a timing requirement.

The board also asked that the committee discuss the possibility of requiring the mail order pharmacy to proactively reach out the patients to provide a consultation for all new or modified prescriptions.

Attachment 2

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PEER REVIEW

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Pharmacy Law Updates 2017

Seminar 2017

Clinical Pearls
Ethics: A Problem in Pharmacy?

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Ethics: A Problem in Pharmacy?

Keith I. Yoshizuka, PharmD, MBA, JD, FCSHP

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What's the big deal about ethics in pharmacy? Isn't ethics simply the discipline dealing with what is right and wrong and with moral duty and obligation?[1] The American Pharmacists Association even has its own Code of Ethics.[2] The evidence suggests that, on occasion, ethics is a problem with pharmacists. The June 2017 edition of the California State Board of Pharmacy Newsletter, *The Script*, lists 27 pharmacists who were subject to disciplinary action by the Board, and **were required to take a course in ethics within 60 calendar days of the hearing as a condition of keeping their license to practice pharmacy.**[3] The requirements for such a course are codified in the California Code of Regulations §1773.5.[4] Isn't ethics simply the discipline dealing with what is right and wrong and with moral duty and obligation?[5]

Contemporary biomedical ethics is largely based upon the model presented by Beauchamp and Childress in 2001 known as the "Georgetown Mantra," which is based on four basic principles[6]:

- Beneficence
- Non-malfeasance
- Respect for autonomy
- Justice

Beneficence is the act of doing good, such as an act of kindness or charity. Derived from the root word benefit, it means to bring or create benefit for others. It is altruism in its purest sense. The corollary to bringing or creating benefit is to protect from harm or evil. The ethical pharmacist has a duty to do good for the patient.

Non-malfeasance is the act of refraining from doing harm. Non-malfeasance is the foundation for the maxim found in the Hippocratic Oath, "first, do no harm," or *primum non nocere*.[7] The underlying principle is to refrain from causing pain, suffering, or loss of life. The pharmacist has an ethical duty not to leave the patient worse off than before the treatment. This ethical obligation has historically functioned as a barrier to physician-assisted suicide but in furtherance of evolving societal concerns has been subordinated to other ethical considerations for autonomy and justice discussed below (see also, California's End of Life Options Act, Codified under Health and Safety Code §433 et seq.). An example of this might be a terminally ill patient not expected to live beyond one year who will have to endure pain and loss of dignity as he/she loses control of normal bodily functions. Such a person may now choose to end his/her life to avoid the pain and humility until inevitable demise. The patient has a right to choose to end his/her life with the assistance of health professionals who may provide medications to accomplish this. This places the pharmacist and other health care professionals in an ethical dilema as it creates a conflict between ethical mandates: non-malfeasance versus the respect for autonomy.

Respect for autonomy is to honor that the patient has the right to choose for him or herself according to the individual's beliefs and values. This principle not only requires the professional to respect the individual's right to determine their own course of therapy but to do so in an informed fashion. It implies that the patient receives full disclosure of the potential benefits and risks of the therapy. It is the foundation for the concept of informed consent (besides avoidance of the risk of being accused of the tort of battery). The inference is that in providing this disclosure, that the pharmacist will also respect the privacy and maintain the confidentiality of the information on behalf of the patient.

Justice refers to the doctrine of fairness and equitable treatment. It deals with the equitable distribution of social benefits and burdens. Theories of justice in bioethics are divided into the theories of utilitarian, egalitarian, and libertarian.[8] All of the theories propose a system of just distribution of benefits and burdens equally without bias or preference. The ethical pharmacist is duty bound to allocate the benefits of drug therapy in a just manner based on objective criteria and not influenced by personal preference or bias.

Others have divided the ethical principles according to whom the duty relates to, such as that owed to the consumer, the community, the profession, the business, and the wider healthcare team.[9] Although there is logic to identifying these duties by stakeholder, the practitioner is left to prioritize these duties on their own to resolve an ethical dilemma.

Other academicians propose a psychological theory of cognitive moral development (CMD), which is based upon an individual's progression through various mental stages of moral development over time.[10] Kohlberg identifies three levels of moral development, with two sub-stages within each level, as:

1) pre-conventional morality, where decisions are made based on what is best for them, with stage 1 consisting of punishment avoidance and obedience and stage 2 being exchange of favors;

2) conventional morality, where decisions are made to please others, especially authority figures and persons with higher status, with stage 3 seeking positive feedback or compliments, and stage 4 consisting of law and order; and

3) post-conventional morality, where decisions are made based upon an abstract principle, with stage 5 reflecting a social contract, and stage 6 being universal ethical principle.[11]

Again, this theory places moral development into "developmental categories" but does not provide the practitioner with any guidance to resolve an ethical dilemma encountered in daily practice. Ethical cognition can, however, differentiate between a good and a not-so-good pharmacist and can help educators with instilling educational values. This is of value to academicians who are educating pharmacy students before they become practicing clinicians.

