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

LICENSING COMMITTEE
CHAIR REPORT

Debbie Veale, Licensee Member, Chairperson
Lavanza Butler, Licensee Member, Vice-Chairperson
Jignesh Patel, Licensee Member
Albert Wong, Licensee Member

a. Discussion and Consideration of Legislative Proposal to Expand the Authority for Pharmacists to Order and Administer Immunizations Approved by the FDA to Prevent a Vaccine-Preventable Diseases

Relevant Law

Business and Professions Code (BPC) section 4052 (a)(11) provides the authority for a pharmacist to administer immunizations pursuant to a protocol with a prescriber.

Business and Professions Code (BPC) section 4052.8 establishes when a pharmacist may independently initiate and administer vaccines.

Background

As the nation and California continues to respond to the current pandemic, it is appropriate to determine if policy changes are necessary to ensure California is positioned to readily deploy vaccines once approved by the FDA in response to the current health crisis, but also in the future.

FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug (IND) application to the FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included is information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.

Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

Committee Discussion

During the meeting members spoke in support of a policy to expand authority for pharmacists to initiate and administer FDA approved vaccines. Further, the committee was advised of recently amended legislation, AB 1710 (Woods) seeking to facilitate such authority. Members and public discussed both the proposal provided for the committee's consideration and the broader approach being offered in the legislation. The committee directed staff to broaden the committee proposal to reflect a similar approach to AB 1710.

Further, as part of the meeting, public comment suggested that the policy proposal should allow pharmacists to order and administer immunization when a vaccine is authorized for use by the FDA versus when the FDA approves a vaccine.

Committee Recommendation: Move forward with broadening the statutory proposal to be consistent with the language in AB 1710 to administer vaccines that are approved by the FDA and to move forward with recommending to the full Board in July. Further, staff and the committee chair to work with legal counsel to modifying the language based on the policy direction discussed.

Recent Update
Subsequent to the meeting, staff amended the proposed amendments to BPC 4052.4 to incorporate the policy changes requested by the committee. Board staff recommends that the proposal establish authority for FDA approved vaccines.

Attachment 1 includes a copy of the draft proposal, a copy of AB 1710 and the Vaccine Product Approval Process produced by the FDA.

b. Discussion and Consideration of Pharmacists' Authority to Perform CLIA Waived Tests for COVID-19

Relevant Law
BPC 4052 (a)(12) establishes the authority for a pharmacist to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. As included in this provision, the pharmacist performing such functions must ensure such testing is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate.

BPC 4052.1 (a)(2) establishes the authority for a pharmacist to order drug therapy-related laboratory tests in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, as specified.

BPC 4052.2 (a)(2) establishes the authority for a pharmacist to order drug therapy-related laboratory tests as part of the care provided in a licensed health care facility, licensed home health agency, licensed correctional clinic, a licensed clinic with physician oversight, or other provider as specified, in accordance with the policies, procedures, or protocols of that facility, home health agency, etc.

BPC 4052.4 establishes the authority for a pharmacist to perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under BPC 1206.5 or BPC 1206.6. The section provides that "routine patient assessment procedures," includes CLIA waived tests as authorized under BPC 1206.5 and 1206.6.

BPC 1206.5 (a)(11) establishes the authority for a pharmacist to perform a clinical laboratory test or examination classified as waived under CLIA as long as the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel.

BPC 1206.6 provides authority for pharmacist at a community pharmacy who, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA in the course of performing assessments as provided in BPC 4052.4. This section also requires the pharmacy to obtain a CLIA certificate of waiver and comply with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. Further, the section provides that the pharmacist-in-charge (PIC) is responsible for directing and supervising testing oversight, decision making and ensures the pharmacy has obtained a registration as required by BPC 1265.

BPC 1265 establishes the licensing requirements for a clinical laboratory as specified. BPC 1265(k) provides authority for the PIC to serve as the laboratory director for registration required under BPC 1206.6.

Background

On May 12, 2020, DCA Director Kirchmeyer issued a waiver to allow for a pharmacist to order and administer COVID-19 tests in California. Along with the waiver, a guidance document was issued that provided additional details regarding the temporary authorities. It is important to note that the waiver does not allow for the processing of the sample at a pharmacy, unless the pharmacy is licensed as a clinical laboratory and meets all of the requirements of BPC 1265.

During the June 18, 2020, Board Meeting, members received public comment requesting a future agenda item to discuss the issue of pharmacists performing CLIA waived COVID-19 antigen testing. The commenter indicated that the current situation is rather murky in terms of whether a pharmacist is able to actually perform such a test as they have CLIA waived equipment and reagents. As part of the comments, members were advised that CDPH has determined that COVID-19 testing shall be performed only in an appropriately licensed lab under direction of a lab director.

Committee Discussion

During the meeting members considered relevant law establishing the authority for pharmacists to order and administer tests which reside in both provisions of Pharmacy Law as well as other provisions of the Business and Professions Code related to the operations of clinical laboratories and authorized staff under the regulation of the California Department of Public Health Laboratory Field Services.

The committee discussion noted that under the provisions of existing law, pharmacists' ability to perform CLIA waived tests are limited to specified tests, including provisions of BPC 4052.4 which provides authority for "pharmacists routine patient assessments procedures"; however, the provisions are limited to blood glucose, hemoglobin A1c, or cholesterol tests. These tests can also be processed at the pharmacy, if the pharmacy is appropriately licensed by the California Department of Public Health, Laboratory Field Services. Aside from the DCA approved waiver, there is no provision of law that allows for pharmacists to order, collect specimens, or process specimens for COVID -19 tests. Further, pharmacies, unless fully licensed as a clinical laboratory under Laboratory Field Services, cannot process specimens.

The committee received presentations on the current legal provisions, provisions for testing under the DCA Director issued waiver, and opportunities for expanded testing if additional authority could be granted to pharmacists. The committee was advised that 42 states allow pharmacists to perform end-to-end testing. Presenters requested the Committee and Board enhance advocacy efforts within the administration to facilitate broader authorities.

The committee spoke in support of such expansion and noted that cross jurisdictional issues would need to be resolved. The committee suggested engagement with DCA and CDPH is necessary to expand access to testing and to facilitate more robust use of point of care testing, that allows for more timely access to test results.

<u>Recent update</u>
Subsequent to the meeting, updated testing guidance was released by the California Department of Public Health (CDPH). As indicated in the guidance, CDPH recommends first prioritizing testing of hospitalized individuals with signs or symptoms of COVID-19 infection followed by testing of other symptomatic individuals and higher risk asymptomatic individuals and then other asymptomatic individuals when certain conditions exist. This guidance should be used for prioritization of patient populations as well as for the purposes of guiding laboratories in managing specimen processing.

Attachment 2 includes the relevant laws, DCA issued waiver, and guidance document related to the DCA issue waiver, and the recent CDPH testing guidance.

c. Update on Implementation of SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

<u>Relevant Law</u>

BPC 4052.02 provides the authority for a pharmacist to initiate and furnish HIV preexposure prophylaxis under specified conditions, including completion of a training program.

BPC 4052.03 provides the authority for a pharmacist to initiate and furnish HIV postexposure prophylaxis under specified conditions, including completion of a training program

California Code of Regulation (CCR), title 16, section 1747 establishes, via emergency regulation, the requirements for the training program required in the underlying statutes.

Committee Discussion

During the meeting members were provided an update on the status of the Board provided training program. The training program is being development in collaboration with subject matter experts, including experts from the Office of AIDS.

Consistent with the emergency regulations, a training program must either be approved by the Board or be provided by a provider accredited by an approved accreditation agency, including the Accreditation Council for Pharmacy Education or the California Pharmacists Association. The committee was advised that the California Society of Health Systems Pharmacists (CSHP) has completed development of a training program that will be offered on July 24, 2020. Members were advised that the training program is free and will be posted online following a few live training programs.

To date the Board has not received any requests for Board approval of training programs.

Attachment 3 includes a copy of the emergency regulation establishing the requirements for the training program required in the underlying statutes.

d. Discussion and Consideration of Proposal to Develop a Temporary Closure Status and Mandatory Notification Requirement for Board Licensed Sites

Background

For the past several years, typically in response to declared disasters, but also in response to construction issues, Board licensed businesses at times must temporarily close. More recently, regrettably, a significant number of pharmacies were damaged or destroyed. In many cases the damages occurred to a number of pharmacies the same region.

Although not required, some facilities notify the Board when temporary closures occur. Such notification allows the Board to maintain a better operational history, albeit in an informal fashion and provides transparency to consumer, licensees and other healthcare practitioners through the Board's website license lookup.

Current law does not establish a requirement for notification of a temporary closure status. Requiring notifications would ensure consistent reporting requirements for businesses licensed by the Board. Further, notification of closures would allow the Board to plan

inspection activity and ensure licensees and consumers have current operational status information when using the license lookup.

Committee Discussion
During the meeting, members discussed the draft policy proposal, noting the importance for the Board to have an accurate operational history as well as the importance of accurate operational status for consumers. Members spoke in support of the policy proposal but expressed concern that, as drafted, could be viewed as punitive.

Committee Recommendation: Move forward with recommending the Board initiate the rulemaking based on the proposed language for CCR 1708.1. The members instructed the executive officer and Committee Chair to work with legal on making minimal edits to clarify when the pharmacy needs to notify the Board on the three days as discussed during the meeting.

Recent update
Subsequent to the meeting, staff updated the policy proposal to incorporate changes recommended by members.

Provided in **Attachment 4** is the revised proposal that could facilitate notification.

e. Discussion and Consideration of Proposed to Amendments to Title 16, California Code of Regulations Section 1704, Change of Address

Relevant Law
CCR Section 1704 establishes the requirement to a licensee to provide a current residence address with the Board and to report any change in a residence address within 30 days of such change.

Background Information
The Board has previously indicated its preference to streamline communication with applicants and licensees. Communication through email is an efficient way to communicate with applicants and licensees; however, there is no requirement for applicants and licensees to provide the Board with an email address, nor maintain such an address when changes occur.