These concepts seem basic enough for pharmacists to follow, but the problems may arise when there are conflicts between moral duty and obligations. These moral dilemmas arise when two or more conflicting issues arise out of a single situation. An example might be when a woman seeking to purchase emergency contraception approaches a pharmacist who subscribes to strict Catholic beliefs regarding abortion and contraception. The pharmacist is faced with the ethical dilemma of pitting the adherence to his religious beliefs versus his duty to the woman as a patient who is seeking him out as a health professional for treatment. Sometimes these dilemmas involve money. Pharmacists have long been challenged between economic and medical/professional motivations in their daily practice, because of the role of the pharmacist as healthcare providers and as business managers.[12] One study demonstrated that pharmacists are aware of the ethical issues and possess the practical skills required to resolve the issues,[13] and another study linked community pharmacists' moral reasoning with clinical performance, showing that pharmacists with a higher capacity for moral reasoning demonstrated a higher level of clinical performance.[14] However, it appears that the longer a pharmacist is employed in a community setting, application of moral reasoning appears to erode.[15] This may be due in part to the "commercialization" of healthcare, and the conflicting obligations of duty to the employer for profitability and managing affordability with beneficence and the other elements of the "Georgetown Mantra."[12]

Pharmacists are faced with ethical challenges daily in their practice.[16] Sometimes the question is not whether or not to dispense but involves managing noncompliant patients.[17] The pharmacist notices that a man is noncompliant with his antihypertensive medications. Upon inquiry, the man admits that he stopped taking the medication because of the erectile dysfunction side effect of the drug. Although the pharmacist is bound by the duty of beneficence, the pharmacist is also bound by the obligation to respect autonomy and self-determination. After a detailed explanation of the consequences, it is ultimately up to the patient to determine whether or not to continue the treatment. Hospital pharmacists are not exempt from these challenges and, in fact, may be subjected to additional challenges, such as being faced with financial constraints or chronic drug shortages.[18] For example, at the time of writing this paper, there is a national shortage of sodium bicarbonate for injection. How is the determination made as to which acidotic patients receive infusions containing bicarbonate? Of course, the

resolution must be determined by an inter-professional group who develop objective guidelines based on clinical criteria, so that the allocation of the scarce resources may be carried out fairly. The issue of ethics in hospital pharmacy practice is not isolated to the United States; in 2014, there was a worldwide pharmacy meeting to discuss the future of hospital pharmacy practices and ethics.[19]

Of course, no discussion of ethics could be complete in the 21st century without a discussion of professional ethics as they relate to social media. Individuals will cite their rights of freedom of speech based upon the first amendment of the Constitution; however, the first amendment only prevents the government from infringing speech. Even the government as an employer can place restrictions as a condition of employment.[20] In the case of McAuliffe v. Mayor of New Bedford, a policeman was terminated from the job for soliciting for political contributions, a violation of police regulations. The policeman initiated a lawsuit to be reinstated because the police regulation was an infringement upon his right to free speech, and political speech is among the category of speech deserving the most protection. The court ruled against the policeman's reinstatement, and in his opinion, Justice Holmes stated, "The petitioner may have a constitutional right to talk politics, but he has no constitutional right to be a policeman."[21]

In this age of social media, it is tempting to share frustrations at work with one's friends on social media. In doing this, extreme care must be taken so as not to violate HIPAA. Even if the identity of the patient could not be discerned, the employer would not be pleased upon seeing one of their pharmacists complaining about patients or making fun of customers in a public forum. This reflects poorly on the company, and the employer could very convincingly argue that such actions would dissuade customers from using not only that pharmacy but the entire pharmacy chain. Some of the postings on social media may run afoul of the ethical principle of non-malfeasance by doing harm to either the subject being complained about or ridiculed or injury to the reputation and standing in the community of the employer.

Faced with these ethical dilemmas, pharmacists and students alike often seek one "right" answer. Therein lies a significant challenge; there is no single "right" answer. Between the good and the bad, there lies an infinite number of shades of gray.[22]

An ethical dilemma, by definition, is the conflict between two different ethical principles which are mutually exclusive. A decision made by an individual practitioner may vary based upon that individual's personal beliefs, moral conviction, and value systems. To make the issue more complex, the goals and priorities of employers may conflict with the individual practitioner's values. Society provides us with some guidance by way of passing laws and regulations to facilitate in our decision-making when faced with these conflicts.[23] One such example is California Business & Professions Code §733(b)(3), which provides the procedures to be followed if a pharmacist refuses to fill an order or prescription based on ethical, moral, or religious grounds.[24] However, laws and regulations will not cover all the ethical dilemmas encountered by the pharmacist in his/her daily practice.

One strategy to develop ethics awareness and skills in practitioners is to provide additional training. The California State Board of Pharmacy adopted a new regulation to require that a portion of the mandatory continuing education hours required for licensure renewal be carved out such that two hours involve a course in ethics and pharmacy law. This is not unusual, as a portion of the

An ethical dilemma, by definition, is the conflict between two different ethical principles which are mutually exclusive.

continuing education hours for attorneys in California has always included mandatory training in ethics, substance abuse, and elimination of bias for licensure renewal. Given the trend in accreditation of schools and colleges for the health professions, it would not be unreasonable to have these programs offered in an inter-professional format.[25] Professionals from different disciplines facing the same ethical challenge from different perspectives are reflective of what occurs in real life, so it makes sense that training in ethics should also occur in an inter-professional venue. With additional training, pharmacists should be able to navigate the challenges of ethical dilemmas encountered in practice by being able to identify and categorize the issues that they are facing, and then arrive at a rational conclusion based upon prioritization of ethical principles.[26]

In conclusion, it appears that ethics, or the lack or attenuation thereof, is an important issue facing practicing pharmacists today. There are both statutory and regulatory provisions to support the requirement of ongoing education and training in ethics. Evidence of formal disciplinary actions by the California State Board of Pharmacy faced requiring pharmacists to take a formal course in ethics as a condition of retention of licensure is sufficient to demonstrate that pharmacists are deviating from the expectations consistent with ethical behavior. Periodic review of the principles of beneficence, non-malfeasance, autonomy, and justice would benefit pharmacists in practice, as evidence infers that a pharmacist's moral reasoning erodes with time. Additional training in ethics may be beneficial to the practicing pharmacist, particularly since there is evidence to support that pharmacists with a higher capacity for moral reasoning demonstrated a higher level of clinical performance. Faced with professionals committing ethical breaches compromising their license and the dilemmas created by the commercialization of healthcare, the California State Board of Pharmacy is warranted in their requirement that a portion of the 30 hours of continuing education required for continued licensure be grounded in the training of ethics. ○

About the Author

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Disclosures

The author has declared that he serves as a consultant for the California State Board of Pharmacy and the Drug Enforcement Administration.

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Notes from Lorie Rice, Former Board Executive Officer and UCSF School of Pharmacy Professor

- Codification via law and regulation typically provides black and white parameters for behavior.

- Ethics is the gray area between the two.

- At the Board of Pharmacy, where consumer protection is the board's overriding mandate, the focus is what is the best thing to do for the patient.

- Typically, law and ethics are partners, but can law and ethics ever conflict?

- The board states that the addition of ethics to the required CE program is necessary to ensure that pharmacists have continuing education on pharmaceutical ethics and the importance of public safety.

- As the profession expands into the area of professional services, there will be greater need for pharmacists to rely on ethical decisions rather than exclusively application of dispensing laws.

- Some examples:

    - Situations regarding life and death
    - Situations regarding rationing
    - Situations regarding justice
    - Situations regarding truthfulness

§ 1773.5. Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

(a) The board will consider for approval an ethics course that at minimum satisfies the following requirements:

(1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.

(2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.

(3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.

(4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.

(5) Content. The course shall contain all of the following components:

(A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.

(B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.

(C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.

(D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.

(E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.

(F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.

(6) Class Size. A class shall not exceed a maximum of 12 participants.

(7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.

(8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.

(9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the case or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Attachment 3

Business and Professions Code section 4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(a) The board may license as a pharmacist an applicant who meets all the following requirements:
  (1) Is at least 18 years of age.
  (2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or
  (B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.
  (3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.
  (4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.
  (5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.
  (6) Has passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.
(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.
(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

Business and Professions Code section 4200.3. Examination Process to be Reviewed Regularly; Required Standards

(a) The examination process shall be regularly reviewed pursuant to Section 139.
(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Professional Examination Services of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.
(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.
(d) The board shall work with the Office of Professional Examination Services or with an equivalent organization to develop the state jurisprudence examination to ensure

that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection and the department as part of its next scheduled review, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

Business and Professions Code section 139

(a) The Legislature finds and declares that occupational analyses and examination validation studies are fundamental components of licensure programs. It is the intent of the Legislature that the policy developed by the department pursuant to subdivision (b) be used by the fiscal, policy, and sunset review committees of the Legislature in their annual reviews of these boards, programs, and bureaus.

(b) Notwithstanding any other provision of law, the department shall develop, in consultation with the boards, programs, bureaus, and divisions under its jurisdiction, and the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners, a policy regarding examination development and validation, and occupational analysis. The department shall finalize and distribute this policy by September 30, 1999, to each of the boards, programs, bureaus, and divisions under its jurisdiction and to the Osteopathic Medical Board of California and the State Board of Chiropractic Examiners. This policy shall be submitted in draft form at least 30 days prior to that date to the appropriate fiscal, policy, and sunset review committees of the Legislature for review. This policy shall address, but shall not be limited to, the following issues:

(1) An appropriate schedule for examination validation and occupational analyses, and circumstances under which more frequent reviews are appropriate.

(2) Minimum requirements for psychometrically sound examination validation, examination development, and occupational analyses, including standards for sufficient number of test items.

(3) Standards for review of state and national examinations.

(4) Setting of passing standards.

(5) Appropriate funding sources for examination validations and occupational analyses.

(6) Conditions under which boards, programs, and bureaus should use internal and external entities to conduct these reviews.

(7) Standards for determining appropriate costs of reviews of different types of examinations, measured in terms of hours required.

(8) Conditions under which it is appropriate to fund permanent and limited term positions within a board, program, or bureau to manage these reviews.

(c) Every regulatory board and bureau, as defined in Section 22, and every program and bureau administered by the department, the Osteopathic Medical Board of California, and the State Board of Chiropractic Examiners, shall submit to the director on or before December 1, 1999, and on or before December 1 of each subsequent year, its method for ensuring that every licensing examination administered by or pursuant to contract with the board is subject to periodic evaluation. The evaluation shall include (1) a description of the occupational analysis serving as the basis for the examination; (2) sufficient item analysis data to permit a psychometric evaluation of the items; (3) an assessment of the appropriateness of prerequisites for admittance to the examination; and (4) an estimate of the costs and personnel required to perform these functions. The evaluation shall be revised and a new evaluation submitted to the director whenever, in the judgment of the board, program, or bureau, there is a substantial change in the examination or the prerequisites for admittance to the examination.