Committee Discussion and Consideration
During the meeting, members considered a regulation change that would require an applicant or licensee to advise the Board of a change in email address, if they have one. Committee members agreed with the advantages of applicants and licensees providing the Board with email addresses but expressed concern that email addresses could them be released to the public. Counsel advised that personal information such as email addresses and telephone numbers are not releasable.

The committee also expressed concern with language in the proposal that referenced the potential for enforcement action for noncompliance with the requirement.

Committee recommendation: Move forward with recommending to the Board imitating the rulemaking process with the proposed language and to remove subsection (c) unless the executive officer has determined this requirement is not included in another section of pharmacy law.

Recent Update
Subsequent to the meeting, staff updated the proposal consistent with the direction of the committee.

Attachment 5 includes suggested language that incorporates the changes requested by the committee.

f. Licensing Statistics

The quarterly licensing statistics for fiscal year 2019/2020, are provided in **Attachment 6.**

During the fiscal year the Board received 14,622 initial applications, including:

- 2,015 intern pharmacists
- 3,750 pharmacist exam applications (includes retake applications)
- 199 advanced practice pharmacists
- 4,422 pharmacy technicians
- 372 community pharmacy license applications
- 112 sterile compounding pharmacy license applications
- 10 nonresident pharmacy license applications
- 33 hospital pharmacy license applications

The Board has received 513 requests for temporary site license applications, including:

- 265 community pharmacy license applications
- 51 sterile compounding pharmacy license applications
- 81 nonresident pharmacy license applications
- 25 hospital pharmacy license applications

The Board issued 9,192 individual licenses, including:

- 1,931 intern pharmacists
- 1,917 pharmacists
- 253 advanced practice pharmacists
- 4,644 pharmacy technicians

The Board issued 2,087 site licenses without temporary license requests, including:

- 1,008 automated drug delivery systems
- 118 community pharmacies

- 1 hospital pharmacies

The Board issued 445 temporary site licenses, including:

- 245 community pharmacies
- 10 hospital pharmacies

A review of three-year data provided in **Attachment 6** indicates a slight reduction in the number of individual applications received as well as licenses issued. Further, there is a modest increase in site applications received. The number of site licenses issued shows a large growth, but this is primarily a reflect of the increase in ADDS licenses and government owned clinics seeking licensure. The Board's overall licensee population remains relatively flat.

Processing Times

The general application and deficiency mail processing times by license type are provided below reflecting data current as of reflecting data current as of June 26, 2020. The data reflects the time from when an application or deficiency response is received by the Board through to the time it is processed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail.

Premises Application Types	Application Processing Times as of 4/24/2020	Application Processing Times as of 6/26/2020	Deficiency Mail Processing Times as of 4/24/2020	Deficiency Mail Processing Times as of 6/26/2020
Pharmacy	25	21	26	8
Nonresident Pharmacy	32	7	23	12
Sterile Compounding	25	23	22	22
Nonresident Sterile Compounding	9	Current	Current	19
Outsourcing	2	Current	Current	Current
Nonresident Outsourcing	Current	11	16	Current
Hospital Satellite Compounding Pharmacy	Current	Current	Current	Current
Hospital	Current	30	4	Current
Clinic	Current	23	Current	2
Wholesaler	21	15	10	9
Nonresident Wholesaler	28	3	Current	9
Third-Party Logistics Provider	11	Current	Current	Current
Nonresident Third-Party Logistics Provider	Current	Current	Current	4

Premises Application Types	Application Processing Times as of 4/24/2020	Application Processing Times as of 6/26/2020	Deficiency Mail Processing Times as of 4/24/2020	Deficiency Mail Processing Times as of 6/26/2020
Automated Drug Delivery System	Current	10	Current	Current
Automated Patient Dispensing System	Current	Current	Current	Current
Emergency Medical Services Automated Drug Delivery System	Current	Current	Current	Current

Individual Application Type	Application Processing Times as of 4/24/2020	Application Processing Times as of 6/26/2020	Deficiency Mail Processing Times as of 4/24/2020	Application Processing Times as of 6/26/2020
Exam Pharmacist	4	11	Current	Current
Pharmacist Initial Licensure	Current	Current	Current	Current
Advanced Practice Pharmacist	Current	Current	Current	Current
Intern Pharmacist	9	Current	Current	Current
Pharmacy Technician	23	23	5	10
Designated Representative	18	4	3	3
Designated Represenatives-3PL	Current	4	Current	3
Designated Representatives-Reverse Distributor	Current	Current	Current	Current
Designated Paramedic	Current	Current	Current	Current

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Business, Consumer Services and Housing Agency
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LICENSING COMMITTEE
DRAFT MEETING MINUTES

DATE: July 8, 2020

LOCATION: Teleconference

MEMBERS PRESENT: Deborah Veale, Licensee Member, Chair
Lavanza (Cheryl) Butler, Licensee Member, Vice-Chairperson
Albert Wong, Licensee Member

MEMBERS NOT PRESENT: Jignesh Patel, Licensee Member

STAFF PRESENT: Anne Sodergren, Executive Officer
Norine Marks, DCA Staff Counsel

1. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 9:23 a.m. and advise all individuals observing or participating in the meeting that the meeting is being conducted consistent with the provisions of Governor Gavin Newsom's Executive Order N-29-20. Participants were advised that individuals watching the web cast would only be able to observe the meeting and that anyone interested in participating in the meeting would need to join the WebEx meeting as indicated on the agenda.

Roll call was taken and a quorum established.

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Lori Walmsley, Walgreens, requested a future agenda item for discussion to consider expanding the authority for pharmacy technicians to provide vaccinations. Ms. Walmsley noted an expected increase for the need in vaccinations in the fall, especially with a potential COVID-19 vaccine coming out, suggesting that expanding pharmacy technician duties to include vaccinations could potentially help consumers as it is expected there to be an increase in vaccinations. Members agreed to add this item to a future agenda item.

Dr. Keith Yoshizuka commented the licensing committee approved in January to recognize in a California recognized school of pharmacy its training and curriculum to furnish PREP and PEP based on SB 159; however, it was left off for the recommendations for the entire Board. He requested this issue go to the full Board for a decision to incorporate into the regulations. The members agreed to direct the executive officer to work with staff to review the current language in the regulation that references ACPE to determine if schools would already be included in the current regulation language.

Robert Stein requested future discussion regarding CLIA waived tests, to consider if such authority should be broadened to include tests for strep throat and influenza, as pharmacists are easily accessible to the public to perform these types of tests.

Holly Strom supported the request from Robert Stein to broaden the discussion on CLIA waived tests to include discussion for pharmacist to test for influenza A and B. Members agreed to consider this as a future topic of discussion.

3. Discussion and Consideration of Legislative Proposal to Expand the Authority for Pharmacists to Order and Administer Immunizations Approved by the FDA to Prevent a Vaccine-Preventable Diseases

Chairperson Veale reported that existing law, Business and Professions Code (BPC) section 4052 (a)(11), provides the authority for a pharmacist to administer immunizations either pursuant to a protocol, or consistent with recommended routine immunization schedules recommended by the Advisory Committee on Immunization Practices (ACIP) as specified in BPC section 4052.8.

Chairperson Veale noted that as the nation and California continue to respond to the current pandemic, it is appropriate to determine if policy changes are necessary to ensure California is positioned to readily deploy vaccines once approved by the FDA in response to the current health crisis, but also in the future.

Ms. Veale referenced information in the meeting materials, noting that the FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug (IND) application to the FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included is information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.

Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

Ms. Veale indicated that under the current law, pharmacists would not be positioned to order and administered an FDA approved COVID-19 vaccine until either a protocol was established with a prescriber, or the vaccine was incorporated into the ACIP routine immunization schedule. Noting, on balance, given the safeguards in place in the FDA approval process including the labeling requirements, it appears appropriate to consider if additional authority should be provided to pharmacists to ensure they are ready to quickly order and administer a COVID-19 vaccine upon approval.

Ms. Veale advised everyone present that subsequent to the release and posting of the materials for this meeting, AB 1710 was amended. As amended this measure would establish authority for pharmacists to independently order and administer vaccines approved by the FDA.

Ms. Veale referenced the policy proposal provided in the materials and expressed her support of both the policy goal as well as the proposal and noted that the broader approach provided in AB 1710 may provide a more immediate access.

The committee discussed the policy proposal provided in the meeting materials as well as the subsequent legislation, AB 1710, noting the difference in the approach with AB 1710 establishes no qualifiers or conditions other than FDA approval. The committee agreed with the approach being offered by AB 1710.

Danny Martinez, CPhA, reported AB 1710 is sponsored by the CPhA and expressed his appreciation of the committees support of the bill. He requested the members to consider not making a separate motion but instead to have the Board's legislative committee take a supporting position on this bill to go to the full Board to eliminate two separate positions.

Sara Rosak, National Association of Chain Drug Stores, reported she is supportive of AB 1710. Ms. Rosak requested consideration of changing the use of the word "approved" to "authorized" as this would allow pharmacist the opportunity to provide vaccines in the investigation phase as well as when its approved. Ms. Rosak noted this may be especially critical during a pandemic. Ms. Rosak suggested that it is important to leverage all members of the pharmacy staff including pharmacy technicians, noting that the Center Disease Control (CDC) is relying heavily on pharmacies and when you use the whole pharmacy team you can vaccine the entire public seven weeks early.

Ms. Veale noted intern pharmacists would similarly have the authority to order and administer vaccines under this proposal.

Ms. Sodergren requested the opportunity to look into the matter further thinking that perhaps it would be under the conditions of a EUA or something along the lines of the FDA issuing authorization in advance of formal approval.

Lori Walmsley, Walgreens, expressed her appreciation of the Board agenizing this topic and indicated support for the committee's position.

Steven Gray, California Society of Health System Pharmacists (CSHP), expressed support for the Board's policy decision and support for the broader approach offered in AB 1710. Dr. Gray expressed concern that the measure did not include an urgency provision which would mean it would not become law until January 2021.

Ms. Veale expressed her appreciation of Dr. Gray's comments regarding the urgency of the waiver and agrees the committee's position is to move forward on this as quickly as possible to assist with the resolution of COVID-19 before the end of 2020 and do we need a statutory change or a regulatory change.