(d) The evaluation may be conducted by the board, program, or bureau, the Office of Professional Examination Services of the department, the Osteopathic Medical Board of California, or the State Board of Chiropractic Examiners or pursuant to a contract with a qualified private testing firm. A board, program, or bureau that provides for development or administration of a licensing examination pursuant to contract with a public or private entity may rely on an occupational analysis or item analysis conducted by that entity. The department shall compile this information, along with a schedule specifying when examination validations and occupational analyses shall be performed, and submit it to the appropriate fiscal, policy, and sunset review committees of the Legislature by September 30 of each year. It is the intent of the Legislature that the method specified in this report be consistent with the policy developed by the department pursuant to subdivision (b).

(Amended by Stats. 2009, Ch. 307, Sec. 1. (SB 821) Effective January 1, 2010.)

Attachment 4

Board of Pharmacy Licensing Statistics - Fiscal Year 2017/18

APPLICATIONS

Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	45	53	37	33	31	40	33	41	46				359
Designated Representatives Vet (EXV)	2	0	0	0	0	0	0	0	0				2
Designated Representatives-3PL (DRL)	4	9	6	7	6	8	6	7	6				59
Intern Pharmacist (INT)	239	623	405	346	51	50	119	97	94				2024
*Pharmacist (exam applications)	203	168	168	189	134	102	163	132	191				1450
Pharmacist (initial licensing applications)	68	202	710	328	190	31	137	44	93				1803
Advanced Practice Pharmacist (APH)	33	12	22	18	13	21	20	23	32				194
Pharmacy Technician (TCH)	368	513	418	433	384	391	459	387	497				3850
	* total includes retake exam applications												
Centralized Hospital Packaging (CHP)	0	0	0	2	0	0	0	0	0				2
Clinics (CLN)	4	8	14	14	6	1	2	6	7				62
Clinics Exempt (CLE)	0	0	1	2	1	3	0	1	0				8
Drug Room (DRM)	0	0	0	0	0	0	0	0	0				0
Drug Room -Temp	0	0	0	0	0	0	0	0	0				0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0				0
Hospitals (HSP)	0	0	5	1	5	7	0	0	2				20
Hospitals - Temp	0	0	6	0	2	6	0	1	0				15
Hospitals Exempt (HPE)	0	1	0	0	1	0	0	0	0				2
Hypodermic Needle and Syringes (HYP)	0	4	0	0	0	6	1	1	0				12
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0				0
Correctional Pharmacy (LCF)	0	1	0	0	1	0	0	0	0				2
Outsourcing Facility (OSF)	0	0	0	0	0	0	0	1	0				1
Outsourcing Facility - Temp	0	0	0	0	0	0	0	0	0				0
Outsourcing Facility Nonresident (NSF)	1	1	1	1	2	0	0	0	0				6
Outsourcing Facility Nonresident - Temp	0	0	0	0	0	1	0	0	0				1
Pharmacy (PHY)	39	41	52	35	50	27	29	32	32				337
Pharmacy - Temp	14	9	29	10	30	12	12	9	9				134
Pharmacy Exempt (PHE)	0	0	0	2	0	1	0	1	0				4
Pharmacy Nonresident (NRP)	16	11	15	10	16	4	9	12	12				105
Pharmacy Nonresident Temp	5	1	7	2	8	4	4	5	6				42
Sterile Compounding (LSC)	2	4	20	7	21	13	2	6	10				85
Sterile Compounding - Temp	0	0	17	1	6	8	0	3	0				35
Sterile Compounding Exempt (LSE)	1	1	0	1	2	0	0	0	0				5
Sterile Compounding Nonresident (NSC)	0	4	1	1	1	1	1	3	2				14
Sterile Compounding Nonresident Temp	0	1	2	1	0	1	1	1	1				8
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0				0
Third-Party Logistics Providers (TPL)	0	0	0	0	0	1	2	0	0				3
Third-Party Logistics Providers - Temp	0	0	0	0	0	1	0	0	0				1
Third-Party Logistics Providers Nonresident (NPL)	0	0	2	4	1	2	2	2	3				16
Third-Party Logistics Providers Nonresident Temp	0	0	1	3	1	1	0	1	0				7
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0				0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0	0	0	0				0
Wholesalers (WLS)	6	8	4	6	5	8	8	8	7				60
Wholesalers - Temp	3	4	0	2	3	3	2	4	2				23
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	1				1
Wholesalers Nonresident (OSD)	10	16	4	10	13	12	9	14	10				98
Wholesalers Nonresident - Temp	1	5	1	6	3	4	2	9	0				31
Total	1064	1700	1948	1475	987	770	1023	851	1063	0	0	0	10881

APPLICATIONS (continued)