The committee expressed its desire for the Board to request a waiver to the DCA Director to expand authority for pharmacists in advance of the measure.

Motion: Move forward with broadening the statutory proposal to be consistent with the language in AB 1710 to administer vaccines that are approved by the FDA and to move forward with recommending to the full Board in July. Further, staff and the committee chair to work with legal counsel to modifying the language based on the policy direction discussed.

M/S: Butler/Wong

Support: 3 Oppose: 0 Abstain: 0

The committee also expressed support for the Board upon approval of the motion by the full Board to direct the Board president and the executive officer to initiate a waiver process through the director of DCA for immediate implementation of the Board's policy proposal.

4. Discussion and Consideration of Pharmacists' Authority to Perform CLIA Waived Tests for COVID-19

Chairperson Veale directed members to Attachment 2 providing the relevant statutes as well as the authority for a pharmacist to perform CLIA waived tests for COVID-19. Ms. Veale also noted some provisions reside within Pharmacy Law, while others reside in other areas of the Business and Professions Code, sections generally under the purview of the Department of Public Health's Laboratory Field Services.

Ms. Veale reported on May 12, 2020, DCA Director Kirchmeyer issued a waiver to allow pharmacists to order and administer or collect specimen for COVID-19 tests. The waiver was approved through September 9, 2020. Along with the waiver, a guidance document was issued by the Board that provided additional details regarding the temporary authorities. Ms. Veale noted that the waiver does not allow for the processing of the sample at a pharmacy, unless the pharmacy is licensed as a clinical laboratory and meets all of the requirements of BPC section 1265.

Members were reminded that this item was placed on the agenda following a request made during the June 18, 2020, Board Meeting. Specifically, following public comment requesting a future agenda item to discuss the issue of pharmacists performing CLIA waived COVID-19 antigen testing. The commenter indicated that the situation was murky in terms of whether a pharmacist is able to actually perform such a test as they have CLIA waived equipment and reagents. As part of the comments, members were advised that CDPH has determined that COVID-19 testing shall be performed only in an appropriately licensed lab under direction of a lab director.

Ms. Veale noted that under the provision of existing law pharmacist ability to perform CLIA Waive test are limited to specific tests as specified in BPC section 4052.4, including routine patient assessment procedures. These tests can be processed at a pharmacy if appropriately licensed by the CDPH. Aside from the DCA's approved waiver there are no provisions in law that allow a pharmacist to collect specimen or process specimens for COVID-19.

Members received a joint presentation from representatives of CPhA and NACDS. The presentation including information on federal actions, including guidance issued pursuant to the Prep Act on March 10, 2020 that essentially said pharmacists are authorized to order and

administer COVID-19 tests including serology tests that FDA has authorized. By using the word "Authorized" means test that were under an Emergency Use Authorization (EUA) that later became FDA approved.

Presenters discussed the limitations in current law and the DCA waiver that prevent more robust involvement by pharmacists in COVID-19 tests. It was noted that a pharmacist's inability to process specimens is slowing down the testing process and that labs are greatly impacted. The requirement for pharmacist to have to contract with a lab director is cost prohibited and difficult of the community pharmacy settings.

Members were advised that nationally 42 states have taken action to allow for pharmacist to do end-to-end COVID-19 testing. Presenters indicated they are requesting the Board to enhance advocacy efforts in joining them with working with the administration regarding pharmacists performing end-to-end COVID-19 testing.

The presenters noted that California still has counties that do not have testing sites. Testing is the key to help fight this pandemic, especially, now since testing has been opened to the public and not just front-line responders. This includes allowing pharmacist to be able to provide CLIA Waive testing.

In response to questions from the committee, members were advised that CLIA Waived tests for COVID-19 is as simple as a pharmacist testing for strep throat and as such, is a test that a pharmacist should clearly be able to perform as well as describing the various roles that could be in place in the pharmacy for the various staff to perform.

When questioned, the presenters clarified they are requesting authority for California pharmacists to be able to perform end-to-end COVID-19 testing which would include CLIA Waive testing.

The committee noted that delays in receiving test results and noted that end-to-end testing could speed up the process and help prevent spreading the virus.

Ms. Veale reported that the Board will need to have a dialog with CDPH in regard to pursuing an executive order.

Members also received a presentation from Dr. Yoshizuka, CSHP. Who noted that the availability of COVID-19 testing by pharmacies is not widespread. He advised members that some pharmacists are performing testing through a collaborative practice agreement with Contra Costa. Dr. Yoskizuka noted common approached by pharmacies including use of drive-up testing, self-swab collection with instruction by pharmacist.

The committee discussed the need for better opportunity for pharmacists to engage in COVID-19 testing, noting the cross jurisdictional issues that need to be considered as well as work with CDPH and the governor. Moving forward to direct staff to work with CDPH and potentially the governor on how to move forward.

Ms. Sodergren based on the discussion by the committee stated she understands the direction of the committee and will reach out to the administration and CDPH as well as looking at some of the prohibitions in the law where there may be some opportunities to enhance some provisions to improve the overall health of Californians.

The members expressed the urgency of authorizing pharmacist to participate in the COVID-19 CLIA Waive testing, especially with the lack of testing sites currently.

Mr. Martinez, CPhA, expressed his appreciation to the committee in the discussion today and requests the committee consider a policy statement related to this issue to be made publicly at the committee or Board level to show the support of this topic.

Robert Stein reported he agrees with the pharmacist being able to perform not only COVID-19 tests in house but other tests as well. There are several road blocks beyond what was discussed during the meeting, such as BPC 4052 series and what is authorized specifically in drug therapy related. Mr. Stein indicated the need to discuss potential tests that move into a more diagnostic but not drug therapy related domain and the possible need for statutory adjustment in those areas as well. Mr. Stein noted a potential concern with the spike of COVID-19 and as such resulting in supply shortage with the manufactures of the CLIA Waive equipment.

Stacie Neroni provided clarification that there is a difference between a CLIA certificate and a lab license. Ms. Neroni noted that pharmacies may be successful in securing CLIA certificate by contracting with a physician to serve as the lab director to qualify for CLIA Waive testing. A pharmacy cannot get a lab license. If the pharmacy receives the certificate for a CLIA waiver with the physician listed as a lab director, then it allows the pharmacist to conduct the waived tests. She agrees we need to move forward to include a pharmacist being able to be a lab director on the CLIA Waiver.

Lori Walmsley, Walgreens, expressed her appreciation for the committee's discussion noting that Walgreens is currently offering COVID-19 testing in 27 states and the majority of the testing locations are the end-to-end testing locations using the point of care via the CLIA Waiver. This is essentially one of the reasons Walgreens has not rolled out to California yet but are looking at opportunities to do so and support the Board in moving forward with what has been discussed today.

Members also heard comments about limitations with antigen testing, including the need to use a special type of analyzer and recommended that pharmacist review liability insurance policies to ensure coverage.

The committee was also reminded that as more traditional health care services resume, more testing will be needed. The committee was also advised that because of the lack of the ability to perform the test in a timely manner, some counties are prohibiting private entities, including physicians and surgeons some patients from performing their own testing. Instead they are requiring people to go through the county to perform the test because the labs are so overwhelmed.

5. Update on Implementation of SB 159 (Weiner, Chapter 532, Statutes of 2019) Related to HIV Preexposure and Postexposure Prophylaxis

Chairperson Veale reported on the relevant statutes and regulations regarding HIV Preexposure prophylaxis. Ms. Veale explained the Board is working on development of the Board provided training program in collaboration with subject matter experts, including experts from the Office of AIDS. Although development activities have slowed in response to the COVID-19 pandemic, Board staff is hopeful that the framework of the training program will be complete for the Board's consideration during its July Board Meeting.

Ms. Veale reported to date the Board has not received any requests for Board to approve a training program.

Committee members were advised that the California Society of Health Systems Pharmacists (CSHP) will be offering a live free event on July 29, which will be recorded. He anticipates a web version will be provided on the website in the future. The training program will be approximately a two-hour event.

6. Discussion and Consideration of Proposal to Develop a Temporary Closure Status and Mandatory Notification Requirement for Board Licensed Sites

Chairperson Veale reported over the past several years, typically in response to declared disasters, but also in response to construction issues, Board licensed businesses at times must temporarily close. More recently, regrettably, a significant number of pharmacies were damaged or destroyed. In many cases the damages occurred to a number of pharmacies in the same region.

Although not required, some facilities notify the Board when temporary closures occur. Such notification allows the Board to maintain a better operational history, albeit in an informal fashion and provides transparency to consumer, licensees and other healthcare practitioners through the Board's website license lookup.

Members considered if establishing a requirement for notification of a temporary closure status is appropriate, noting that requiring notifications would ensure consistent reporting requirements for businesses licensed by the Board. Further, notification of closures would allow the Board to plan inspection activity and ensure licensees and consumers have current operational status information when using the license lookup.

Members spoke in support of the proposed regulation change to Title 16, California Code of Regulations section in CCR 1708.1.

Mr. Martinez, CPhA reported they do not have an official position on moving forward with changes to this regulation. He is concerned with how the language is written, requesting clarification on what type of discipline the Board would take if a pharmacy failed to report a closure.

Chairperson Veal responded, the intent is not to be punitive but to make the information available to the public because of our experience with the natural disaster and civil unrest recently.

Steven Gray, CHSP and personal experience, indicated that it has always been confusing on what the Board's policy was on the temporary closure of a pharmacy and pointed out under current BPC section 4312(e) the Board already has authority if the pharmacy has not been open one day per each week within a 120-day period allows the Board to cancel a license. Dr. Gray suggested the need for additional discussion or guidance that can be given to the pharmacy and the public when the pharmacy is closed.

Chairperson Veale responded there may need to be a FAQ once this regulation is initiated.

Ms. Marks advised the committee that while the intent is not to be punitive any violation could result in a citation. Further Ms. Marks suggested that to provide clarity language "will exceed three consecutive days" means that the notification would be prior to the third day. If the expectation is that if after the third day the pharmacy then needs to notify the Board of the closure, then the proposed language may need to be modified to be clearer.