Issued	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	26	18	39	19	29	61	34	28	25				279
Designated Representatives Vet (EXV)	0	0	2	0	0	0	0	0	0				2
Designated Representatives-3PL (DRL)	3	1	2	3	10	13	0	16	9				57
Intern Pharmacist (INT)	238	232	631	358	124	107	61	91	84				1926
Pharmacist (initial licensing applications)	109	228	691	311	103	145	89	76	41				1793
Advanced Practice Pharmacist (APH)	5	23	17	15	9	13	36	23	8				149
Pharmacy Technician (TCH)	616	609	397	474	287	359	374	459	389				3964
Centralized Hospital Packaging (CHP)	0	1	0	2	0	0	0	0	0				3
Clinics (CLN)	2	6	3	10	0	7	9	3	4				44
Clinics Exempt (CLE)	2	1	0	0	1	2	3	0	0				9
Drug Room (DRM)	0	0	0	0	0	0	0	0	0				0
Drug Room-Temp	0	0	0	0	0	0	0	0	0				0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0				0
Hospitals (HSP)	0	1	0	1	0	0	1	0	0				3
Hospitals - Temp	0	0	0	0	0	0	0	2	5				7
Hospitals Exempt (HPE)	0	2	0	0	0	0	0	0	0				2
Hypodermic Needle and Syringes (HYP)	2	0	1	1	0	0	0	0	0				4
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0				0
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	0				0
Outsourcing Facility (OSF)	0	1	0	1	0	0	0	0	0				2
Outsourcing Facility - Temp	0	0	0	0	0	0	0	0	0				0
Outsourcing Facility Nonresident (NSF)	1	0	3	0	1	3	0	1	3				12
Outsourcing Facility Nonresident - Temp	0	0	0	0	0	1	0	1	0				2
Pharmacy (PHY)	16	16	20	10	35	16	43	24	15				195
Pharmacy - Temp	16	10	10	5	4	28	8	11	10				102
Pharmacy Exempt (PHE)	0	0	0	1	0	0	1	1	0				3
Pharmacy Nonresident (NRP)	6	4	5	2	7	11	12	0	6				53
Pharmacy Nonresident Temp	2	2	1	1	2	12	8	3	5				36
Sterile Compounding (LSC)	1	3	2	0	0	9	3	2	4				24
Sterile Compounding - Temp	1	0	4	0	0	10	0	4	9				28
Sterile Compounding Exempt (LSE)	0	2	0	0	0	2	0	1	0				5
Sterile Compounding Nonresident (NSC)	2	1	0	0	0	3	0	0	0				6
Sterile Compounding Nonresident Temp	0	0	0	0	0	1	1	0	1				3
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0				0
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0	0	0	0				0
Third-Party Logistics Providers-Temp	0	0	0	0	0	1	0	0	0				1
Third-Party Logistics Providers Nonresident (NPL)	1	0	1	0	0	0	0	0	0				2
Third-Party Logistics Providers Nonresident Temp	0	0	0	0	1	0	3	1	1				6
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0				0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0	0	0	0				0
Wholesalers (WLS)	5	4	5	2	4	1	8	5	5				39
Wholesalers - Temp	0	1	0	0	1	1	2	1	4				10
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	1				1
Wholesalers Nonresident (OSD)	7	5	3	6	3	4	2	5	6				41
Wholesalers Nonresident - Temp	2	2	1	1	1	1	3	0	10				21
Total	1063	1173	1838	1223	622	811	701	758	645	0	0	0	8834

APPLICATIONS (continued)

Pending	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
Designated Representatives (EXC)	307	338	333	347	348	326	318	327	337			
Designated Representatives Vet (EXV)	3	3	1	1	1	1	1	1	1			
Designated Representatives-3PL (DRL)	78	86	92	94	92	88	97	88	85			
Intern Pharmacist (INT)	205	287	341	308	232	170	216	210	194			
Pharmacist (exam applications)	1424	1435	1811	1351	1306	1121	1060	962	880			
Pharmacist (eligible exam(Status A))	2261	2107	1257	1457	1368	1471	1424	1367	1354			
Advanced Practice Pharmacist (APH)	148	138	143	146	151	159	141	141	164			
Pharmacy Technician (TCH)	1407	1298	1266	1220	1325	1291	1361	1326	1173			
Centralized Hospital Packaging (CHP)	5	3	3	3	3	2	2	2	2			
Clinics (CLN)	42	43	54	58	63	57	49	52	55			
Clinics Exempt (CLE)	9	8	9	11	11	12	9	10	10			
Drug Room (DRM)	0	0	0	0	0	0	0	0	0			
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0			
Hospitals (HSP)	4	3	8	8	14	19	18	16	7			
Hospitals Exempt (HPE)	1	0	0	0	1	1	1	1	1			
Hypodermic Needle and Syringes (HYP)	7	10	9	8	8	14	17	18	18			
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0			
Correctional Pharmacy (LCF)	1	1	1	1	2	2	2	2	2			
Outsourcing Facility (OSF)	6	5	4	3	3	3	2	3	3			
Outsourcing Facility Nonresident (NSF)	29	29	27	30	29	26	22	21	15			
Pharmacy (PHY)	132	140	162	182	185	169	141	136	133			
Pharmacy Exempt (PHE)	1	1	1	2	2	3	2	2	2			
Pharmacy Nonresident (NRP)	105	103	111	105	112	88	75	82	84			
Sterile Compounding (LSC)	34	35	49	56	75	70	69	70	69			
Sterile Compounding - Exempt (LSE)	8	6	6	8	10	8	8	9	9			
Sterile Compounding Nonresident (NSC)	16	17	18	19	20	15	16	18	19			
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0			
Third-Party Logistics Providers (TPL)	8	8	8	8	7	7	9	9	9			
Third-Party Logistics Providers Nonresident (NPL)	43	42	43	46	46	48	46	47	47			
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	1	1	1	1	1	1			
Wholesalers (WLS)	37	40	38	42	42	48	47	47	46			
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0			
Wholesalers Nonresident (OSD)	82	90	88	92	100	106	107	114	108			
Total	6404	6277	5884	5607	5557	5326	5261	5082	4828	0	0	0