Chairperson Veale clarified that the Board wants to be notified at the time when the pharmacy is closed past three days and suggested that staff work with legal as well as the chair to modify the language to bring to the full Board at the July Board Meeting if members agree.

Members expressed their concern the language needs to be written as such it is not punitive and the Board works with the pharmacy during closures if closed past three days.

Motion: Move forward with recommending the Board initiate the rulemaking based on the proposed language for CCR 1708.1. The members instructed the executive officer and Committee Chair to work with legal on making minimal edits to clarify when the pharmacy needs to notify the Board on the three days as discussed during the meeting.

M/S: Wong/Butler

Support: 3 Oppose: 0 Abstain: 0

7. Discussion and Consideration of Proposed to Amendments to Title 16, California Code of Regulations Section 1704, Change of Address

Chairperson Veale reported on the relevant regulation and explained the Board had previously indicated its preference to streamline communication with applicants and licensees. Communication through email is an efficient way to communicate with applicants and licensees; however, there is no requirement for applicants and licensees to provide the Board with an email address, nor maintain such an address when changes occur.

Ms. Veale indicated Board staff requested the committee to consider a regulation change that would require an applicant or licensee to advise the Board of a change in email address, if they have one. Such a proposal would facilitate better email notification with applicants and licensees

who maintain an email address with the Board. Ms. Veale directed members to the suggested language that could be used to implement such a policy change if deemed appropriate by the Committee and Board.

Ms. Butler asked if the email address is made public and was advised that personal information such as the email address and phone number is not releasable.

Members agreed with the advantages of applicants and licensees providing an email address for the Board to communicate electronically, when needed, however noted concern with language proposal indicating that failure to comply could result in enforcement action.

Ms. Marks clarified that as proposed, an individual would not be required to provide an email address if you don't have one but that if you do, the Board shall receive notice the Board when updated.

Ms. Sodergren indicated there are sections within the law that require notification of records to be updated. It is important with moving forward with electronic communication to have a regulation that does require notification but does not believe it would be necessary to include subsection (c) in the proposed language.

The committee received the following comments from the public.

Steven Gray suggested it is important to specify the intent of this regulation including if the email address was going to substitute the address of record. Additionally, BPC section 4013 already requires licensees to supply the Board with an email address and update within 30 days of any change.

Ms. Marks clarified BPC section 4013 specifically refers to signing up for the Board's subscriber alert which is completely different than notifying the Board of their email address. The Board does not have access to the subscriber alert's database; therefore, the email address does not become part of the applicant or licensees record.

Motion: Move forward with recommending to the Board initiating the rulemaking process with the proposed language and to remove subsection (c) unless the executive officer has determined this requirement is not included in another section of pharmacy law.

M/S: Butler/Wong

Support: 3 Oppose: 0 Abstain: 0

8. Licensing Statistics

Chairperson Veale reported on the licensing statistics and reviewed some of the data points as of June 24, 2020 and June 30, 2020.

As of June 24, 2020, the Board has received 12,594 initial applications, including:

- 2,008 intern pharmacists

- 2,388 pharmacist exam applications
- 198 advanced practice pharmacists
- 4,351 pharmacy technicians
- 371 community pharmacy license applications
- 110 sterile compounding pharmacy license applications
- 120 nonresident pharmacy license applications
- 31 hospital pharmacy license applications

As of June 24, 2020, the Board has received 508 requests for temporary site license applications, including:

- 262 community pharmacy license applications
- 53 sterile compounding pharmacy license applications
- 79 nonresident pharmacy license applications
- 24 hospital pharmacy license applications

As of June 30, 2020, the Board has issued 9,192 individual licenses, including:

- 1,931 intern pharmacists
- 1,917 pharmacists
- 253 advanced practice pharmacists
- 4,644 pharmacy technicians

As of June 30, 2020, the Board has issued 2,087 site licenses without temporary license requests, including:

- 1,008 automated drug delivery systems
- 118 community pharmacies
- 1 hospital pharmacies

As of June 30, 2020, the Board has issued 445 temporary site licenses, including:

- 245 community pharmacies
- 10 hospital pharmacies

Ms. Veale reported the general application and deficiency mail processing times by license type expressed her appreciation of all the staff's efforts in reducing the processing times especially during this unforeseen time.

Ms. Sodergren clarified processing times reflect as "Current" means staff is current on the workload for that specific license type.

9. Adjournment

The licensing committee adjourned at 12:32 p.m.

Attachment 1

ARTICLE 3. Scope of Practice and Exemptions [4050 - 4068]

(Article 3 added by Stats. 1996, Ch. 890, Sec. 3.)

4052.8.

(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines approved by the federal Food and Drug Administration ~~listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC)~~ for persons three years of age and older.

(b)In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

(Added by Stats. 2013, Ch. 469, Sec. 9. (SB 493) Effective January 1, 2014.)

AMENDED IN SENATE JULY 2, 2020
AMENDED IN ASSEMBLY MAY 20, 2019
AMENDED IN ASSEMBLY APRIL 30, 2019
AMENDED IN ASSEMBLY APRIL 4, 2019
CALIFORNIA LEGISLATURE—2019–20 REGULAR SESSION

ASSEMBLY BILL No. 1710

Introduced by Assembly Member Wood

February 22, 2019

An act to ~~add Section 26203 to the Business and Professions Code, relating to cannabis.~~ *amend Section 4052.8 of the Business and Professions Code, relating to pharmacy.*

LEGISLATIVE COUNSEL'S DIGEST

AB 1710, as amended, Wood. ~~Cannabis.~~ *Pharmacy practice: vaccines.*

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime. Existing law authorizes a pharmacist to independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons 3 years of age or older.

This bill would also authorize a pharmacist to independently initiate and administer vaccines approved by the federal Food and Drug

Administration (FDA) under the circumstances described above. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

~~The Control, Regulate and Tax Adult Use of Marijuana Act (AUMA), an initiative statute approved as Proposition 64 at the November 8, 2016, statewide general election, authorizes a person who obtains a state license under AUMA to engage in commercial adult-use cannabis activity pursuant to that license and applicable local ordinances. The Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA), among other things, consolidates the licensure and regulation of commercial medicinal and adult-use cannabis activities.~~

~~Existing law provides a local jurisdiction, defined as a city, city and county, or county, with specified powers regarding commercial cannabis activity, including adopting and enforcing local ordinances regulating commercial cannabis activity, including prohibiting that activity. Existing law prohibits a licensing authority from approving an application for a state license if approval will violate the provisions of a local ordinance or regulation.~~

~~This bill would amend AUMA by authorizing the Elk Valley Rancheria, California, a federally recognized Indian tribe, and the County of Del Norte to enter into an agreement, as defined, regarding local authorization for, and tribal regulation of, commercial cannabis activity. The bill would provide that the agreement would satisfy the requirements of MAUCRSA regarding the approval of a local jurisdiction for state license purposes and would require that the licensee or applicant be subject to all of the requirements of MAUCRSA for the applicable license type. The bill would exempt the agreement from the California Environmental Quality Act (CEQA), but would not limit the licensee's requirement to comply with all state laws, including CEQA.~~

~~This bill would make legislative findings and declarations as to the necessity of a special statute for Elk Valley Rancheria and the County of Del Norte.~~

~~AUMA authorizes legislative amendment of its provisions with a 2/3 vote of both houses of the Legislature, without submission to the voters, to further its purposes and intent.~~

~~This bill would declare that its provisions further specified purposes and intent of the Control, Regulate and Tax Adult Use of Marijuana Act.~~

Vote: 2/3-*majority*. Appropriation: no. Fiscal committee: ~~no~~ yes. State-mandated local program: ~~no~~ yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4052.8 of the Business and Professions Code is amended to read:

4052.8. (a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines *approved by the federal Food and Drug Administration (FDA), or* listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

~~SECTION 1. Section 26203 is added to the Business and Professions Code, to read:~~

~~26203. (a) The Elk Valley Rancheria, California, a federally recognized Indian tribe, and the County of Del Norte may enter into an agreement regarding commercial cannabis activities on the tribe's trust lands. An agreement that was entered into by the tribe and the county prior to January 1, 2020, remains valid if it otherwise complies with this section.~~

~~(b) The agreement shall satisfy the requirement of this chapter regarding the approval of a local jurisdiction for state license purposes. The agreement shall require that the licensee or applicant is subject to all of the requirements of this division for the applicable license type.~~

~~(c) The execution of an agreement pursuant to this section does not constitute a project and shall be exempt from the California Environmental Quality Act (Division 13 (commencing with Section 21000) of the Public Resources Code). This exemption does not limit the requirement of the licensee to comply with all state laws, including the California Environmental Quality Act, that are applicable to them as a licensee.~~

~~(d) For purposes of this section, "agreement" means a memorandum of understanding, intergovernmental agreement joint powers agreement, or other type of agreement regarding local authorization for, and tribal regulation of, commercial cannabis activity.~~

~~SEC. 2. The Legislature finds and declares that a special statute is necessary and that a general statute cannot be made applicable within the meaning of Section 16 of Article IV of the California Constitution because of the unique circumstances facing the Elk Valley Rancheria and the County of Del Norte.~~

~~SEC. 3. The Legislature finds and declares that this act furthers the purposes and intent of the Control, Regulate and Tax Adult Use of Marijuana Act.~~

O

Vaccine Product Approval Process

FDA's Center for Biologics Evaluation and Research (CBER) is responsible for regulating vaccines in the United States. Current authority for the regulation of vaccines resides primarily in Section 351 of the Public Health Service Act and specific sections of the Federal Food, Drug and Cosmetic Act.

Vaccine clinical development follows the same general pathway as for drugs and other biologics. A sponsor who wishes to begin clinical trials with a vaccine must submit an Investigational New Drug application (IND) to FDA. The IND describes the vaccine, its method of manufacture, and quality control tests for release. Also included are information about the vaccine's safety and ability to elicit a protective immune response (immunogenicity) in animal testing, as well as the proposed clinical protocol for studies in humans.