The number of temporary applications are included in the primary license type.

APPLICATIONS (continued)

Withdrawn	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	0	1	2	2	0	3	7	2	1				18
Designated Representatives Vet (EXV)	0	0	0	0	0	0	0	0	0				0
Designated Representatives-3PL (DRL)	0	1	0	1	0	0	1	0	0				3
Intern Pharmacist (INT)	0	2	0	1	0	0	0	1	1				5
Pharmacist (exam applications)	0	0	2	11	4	56	167	386	129				755
Advanced Practice Pharmacist (APH)	0	0	0	0	0	0	0	0	0				0
Pharmacy Technician (TCH)	8	8	4	5	7	18	13	8	241				312
Centralized Hospital Packaging (CHP)	0	1	0	0	0	1	0	0	0				2
Clinics (CLN)	0	0	0	1	0	0	0	0	0				1
Clinics Exempt (CLE)	0	0	0	0	0	0	0	0	0				0
Drug Room (DRM)	0	0	0	0	0	0	0	0	0				0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0				0
Hospitals (HSP)	0	0	0	0	0	1	0	0	1				2
Hospitals Exempt (HPE)	0	0	0	0	0	0	0	0	0				0
Hypodermic Needle and Syringes (HYP)	0	1	0	0	0	0	0	0	0				1
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0				0
Correctional Pharmacy (LCF)	0	1	0	0	0	0	0	0	0				1
Outsourcing Facility (OSF)	0	0	0	0	0	0	0	0	0				0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0	0	0	0	2				2
Pharmacy (PHY)	10	1	1	1	1	0	4	1	1				20
Pharmacy Exempt (PHE)	0	0	0	0	0	0	0	0	0				0
Pharmacy Nonresident (NRP)	2	2	1	15	1	4	2	0	0				27
Sterile Compounding (LSC)	0	0	0	0	0	0	0	0	0				0
Sterile Compounding Exempt (LSE)	0	1	0	0	0	0	0	0	0				1
Sterile Compounding Nonresident (NSC)	0	1	1	0	0	1	0	0	0				3
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0				0
Third-Party Logistics Providers (TPL)	0	0	0	0	1	0	0	0	0				1
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0	1	0	1				2
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0				0
Wholesalers (WLS)	3	1	0	0	0	1	0	0	0				5
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0				0
Wholesalers Nonresident (OSD)	0	0	0	0	0	4	3	0	0				7
Total	23	21	11	37	14	89	198	398	377	0	0	0	1168

The number of temporary applications withdrawn is reflected in the primary license type.

APPLICATIONS (continued)

Denied	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	0	1	0	0	0	0	0	0	0				1
Designated Representatives Vet (EXV)	0	0	0	0	0	0	0	0	0				0
Designated Representatives-3PL (DRL)	0	0	0	0	0	0	0	0	0				0
Intern Pharmacist (INT)	1	1	1	0	0	1	0	1	0				5
Pharmacist (exam applications)	1	1	2	0	1	1	0	0	0				6
Pharmacist (eligible)	0	0	0	0	0	0	0	0	0				0
Advanced Practice Pharmacist (APH)	0	0	0	0	0	0	0	0	0				0
Pharmacy Technician (TCH)	1	3	2	8	1	5	0	2	3				25
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0	0	0	0				0
Clinics (CLN)	0	0	0	0	0	0	0	0	0				0
Clinics Exempt (CLE)	0	0	0	0	0	0	0	0	0				0
Drug Room (DRM)	0	0	0	0	0	0	0	0	0				0
Drug Room Exempt (DRE)	0	0	0	0	0	0	0	0	0				0
Hospitals (HSP)	0	0	0	0	0	0	0	0	0				0
Hospitals Exempt (HPE)	0	0	0	0	0	0	0	0	0				0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0	0	0	0	0				0
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0				0
Correctional Pharmacy (LCF)	0	0	0	0	0	0	0	0	0				0
Outsourcing Facility (OSF)	1	0	1	0	0	0	0	0	0				2
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0	0	1	1	2				4
Pharmacy (PHY)	4	0	1	1	1	1	2	2	0				12
Pharmacy Exempt (PHE)	0	0	0	0	0	0	0	0	0				0
Pharmacy Nonresident (NRP)	0	3	0	0	0	0	0	0	1				4
Sterile Compounding (LSC)	1	0	0	0	0	0	0	0	0				1
Sterile Compounding Exempt (LSE)	0	0	0	0	0	0	0	0	0				0
Sterile Compounding Nonresident (NSC)	0	0	0	0	0	0	0	0	0				0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0	0	0	0				0
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0	0	0	0				0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0	0	0	0				0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0	0	0	0				0
Wholesalers (WLS)	0	0	0	0	0	0	0	1	0				1
Wholesalers Exempt (WLE)	0	0	0	0	0	0	0	0	0				0
Wholesalers Nonresident (OSD)	0	0	0	0	0	0	0	0	0				0
Total	9	9	7	9	3	8	3	7	6	0	0	0	61