Pre-marketing (pre-licensure) vaccine clinical trials are typically done in three phases, as is the case for any drug or biologic. Initial human studies, referred to as Phase 1, are safety and immunogenicity studies performed in a small number of closely monitored subjects. Phase 2 studies are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase 3 trials typically enroll thousands of individuals and provide the critical documentation of effectiveness and important additional safety data required for licensing. At any stage of the clinical or animal studies, if data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies, or may halt ongoing clinical studies.

If successful, the completion of all three phases of clinical development can be followed by the submission of a Biologics License Application (BLA). To be considered, the license application must provide the multidisciplinary FDA reviewer team (medical officers, microbiologists, chemists, biostatisticians, etc.) with the efficacy and safety information necessary to make a risk/benefit assessment and to recommend or oppose the approval of a vaccine. Also during this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail.

Following FDA's review of a license application for a new indication, the sponsor and the FDA may present their findings to FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC). This non-FDA expert committee (scientists, physicians, biostatisticians, and a consumer representative) provides advice to the Agency regarding the safety and efficacy of the vaccine for the proposed indication.

Vaccine approval also requires the provision of adequate product labeling to allow health care providers to understand the vaccine's proper use, including its potential benefits and risks, to communicate with patients and parents, and to safely deliver the vaccine to the public.

The FDA continues to oversee the production of vaccines after the vaccine and the manufacturing processes are approved, in order to ensure continuing safety. After licensure, monitoring of the product and of production activities, including periodic facility inspections, must continue as long as the manufacturer holds a license for the product. If requested by the FDA, manufacturers are required to submit to the FDA the results of their own tests for potency, safety, and purity for each vaccine lot. They may also required to submit samples of each vaccine lot to the FDA for testing. However, if the sponsor describes an alternative procedure which provides continued assurance of safety, purity and potency, CBER may determine that routine submission of lot release protocols (showing results of applicable tests) and samples is not necessary.

Until a vaccine is given to the general population, all potential adverse events cannot be anticipated. Thus, many vaccines undergo Phase 4 studies-formal studies on a vaccine once it is on the market. Also, the government relies on the Vaccine Adverse Event Reporting System (VAERS) to identify problems after marketing begins. The VAERS system and how it works is discussed further on this website.

References

- National Vaccine Advisory Committee. "United States Vaccine Research: A Delicate Fabric of Public and Private Collaboration." *Pediatrics*, Vol 100(6), Dec.1997, pp. 1015-1020.
- Parkman PD, Hardegree MC. "Regulation and Testing of Vaccines." In Plotkin SA, Orenstein WA, [eds.]. *Vaccines*, 3d ed. Philadelphia: Saunders; 1999, pp.1131-1143.
- Stehlin, Isadora. "How FDA Works to Ensure Vaccine Safety." *FDA Consumer Magazine*, March 1996.

Related Links from the Centers for Disease Control and Prevention

- What Would Happen If We Stopped Vaccinations (http://www.cdc.gov/vaccines/vac-gen/whatifstop.htm)
- Ten Things You Need To Know About Immunizations (http://www.cdc.gov/vaccines/vac-gen/10-shouldknow.htm)
- CDC National Immunization Program (http://www.cdc.gov/vaccines/)

Attachment 2

State of California

BUSINESS AND PROFESSIONS CODE

Section 4052

4052. (a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) (i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

(ii) Nicotine replacement products, as authorized by Section 4052.9.

(iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist

shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

(Amended by Stats. 2019, Ch. 532, Sec. 1. (SB 159) Effective January 1, 2020.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 4052.1

4052.1. (a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(Added by Stats. 2006, Ch. 777, Sec. 5. Effective January 1, 2007.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 4052.2

4052.2. (a) Notwithstanding any other law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

(Amended by Stats. 2019, Ch. 497, Sec. 5. (AB 991) Effective January 1, 2020.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 4052.4

4052.4. Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(Amended by Stats. 2012, Ch. 874, Sec. 5. (SB 1481) Effective January 1, 2013.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 1206.5

1206.5. (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A person licensed under Chapter 6.5 (commencing with Section 2840).

(8) A perfusionist if authorized by and performed in compliance with Section 2590.

(9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.

(11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, or if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section 4052.1.

(12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.

(13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).

(14) Other health care personnel providing direct patient care.

(15) Any other person performing nondiagnostic testing pursuant to Section 1244.

(b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A person licensed under Chapter 6 (commencing with Section 2700).

(7) A perfusionist if authorized by and performed in compliance with Section 2590.

(8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(10) Any person if performing blood gas analysis in compliance with Section 1245.

(11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that he or she is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.

(B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or

examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a "preceptor program" means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.

(12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient's physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.

(c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:

(1) A licensed physician and surgeon holding a M.D. or D.O. degree.

(2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within his or her practice.

(3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person's licensure.

(4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person's certification.

(5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

(6) A perfusionist if authorized by and performed in compliance with Section 2590.

(7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).

(8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.

(9) Any person if performing blood gas analysis in compliance with Section 1245.

(10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who

shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.

(d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:

(1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.

(3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(Amended by Stats. 2012, Ch. 874, Sec. 1.5. (SB 1481) Effective January 1, 2013.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 1206.6

1206.6. Subdivision (a) of Section 1206.5 shall not apply to a pharmacist at a community pharmacy who, upon customer request, performs only blood glucose, hemoglobin A1c, or cholesterol tests that are classified as waived under CLIA and are approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that all of the following requirements are satisfied:

(a) The pharmacy obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal regulations. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decisionmaking shall be the pharmacist-in-charge, as defined in Section 4036.5.

(b) The pharmacy obtains a registration from the department pursuant to Section 1265 and complies with this chapter.

(c) The tests are performed only by a pharmacist, as defined in Section 4036, in the course of performing routine patient assessment procedures in compliance with Section 4052.4.

(Added by Stats. 2012, Ch. 874, Sec. 2. (SB 1481) Effective January 1, 2013.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 1265

1265. (a) (1) A clinical laboratory performing clinical laboratory tests or examinations classified as of moderate or of high complexity under CLIA shall obtain a clinical laboratory license pursuant to this chapter. The department shall issue a clinical laboratory license to any person who has applied for the license on forms provided by the department and who is found to be in compliance with this chapter and the regulations pertaining thereto. No clinical laboratory license shall be issued by the department unless the clinical laboratory and its personnel meet the CLIA requirements for laboratories performing tests or examinations classified as of moderate or high complexity, or both.

(2) A clinical laboratory performing clinical laboratory tests or examinations subject to a certificate of waiver or a certificate of provider-performed microscopy under CLIA, shall register with the department. The department shall issue a clinical laboratory registration to any person who has applied for the registration on forms provided by the department and is found to be in compliance with this chapter, the regulations pertaining thereto, and the CLIA requirements for either a certificate of waiver or a certificate of provider-performed microscopy.

(b) An application for a clinical laboratory license or registration shall include the name or names of the owner or the owners, the name or names of the laboratory director or directors, the name and location of the laboratory, a list of the clinical laboratory tests or examinations performed by the laboratory by name and total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance, or proficiency testing purposes). The application shall also include a list of the tests and the test kits, methodologies, and laboratory equipment used, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures, and any other relevant information as may be required by the department. If the laboratory is performing tests subject to a provider-performed microscopy certificate, the name of the provider or providers performing those tests shall be included on the application. Application shall be made by the owners of the laboratory and the laboratory directors prior to its opening. A license or registration to conduct a clinical laboratory if the owners are not the laboratory directors shall be issued jointly to the owners and the laboratory directors and the license or registration shall include any information as may be required by the department. The owners and laboratory directors shall be severally and jointly responsible to the department for the maintenance and conduct thereof or for any violations of this chapter and regulations pertaining thereto.

(c) The department shall not issue a license or registration until it is satisfied that the clinical laboratory will be operated within the spirit and intent of this chapter, that the owners and laboratory directors are each of good moral character, and that the granting of the license will not be in conflict with the interests of public health.

(d) A separate license or registration shall be obtained for each laboratory location, with the following exceptions:

(1) Laboratories that are not at a fixed location, that is, laboratories that move from one testing site to another, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations, may apply for and obtain one license or registration for the designated primary site or home base, using the address of that primary site.

(2) Not-for-profit, or federal, state, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests, as defined under CLIA, per license) public health testing may apply for and obtain a single license or registration.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction, may file a single application or multiple applications for a license or registration of laboratory locations within the same campus or street address.

(4) Locations within a single street and city address that are under common ownership may apply for and obtain a single license or registration or multiple licenses or registrations, at the discretion of the owner or owners.

(e) (1) A license or registration shall be valid for one year unless revoked or suspended. A clinical laboratory license or registration shall be automatically revoked 30 days from a major change of laboratory directorship or ownership. The clinical laboratory shall be required to submit a completed application for a new clinical laboratory license or registration within those 30 days or cease engaging in clinical laboratory practice.

(2) If a clinical laboratory intends to continue to engage in clinical laboratory practice during the 30 days after a major change in directorship occurs and before the laboratory license or registration is automatically revoked, the laboratory owner may appoint an interim director who meets the requirements of this chapter and CLIA. The interim director shall be appointed within five business days of the major change of the directorship. Written notice shall be provided to the department of the appointment of the laboratory director pursuant to this paragraph within five business days of the appointment.

(f) If the department does not within 60 days after the date of receipt of the application issue a license or registration, it shall state the grounds and reasons for its refusal in writing, serving a copy upon the applicant by certified mail addressed to the applicant at his or her last known address.

(g) The department shall be notified in writing by the laboratory owners or delegated representatives of the owners and the laboratory directors of any change in ownership, directorship, name, or location, including the addition or deletion of laboratory owners or laboratory directors within 30 days. However, notice of change in ownership shall

be the responsibility of both the current and new owners. Laboratory owners and directors to whom the current license or registration is issued shall remain jointly and severally responsible to the department for the operation, maintenance, and conduct of the clinical laboratory and for any violations of this chapter or the regulations adopted thereunder, including any failure to provide the notifications required by this subdivision, until proper notice is received by the department. In addition, failure of the laboratory owners and directors to notify the department within 30 days of any change in laboratory directors, including any additions or deletions, shall result in the automatic revocation of the clinical laboratory's license or registration.