RESPOND TO STATUS REQUESTS

A. Email Inquiries	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist/Intern Received	844	918	811	855	676	479	684	497	666				6430
Pharmacist/Intern Responded	630	759	608	682	487	355	665	452	446				5084
Designated Representative Received	N/A	N/A	N/A	N/A	97	98	201	147	144				687
Designated Representative Responded	N/A	N/A	N/A	N/A	9	40	100	63	82				294
Pharmacy Technician Received	463	417	187	354	479	297	444	316	636				3593
Pharmacy Technician Responded	620	295	226	144	505	225	290	261	402				2968
Pharmacy Received	187	738	314	720	717	490	663	470	594				4893
Pharmacy Responded	148	420	314	657	596	578	773	502	641				4629
Sterile Compounding/Outsourcing Received	160	207	393	407	373	397	532	368	417				3254
Sterile Compounding/Outsourcing Responded	40	238	225	173	201	269	862	454	457				2919
Wholesale/Clinic/Hypodermic/3PL Received	239	379	376	357	317	281	294	348	340				2931
Wholesale/Clinic/Hypodermic/3PL Responded	175	293	250	453	160	217	205	282	261				2296
Pharmacist-in-Charge Received	29	186	160	56	128	159	202	127	155				1202
Pharmacist-in-Charge Responded	53	141	117	31	90	138	197	101	88				956
Change of Permit Received	476	518	458	630	322	405	567	349	456				4181
Change of Permit Responded	338	346	383	424	242	423	603	303	365				3427
Renewals Received	305	490	504	560	452	370	454	438	434				4007
Renewals Responded	294	378	489	511	345	272	353	358	338				3338

B. Telephone Calls Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist/Intern	49	38	50	71	47	48	28	23	19				373
Designated Rep	N/A	N/A	N/A	N/A	N/A	N/A	2	0	0				2
Pharmacy	89	88	78	67	101	75	89	60	82				729
Sterile Compounding/Outsourcing	5	35	30	35	34	39	26	27	34				265
Wholesale/Clinic/Hypodermic/3PL	64	89	93	67	60	55	44	56	39				567
Pharmacist-in-Charge	53	97	74	82	70	62	62	49	49				598
Change of Permit	64	42	94	100	68	48	49	53	67				585
Renewals	449	667	765	696	719	587	706	581	557				5727

UPDATE LICENSING RECORDS

A. Change of Pharmacist-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	175	156	164	230	185	187	215	159	171				1642
Processed	209	190	128	207	215	161	191	266	103				1670
Approved	178	193	160	190	215	161	193	263	157				1710
Pending	284	249	260	303	273	282	232	185	199				199

B. Change of Desig. Representative-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	8	13	9	8	12	12	4	12	14				92
Processed	8	17	9	8	12	13	4	13	14				98
Approved	7	11	12	7	7	14	5	12	7				82
Pending	28	30	28	28	33	31	30	31	38				38

C. Change of Responsible Manager	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	4	1	1	1	1	1	2	2	2				15
Processed	3	1	1	2	1	1	0	4	1				14
Approved	2	1	1	3	0	2	0	4	0				13
Pending	7	7	6	4	5	4	6	4	6				6

D. Change of Permits	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	152	118	141	178	105	90	126	110	168				1188
Processed	225	107	204	108	60	202	192	69	131				1298
Approved	122	153	181	117	115	82	167	172	45				1154
Pending	942	899	876	953	943	952	911	848	970				970

E. Discontinuance of Business	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	23	50	22	47	32	23	44	23	31				295
Processed	18	66	33	28	26	47	31	30	9				288
Approved	25	53	42	21	23	43	23	24	12				266
Pending	120	118	100	125	134	114	120	123	141				141

F. Requests Approved	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Address/Name Changes	1215	1067	836	942	822	745	930	878	964				8399
Off-site Storage		84			14			24					122
Transfer of Intern Hours	10	3	1	6	4	9	8	4	2				47
License Verification	163	217	153	102	175	241	202	153	89				1495