(h) The withdrawal of an application for a license or registration or for a renewal of a license, or registration, issuable under this chapter, shall not, after the application has been filed with the department, deprive the department of its authority to institute or continue a proceeding against the applicant for denial of the license, registration, or renewal upon any ground provided by law or to enter an order denying the license, registration, or renewal upon any such ground, unless the department consents in writing to the withdrawal.

(i) The suspension, expiration, or forfeiture by operation of law of a license or registration issued under this chapter, or its suspension, forfeiture, or cancellation by order of the department or by order of a court of law, or its surrender without the written consent of the department, shall not deprive the department of its authority to institute or continue an action against a license or registration issued under this chapter or against the laboratory owner or laboratory director upon any ground provided by law or to enter an order suspending or revoking the license or registration issued under this chapter.

(j) (1) Whenever a clinical laboratory ceases operations, the laboratory owners, or delegated representatives of the owners, and the laboratory directors shall notify the department of this fact, in writing, within 30 calendar days from the date a clinical laboratory ceases operation. For purposes of this subdivision, a laboratory ceases operations when it suspends the performance of all clinical laboratory tests or examinations for 30 calendar days at the location for which the clinical laboratory is licensed or registered.

(2) (A) Notwithstanding any other provision of law, owners and laboratory directors of all clinical laboratories, including those laboratories that cease operations, shall preserve medical records and laboratory records, as defined in this section, for three years from the date of testing, examination, or purchase, unless a longer retention period is required pursuant to any other provision of law, and shall maintain an ability to provide those records when requested by the department or any duly authorized representative of the department.

(B) For purposes of this subdivision, "medical records" means the test requisition or test authorization, or the patient's chart or medical record, if used as the test requisition, the final and preliminary test or examination result, and the name of the person contacted if the laboratory test or examination result indicated an imminent life-threatening result or was of panic value.

(C) For purposes of this subdivision, “laboratory records” means records showing compliance with CLIA and this chapter during a laboratory’s operation that are actual or true copies, either photocopies or electronically reproducible copies, of records for patient test management, quality control, quality assurance, and all invoices documenting the purchase or lease of laboratory equipment and test kits, reagents, or media.

(D) Information contained in medical records and laboratory records shall be confidential, and shall be disclosed only to authorized persons in accordance with federal, state, and local laws.

(3) The department or any person injured as a result of a laboratory’s abandonment or failure to retain records pursuant to this section may bring an action in a court of proper jurisdiction for any reasonable amount of damages suffered as a result thereof.

(k) For purposes of this section, in the case of a pharmacy that applies for a registration pursuant to Section 1206.6, “laboratory director” means the pharmacist-in-charge identified pursuant to subdivision (a) of Section 1206.6.

(Amended by Stats. 2012, Ch. 874, Sec. 4. (SB 1481) Effective January 1, 2013.)

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR

Executive Office
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Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests

On March 4, 2020, the Governor proclaimed a State of Emergency to exist in California as a result of the impacts of COVID-19 to make additional resources available, formalize emergency actions already underway across multiple state agencies and departments, and help the state prepare to respond to an increasing number of individuals requiring medical care and hospitalization as a result of a broader spread of COVID-19.

Pursuant to the Governor's Executive Order N-39-20, during the State of Emergency, the Director of the California Department of Consumer Affairs may waive any statutory or regulatory professional licensing requirements and amend scopes of practice pertaining to individuals licensed pursuant to Division 2 of the Business and Professions Code. This authority allows the Director to waive restrictions on activities that licensees may undertake.

Business and Professions Code section 4050, subdivision (c), states that pharmacists are health care providers who may provide health care services. Business and Professions Code section 4051, subdivision (b) authorizes pharmacists to provide any "clinical advice, services, information, or patient consultation" set forth in Chapter 9 of Division 2 of the Business and Professions Code, if certain conditions are met. Business and Professions Code section 4052, subdivision (a)(12) authorizes pharmacists to order only certain tests, subject to certain conditions.

Pursuant to Executive Order N-39-20, the Director waives Business and Professions Code section 4051, subdivision (b) and section 4052, subdivision (a)(12), to the extent those provisions would otherwise prohibit pharmacists from ordering or otherwise authorizing tests for the presence of the virus SARS-CoV-2 ("COVID 19 tests") in individual patients, and without coordination with the patient's primary care provider or diagnosing prescriber. Those provisions are also waived to the extent they would otherwise prohibit pharmacists from physically collecting (such as through the use of nasopharyngeal swabs or other means) specimens necessary to perform such COVID-19 tests. This waiver does not authorize the analysis or testing of samples collected, to the extent such analysis or testing is not otherwise authorized by law.

The waiver is subject to the following conditions:

- The test is authorized by the United States Food and Drug Administration (FDA) and is processed in a public health, commercial, or clinical laboratory pursuant to state and federal rules; and,
- The pharmacist is competent and trained to collect the specimen necessary to perform the test, and the specimen is collected consistent with the provisions of an Emergency Use Authorization issued by the FDA.

Pharmacists acting within the scope of this wavier may order and collect specimens for authorized COVID-19 tests.

This order is effective immediately, and may be amended from time to time in the discretion of the Director.

This order terminates 60 days from the date of the order, unless further extended.

Dated: May 12, 2020

Signature on File

Kimberly Kirchmeyer
Director

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR

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MEMORANDUM

DATE	May 12, 2020
TO	Pharmacists
FROM	Kimberly Kirchmeyer, Director, Department of Consumer Affairs Anne Sodergren, Executive Officer, California State Board of Pharmacy
SUBJECT	**Important Information for California State Board of Pharmacy Licensees Related to COVID-19 Testing**[1]

The California Department of Consumer Affairs (DCA) and the California State Board of Pharmacy (Board) received inquiries regarding a pharmacist's authority to order and administer COVID-19 tests in California. In short, a pharmacist may, under the circumstances specified below, order and collect specimens for authorized COVID-19 tests. Pharmacists may also serve as qualified laboratory testing personnel to perform COVID-19 tests, but only in an appropriately licensed or registered laboratory, and only under the direction of a laboratory director.

Ordering and Collecting Specimens for COVID-19 Tests

Effective May 12, 2020, pursuant to the waiver order issued by the Director of the Department of Consumer Affairs, pharmacists may now order tests for the presence of the virus SARS-CoV-2 ("COVID 19 tests") in individual patients, and without coordination with the patient's primary care provider or diagnosing prescriber. Pharmacists may also collect test specimens (such as through the use of nasopharyngeal swabs or other means) necessary to allow for analysis and interpretation of such COVID-19 tests.

The test must be authorized by the United States Food and Drug Administration (FDA), the pharmacist must be competent and trained to collect the specimen needed for the particular test, and the specimen must be collected consistent with the provisions of an Emergency Use Authorization issued by the FDA.

The waiver order does not, however, authorize the analysis or testing of samples collected, to the extent such analysis or testing is not otherwise authorized by law. This must be done by a public health, commercial, or clinical laboratory

[1] This guidance was developed by the California Department of Consumer Affairs, Department of Public Health, and State Board of Pharmacy.

pursuant to state and federal rules, which are enforced by the California Department of Public Health (CDPH).

The DCA and Board encourage pharmacists to contact their partner laboratories to obtain information about reporting requirements, specimen handling, transportation requirements, and reimbursement.

Pharmacists Serving as Laboratory Personnel Performing COVID-19 Tests in a Licensed Laboratory

Separately, on March 12, 2020, the Governor issued Executive Order N-25-20, which suspended certification and licensure requirements for persons performing COVID-19 tests in licensed clinical laboratories.

On April 8, 2020, the CDPH's Laboratory Field Services (LFS) released guidelines on the qualifications of testing personnel based, in part, on Executive Order N-25-20. As explained in the guidance, for the duration of the COVID-19 emergency, persons may perform testing for SARS-CoV-2, the virus that causes COVID-19, without holding a California license to perform such testing, if they meet the requirements specified in federal regulations at 42 CFR 493.1489 for high-complexity testing personnel.

Although pharmacists are not specifically included in the referenced section of the CFR, in the Board's view, a pharmacist would satisfy those requirements by virtue of the education required for licensure. Accordingly, pharmacists may serve as laboratory personnel and perform COVID-19 testing under the guidelines issued by the LFS. However, the LFS guidance also makes clear that the facilities at which such testing may occur, the qualifications for a laboratory director, clinical consultant, technical consultant, and technical supervisor, and the supervision requirements **remain in effect**. Consequently, a pharmacist performing a test for COVID-19 (beyond specimen collection) must perform such tests in a facility with the applicable state and federal clinical laboratory license, under an appropriately-qualified laboratory director.

According to the CDPH, there are currently two types of COVID-19 tests that a pharmacist may perform as laboratory testing personnel: serological (antibody) tests and molecular (RNA) tests. The FDA has issued only a few Emergency Use Authorizations (EUA) for serological (antibody) tests intended for use by clinical laboratories. These EUAs limit the actual performance of serological tests to clinical laboratories with a federal CLIA certificate of compliance or certification of accreditation and a California clinical laboratory license.

Regarding molecular (RNA) tests, the FDA has approved numerous tests that include three molecular (RNA) tests for testing in a laboratory with a federal CLIA certificate of waiver and a California clinical laboratory registration.

For more information on the current list of COVID-19 tests receiving FDA EUA approval, please see the Internet link below. For further information on the circumstances under which a test can be performed, please refer to the appropriate FDA-EUA approved manufacturer test kit's "Instructions for Use" literature.

For questions about personnel or laboratory testing related to COVID-19, please contact LFS at LFSCOVID@cdph.ca.gov. LFS has also posted FAQs for laboratories: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19.aspx.

Resources

For additional information, the DCA and the Board recommend that any licensee interested in ordering COVID-19 tests, collecting specimens, and performing tests in laboratory settings review the following information:

- FAQs provided for "Laboratory Questions" and "Resources for Laboratories".