Licenses Renewed

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	192	227	200	194	167	191	235	216	251				1,873
Designated Representatives Vet (EXV)	7	5	0	4	1	3	3	5	6				34
Designated Representatives-3PL (DRL)	17	22	25	17	12	16	9	10	13				141
Pharmacist (RPH)	1508	1749	2021	1725	1488	1762	1884	1384	1949				15,470
Advanced Practice Pharmacist (APH)	3	1	7	6	6	13	8	7	8				59
Pharmacy Technician (TCH)	2443	2434	2776	2560	2184	2357	2922	1940	3038				22,654
Centralized Hospital Packaging (CHP)	2	0	0	3	0	0	3	0	0				8
Clinics (CLN)	91	70	98	116	56	64	90	89	95				769
Clinics Exempt (CLE)	0	0	48	167	6	1	4	5	0				231
Drug Room (DRM)	3	1	1	3	2	1	1	2	4				18
Drug Room Exempt (DRE)	0	0	1	7	2	0	0	0	0				10
Hospitals (HSP)	28	21	21	82	20	25	38	37	33				305
Hospitals Exempt (HPE)	0	1	38	40	3	0	1	0	1				84
Hypodermic Needle and Syringes (HYP)	12	26	19	21	18	0	24	21	17				158
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0				0
Correctional Pharmacy (LCF)	0	0	23	33	1	0	0	0	0				57
Outsourcing Facility (OSF)	0	0	0	0	0	0	0	0	0				0
Outsourcing Facility Nonresident (NSF)	0	0	0	0	0	0	0	0	0				0
Pharmacy (PHY)	222	185	761	1117	552	279	676	172	835				4,799
Pharmacy Exempt (PHE)	0	0	66	49	4	0	1	0	1				121
Pharmacy Nonresident (NRP)	23	26	39	33	32	43	47	44	46				333
Sterile Compounding (LSC)	58	41	40	148	45	38	48	63	48				529
Sterile Compounding Exempt (LSE)	0	6	0	98	1	2	0	0	1				108
Sterile Compounding Nonresident (NSC)	6	1	3	10	3	12	4	4	3				46
Surplus Medication Collection Distribution Intermediary (SME)	0	0	1	0	0	0	0	0	0				1
Third-Party Logistics Providers (TPL)	2	1	3	2	0	1	5	0	2				16
Third-Party Logistics Providers Nonresident (NPL)	2	6	5	7	1	9	6	3	1				40
Veterinary Food-Animal Drug Retailer (VET)	1	1	0	2	2	3	0	0	2				11
Wholesalers (WLS)	43	38	45	35	31	43	23	34	41				333
Wholesalers Exempt (WLE)	1	0	7	4	1	0	1	0	0				14
Wholesalers Nonresident (OSD)	52	49	69	43	48	39	57	37	48				442
Total	4716	4911	6317	6526	4686	4902	6090	4073	6443	0	0	0	48664

Current Licensees

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	2963	2945	2984	2944	2935	2994	3021	2971	2967				2967
Designated Representatives Vet (EXV)	72	72	74	73	72	72	72	71	70				70
Designated Representatives-3PL (DRL)	256	256	258	258	260	273	273	279	286				286
Intern Pharmacist (INT)	6719	6866	6778	6878	6941	6928	6927	6966	7008				7008
Pharmacist (RPH)	44911	45052	45677	45890	45930	45984	4598	45969	45931				45931
Advanced Practice Pharmacist (APH)	140	169	173	191	199	212	248	271	279				279
Pharmacy Technician (TCH)	72579	72568	72413	72412	72172	72069	71876	71698	71589				71589
Centralized Hospital Packaging (CHP)	8	9	9	11	11	11	11	10	10				10
Clinics (CLN)	1100	1099	1097	1106	1105	1105	1112	1112	1115				1115
Clinics Exempt (CLE)	239	238	238	238	239	239	242	242	242				242
Drug Room (DRM)	23	23	23	23	23	23	23	23	23				23
Drug Room Exempt (DRE)	11	11	11	10	10	10	10	10	10				10
Hospitals (HSP)	395	394	392	393	393	391	391	385	386				386
Hospitals Exempt (HPE)	84	85	85	85	85	84	84	84	84				84
Hypodermic Needle and Syringes (HYP)	296	296	292	298	298	297	296	295	295				295
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0	0	0	0				0
Correctional Pharmacy (LCF)	59	59	59	59	58	58	57	57	57				57
Outsourcing Facility (OSF)	1	1	1	2	2	2	2	2	2				2
Outsourcing Facility Nonresident (NSF)	3	3	6	6	7	11	12	13	15				15
Pharmacy (PHY)	6471	6464	6459	6468	6474	6482	6498	6505	6519				6519
Pharmacy Exempt (PHE)	124	124	124	124	124	124	125	125	125				125
Pharmacy Nonresident (NRP)	535	533	534	532	529	535	544	542	547				547
Sterile Compounding (LSC)	765	760	757	751	745	750	752	751	754				754
Sterile Compounding Exempt (LSE)	116	117	117	115	115	115	115	116	116				116
Sterile Compounding Nonresident (NSC)	92	92	89	89	87	86	86	85	82				82
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	1	1	1	1	1	1				1
Third-Party Logistics Providers (TPL)	23	22	22	21	21	22	22	22	22				22
Third-Party Logistics Providers Nonresident (NPL)	67	62	63	64	65	64	64	64	64				64
Veterinary Food-Animal Drug Retailer (VET)	23	23	23	23	23	23	23	23	23				23
Wholesalers (WLS)	533	533	537	536	536	537	539	541	544				544
Wholesalers Exempt (WLE)	16	16	16	16	16	16	16	16	16				16
Wholesalers Nonresident (OSD)	745	745	754	746	746	749	746	745	752				752
Total	139370	139638	140066	140363	140222	140267	98786	139994	139934	0	0	0	139934