- CDC's Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

- Guidance on COVID-19 for Pharmacy Personnel: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/GuidanceforPharmacies.aspx

- Guidance on Resource Requests for Health Care Providers: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/ResourceRequestingforHealthCareProviders.aspx

- Guidance on Expanded Access to Testing: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Expanding-Access-to-Testing-Updated-Interim-Guidance-on-Prioritization-for-COVID-19-Laboratory-Testing-0501.aspx

- Guidance on Medical Waste Management: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/MedicalWasteManagementInterimGuidelines.aspx

Information about FDA-authorized COVID-19 tests can be found on FDA's website under Emergency Use Authorizations: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations.

Information on the Coronavirus Disease 2019 (COVID-19) from California Emergency Medical Authority can be found on its website under: https://emsa.ca.gov/covid19/

Resources to determine pharmacies' ability to be licensed as a clinical laboratory can be found on CDPH's website here: https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/ClinicalLaboratoryFacilities.aspx.

The Board does not have the authority to waive provisions of California law related to clinical laboratory licensing and testing requirements, including the provisions detailed in the LFS guidance.

State of California—Health and Human Services Agency
California Department of Public Health

SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

GAVIN NEWSOM
Governor

July 14, 2020

TO: Public health officials, healthcare providers and laboratories

SUBJECT: Updated COVID-19 Testing Guidance

This guidance is an update to the interim COVID-19 testing guidance issued by the California Department of Public Health (CDPH) on May 1, 2020. This updated guidance is intended to support public health officials, health care providers, and laboratories in determining who should be tested given the current context of the COVID-19 pandemic in California.

What's new in this revision compared to May 1, 2020 Testing Guidance?

COVID-19 testing in California has rapidly expanded over the past three months and we have learned much about COVID-19 and which populations and communities it impacts disproportionately.

Consequently, CDPH recommends first prioritizing testing of hospitalized individuals with signs or symptoms of COVID-19 infection followed by testing of other symptomatic individuals and higher risk asymptomatic individuals and then other asymptomatic individuals when certain conditions exist. This guidance should be used for prioritization of patient populations as well as for the purposes of guiding laboratories in managing specimen processing.

Tier One Priority

- Hospitalized individuals with COVID-19 symptoms.
- Investigation and management of outbreaks, under direction of state and local public health departments (includes contact tracing).
- Close contacts of confirmed cases.

Tier Two Priority

- All other individuals with COVID-19 symptoms.
- Individuals who are asymptomatic (having no symptoms of COVID 19), who fall into one of the following categories:

    1. Live in higher risk congregate care facilities including skilled nursing facilities, residential care facilities for the elderly, correctional facilities, or homeless shelters.
    2. Work in the health care sector who have frequent interactions with the public or with people who may have COVID-19 or have been exposed to SARS-CoV-2. The health care sector includes: hospitals; skilled nursing facilities; long-term care facilities; ambulatory surgery centers; health

care providers' offices; health care clinics; pharmacies; blood banks; dialysis centers; hospices; and, home health providers

3. Work in a congregate care facility, including shelters for people experience homelessness and residential care facilities for the elderly.
4. Provide care to an elderly person or a person with a disability in the home, including a person providing care through California's In-Home Supportive Services Program.
5. Work in the emergency services sector who have frequent interactions with the public or with people who may have COVID-19 or have been exposed to SARS-CoV-2. The emergency services sector includes police and public safety departments, fire departments, and emergency service response operations.
6. Work in a correctional facility.
7. Patients requiring pre-operative/pre-hospital admission screening.
8. Patients being discharged from hospitals to lower levels of care.

Tier Three Priority

- Individuals who work in the retail or manufacturing sectors who have frequent interactions with the public or who works in an environment where it is not practical to maintain at least six feet of space from other workers on a consistent basis.
- Individuals who work in the food services sector who have frequent interactions with the public. The food services sector includes grocery stores, convenience stores, restaurants, and grocery or meal delivery services.
- Individuals who work in the agricultural or food manufacturing sector who have frequent interactions with the public or who works in an environment where it is not practical to maintain at least six feet of space from other workers on a consistent basis. The agricultural or food manufacturing sector includes food production and processing facilities, slaughter facilities, harvesting sites or facilities, and food packing facilities.
- Individuals who work in the public transportation sector who have frequent interactions with the public. The public transportation sector includes public transit, passenger rail service, passenger ferry service, public airports, and commercial airlines.
- Individuals who work in the education sector who have frequent interactions with students or the public. The education sector includes public and private childcare establishments; public and private pre-kindergarten programs; primary and secondary schools; and public and private colleges and universities.

Tier Four Priority

Tier Four would be implemented when the state's testing turnaround time, as monitored by CDPH, is less than 48 hours.

- Other individuals not specified above including: those who are asymptomatic but believe they have a risk for being actively infected as well as routine testing by employers.

Testing Discrimination and Inappropriate Workplace Testing

As modifications are made to public health directives and more sectors of the economy open with adaptations, it is important that employers do not use testing to impermissibly discriminate against employees who have previously tested positive for COVID-19 (such as by preventing them from resuming work after they can do so in a manner consistent with public health and safety). This does not mean an employer must allow an employee who currently has COVID-19 to return to work before the employee's infection is resolved. **Further, because PCR tests can**

remain positive long after an individual is no longer infectious, proof of a negative test should not be required prior to returning to the workplace after documented COVID infection. Rather, symptom- or protocol-based criteria should be used in determining when an employee is safe to return to the workplace.

Types of Tests

Diagnostic Tests

Assesses the presence of the virus at a given point in time. A negative means only that an individual was negative at the time the test.

- Polymerase Chain Reaction (PCR) Tests and Nucleic Acid Amplification Testing: Detects the RNA genetic material in the COVID-19 virus and are often collected via nasal pharyngeal, mid turbinate, nasal, oral or throat swab or saliva collection.
- Antigen Tests: Not currently widely utilized. Detects the presence of COVID-19 specific protein particles and is collected via a respiratory sample.

Note: No test is perfect. There is a false negative rate and false positive rate that varies depending on the test and the collection modality

Non- Diagnostic Tests

- Serology (Antibody) Tests: Detect antibodies in the blood indicating possible prior exposure to COVID-19, which may develop 6-14 days after infection. Please see CDPH guidance on Serology Tests for further information.
- **Note:** Commercially available antibody tests have variable performance—see FDA EUA Authorized Serology Test Performance Website.

Reminder - These are statewide guidelines. Local jurisdictions may modify these guidelines to account for local conditions or patterns of transmission.

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Page Last Updated : July 14, 2020

Attachment 3

Title 16. Board of Pharmacy

Section 1747

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:

(A) HIV preexposure and postexposure prophylaxis pharmacology.

(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.

(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.

(D) Patient referral resources and supplemental resources for pharmacists.

(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).

(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, and 4052.03, Business and Professions Code; Section 120972, Health and Safety Code.

Attachment 4

Proposal to Add Title 16, California Code of Regulations Section 1708.1 as follows:

§ 1708.1. Notification of Temporary Closure.

A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information.

Reference: BPC 4312

Attachment 5

§ 1704. ~~Change of~~ Providing Addresses.

(a) Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

(b) Each applicant and person holding a certificate, license, permit, or registration who has an electronic mail address shall provide to the Board that electronic mail address and shall maintain a current electronic mail address, if any, with the Board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4100, Business and Professions Code.

Attachment 6

CALIFORNIA STATE BOARD OF PHARMACY
QUARTERLY LICENSING STATISTICS FISCAL YEAR 2019/2020

APPLICATIONS RECEIVED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	101	114	75	54	344
Designated Representatives Vet (EXV)	4	1	2	0	7
Designated Representatives-3PL (DRL)	32	19	23	11	85
Designated Representatives-Reverse Distributor (DRR)	0	1	0	1	2
Designated Paramedic (DPM)	0	3	0	0	3
Intern Pharmacist (INT)	1,425	176	215	199	2,015
Pharmacist Exam Applications	340	157	193	1,727	2,417
Pharmacist Retake Exam Applications	231	365	507	230	1,333
Pharmacist Initial License Application (RPH)	240	915	599	204	1,958
Advanced Practice Pharmacist (APH)	60	54	52	33	199
Pharmacy Technician (TCH)	1,277	1,140	1,257	748	4,422
Total	**3,710**	**2,945**	**2,923**	**3,207**	**12,785**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	148	75	55	47	325
Automated Drug Delivery System EMS (ADE)	0	0	1	0	1
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	2	0	2
Centralized Hospital Packaging (CHP)	0	0	1	0	1
Clinics (CLN)	42	34	22	24	122
Clinics Government Owned (CLE)	129	99	99	188	515
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	8	9	3	10	30
Hospitals Government Owned (HPE)	0	0	1	2	3
Hospital Satellite Sterile Compounding (SCP)	0	1	1	0	2
Hospital Satellite Sterile Compounding Government Owned (SCE)	1	1	0	0	2
Hypodermic Needle and Syringes (HYP)	2	0	2	2	6
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	1	1
Outsourcing Facility Nonresident (NSF)	5	1	3	3	12
Pharmacy (PHY)	89	80	96	69	334
Pharmacy (PHY) Chain	19	8	8	3	38
Pharmacy Government Owned (PHE)	3	2	1	0	6
Remote Dispensing Pharmacy (PHR)	0	0	1	3	4
Pharmacy Nonresident (NRP)	28	31	39	26	124
Sterile Compounding (LSC)	37	22	25	16	100
Sterile Compounding Government Owned (LSE)	8	2	1	1	12
Sterile Compounding Nonresident (NSC)	1	4	3	2	10
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	1	0	3	3	7
Third-Party Logistics Providers Nonresident (NPL)	5	6	8	3	22
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	17	17	8	14	56
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	33	24	24	21	102
Total	**576**	**416**	**407**	**438**	**1,837**

Applications Received with Temporary License Requests	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0	0	0	0	0
Hospitals - Temp (HSP)	7	11	0	7	25
Hospital Satellite Sterile Compounding - Temp (SCP)	0	1	0	0	1
Outsourcing Facility - Temp (OSF)	0	0	0	1	1
Outsourcing Facility Nonresident - Temp (NSF)	1	1	1	3	6
Pharmacy - Temp (PHY)	63	66	74	62	265
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	1	1
Pharmacy Nonresident - Temp (NRP)	16	25	23	17	81
Sterile Compounding - Temp (LSC)	16	11	11	13	51
Sterile Compounding Nonresident - Temp (NSC)	1	2	0	1	4
Third-Party Logistics Providers - Temp (TPL)	0	0	1	3	4
Third-Party Logistics Providers Nonresident - Temp (NPL)	2	2	3	0	7
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesalers - Temp (WLS)	17	6	5	9	37
Wholesalers Nonresident - Temp (OSD)	6	9	7	8	30
Total	**129**	**134**	**125**	**125**	**513**

LICENSES ISSUED

Individual Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	67	96	105	81	349
Designated Representatives Vet (EXV)	2	2	2	0	6
Designated Representatives-3PL (DRL)	17	34	16	20	87
Designated Representatives-Reverse Distributor (DRR)	0	0	1	1	2
Designated Paramedic (DPM)	0	0	3	0	3
Intern Pharmacist (INT)	1,289	302	129	211	1,931
Pharmacist (RPH)	230	893	598	196	1,917
Advanced Practice Pharmacist (APH)	24	50	71	108	253
Pharmacy Technician (TCH)	1,333	1,193	1,190	928	4,644
Total	**2,962**	**2,570**	**2,115**	**1,545**	**9,192**

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	788	133	51	36	1,008
Automated Drug Delivery System EMS (ADE)	0	0	1	0	1
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	1	0	1
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	115	17	24	46	202
Clinics Government Owned (CLE)	112	86	92	241	531
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	1	1
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	1	1
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	1	0	1
Hypodermic Needle and Syringes (HYP)	2	1	1	2	6
Correctional Pharmacy (LCF)	0	0	1	0	1
Outsourcing Facility (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident (NSF)	0	3	1	0	4
Pharmacy (PHY)	31	39	20	28	118
Pharmacy Government Owned (PHE)	0	0	3	2	5
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	6	5	12	5	28
Sterile Compounding (LSC)	13	13	12	19	57
Sterile Compounding Government Owned (LSE)	0	0	2	2	4
Sterile Compounding Nonresident (NSC)	1	0	1	0	2
Surplus Medication Collection Distribution Intermediary (SME)	1	0	0	0	1
Third-Party Logistics Providers (TPL)	3	1	0	1	5
Third-Party Logistics Providers Nonresident (NPL)	3	6	3	4	16
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	9	6	9	7	31
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	8	24	14	17	63
Total	**1,092**	**334**	**249**	**412**	**2,087**

Site Temporary Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0	0	0	0	0
Hospitals - Temp (HSP)	1	6	1	2	10
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	0	0	0
Outsourcing Facility Nonresident - Temp (NSF)	0	1	0	2	3
Pharmacy - Temp (PHY)	55	58	73	59	245
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	13	15	27	22	77
Sterile Compounding - Temp (LSC)	16	9	8	2	35
Sterile Compounding Nonresident - Temp (NSC)	3	1	0	3	7
Third-Party Logistics Providers - Temp (TPL)	0	0	1	2	3
Third-Party Logistics Providers Nonresident - Temp (NPL)	4	0	2	1	7
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0	0
Wholesalers - Temp (WLS)	8	4	5	7	24
Wholesalers Nonresident - Temp (OSD)	14	5	10	5	34
Total	**114**	**99**	**127**	**105**	**445**

PENDING APPLICATIONS (Data reflects number of pending applications at the end of the quarter)

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Designated Representatives (EXC)	423	436	403	379
Designated Representatives Vet (EXV)	7	6	6	5
Designated Representatives-3PL (DRL)	123	105	112	103
Designated Representatives-Reverse Distributor (DRR)	2	3	2	2
Designated Paramedic (DPM)	0	3	0	0
Intern Pharmacist (INT)	252	106	148	113
Pharmacist (exam not eligible)	1,090	1,163	1,246	1,120
Pharmacist (exam eligible)	2,349	1,502	852	2,417
Advanced Practice Pharmacist (APH)	229	232	217	71
Pharmacy Technician (TCH)	1,264	1,189	1,260	1,091
Total	**5,739**	**4,745**	**4,246**	**5,301**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD)	167	104	85	144
Automated Drug Delivery System EMS (ADE)	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	1	1
Centralized Hospital Packaging (CHP)	4	4	4	4
Clinics (CLN)	105	118	114	91
Clinics Government Owned (CLE)	65	96	109	28
Drug Room (DRM)	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0
Hospitals (HSP)	13	15	15	20
Hospitals Government Owned (HPE)	1	1	1	2
Hospital Satellite Sterile Compounding (SCP)	2	3	2	2
Hospital Satellite Sterile Compounding Government Owned (SCE)	3	3	2	2
Hypodermic Needle and Syringes (HYP)	10	1	2	2
Correctional Pharmacy (LCF)	1	0	0	0
Outsourcing Facility (OSF)	2	2	0	1
Outsourcing Facility Nonresident (NSF)	11	5	4	5
Pharmacy (PHY)	200	177	172	150
Pharmacy Government Owned (PHE)	3	5	3	2
Remote Dispensing Pharmacy (PHR)	0	0	1	3
Pharmacy Nonresident (NRP)	134	140	130	128
Sterile Compounding (LSC)	96	95	91	84
Sterile Compounding - Government Owned (LSE)	12	13	13	10
Sterile Compounding Nonresident (NSC)	5	8	10	9
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0
Third-Party Logistics Providers (TPL)	5	0	3	0
Third-Party Logistics Providers Nonresident (NPL)	52	43	47	43
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	1
Wholesalers (WLS)	46	46	39	37
Wholesalers Government Owned (WLE)	1	1	1	1
Wholesalers Nonresident (OSD)	118	101	89	89
Total	**1,057**	**982**	**939**	**859**

Applications Pending with Temporary Licenses Issued - Pending Full License	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Drug Room -Temp (DRM)	0	0	0	0
Hospitals - Temp (HSP)	5	7	4	3
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	0
Outsourcing Facility - Temp (OSF)	0	0	0	0
Outsourcing Facility Nonresident - Temp (NSF)	0	1	1	2
Pharmacy - Temp (PHY)	106	100	111	126
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	0
Pharmacy Nonresident - Temp (NRP)	28	29	36	45
Sterile Compounding - Temp (LSC)	21	20	12	9
Sterile Compounding Nonresident - Temp (NSC)	6	3	1	3
Third-Party Logistics Providers - Temp (TPL)	1	0	1	1
Third-Party Logistics Providers Nonresident - Temp (NPL)	3	0	2	0
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	0	0	0
Wholesalers - Temp (WLS)	7	2	5	7
Wholesalers Nonresident - Temp (OSD)	11	4	9	3
Total	**188**	**166**	**182**	**199**

APPLICATIONS WITHDRAWN

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	1	1	4	9	15
Designated Representatives Vet (EXV)	1	0	0	0	1
Designated Representatives-3PL (DRL)	2	1	1	2	6
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	0	0	3	2	5
Pharmacist (exam applications)	0	0	159	20	179
Advanced Practice Pharmacist (APH)	0	0	0	69	69
Pharmacy Technician (TCH)	13	10	18	22	63
Total	**17**	**12**	**185**	**124**	**338**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	65	16	17	2	100
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	1	0	1	0	2
Clinics (CLN)	0	2	1	0	3
Clinics Government Owned (CLE)	0	3	0	28	31
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	2	2	4
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	9	0	0	9
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	1	0	1
Outsourcing Facility Nonresident (NSF)	1	1	2	0	4
Pharmacy (PHY)	6	9	8	8	31
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	1	1	3	3	8
Sterile Compounding (LSC)	3	0	5	7	15
Sterile Compounding - Government Owned (LSE)	0	1	0	0	1
Sterile Compounding Nonresident (NSC)	0	0	1	0	1
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	4	0	1	5
Third-Party Logistics Providers Nonresident (NPL)	2	9	0	2	13
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	0	5	2	1	8
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	7	12	9	3	31
Total	**86**	**72**	**52**	**57**	**267**

APPLICATIONS DENIED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	0	0	0	0	0
Designated Representatives Vet (EXV)	0	0	0	0	0
Designated Representatives-3PL (DRL)	0	0	0	0	0
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0
Designated Paramedic (DPM)	0	0	0	0	0
Intern Pharmacist (INT)	0	0	1	0	1
Pharmacist (exam not eligible)	2	2	0	0	4
Pharmacist (exam eligible)	0	0	0	0	0
Advanced Practice Pharmacist (APH)	0	0	0	0	0
Pharmacy Technician (TCH)	8	11	4	4	27
Total	**10**	**13**	**5**	**4**	**32**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	0	0	0	0	0
Clinics Government Owned (CLE)	0	0	0	0	0
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	0	0	0
Hospitals Government Owned (HPE)	0	0	0	0	0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	1	0	1
Outsourcing Facility Nonresident (NSF)	0	1	0	0	1
Pharmacy (PHY)	2	6	0	3	11
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	0	0	0	0	0
Sterile Compounding (LSC)	2	0	0	0	2
Sterile Compounding Government Owned (LSE)	0	0	0	0	0
Sterile Compounding Nonresident (NSC)	0	0	0	0	0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	0	0	0	0	0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0
Wholesalers (WLS)	0	0	1	0	1
Wholesalers Government Owned (WLE)	0	0	0	0	0
Wholesalers Nonresident (OSD)	0	0	0	0	0
Total	**4**	**7**	**2**	**3**	**16**

RESPOND TO STATUS INQUIRIES

Email Inquiries	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representative Received	540	419	265	683	1,907
Designated Representative Responded	89	127	71	417	704
Advanced Practice Pharmacist Received	314	122	228	96	760
Advanced Practice Pharmacist Responded	169	148	106	96	519
Pharmacist/Intern Received	1,580	1,169	1,286	2,507	6,542
Pharmacist/Intern Responded	844	3,020	1,405	2,246	7,515
Pharmacy Technician Received	1,363	584	1,191	1,460	4,598
Pharmacy Technician Responded	1,241	1,073	1,101	1,020	4,435
Pharmacy Received	2,242	2,021	2,097	2,155	8,515
Pharmacy Responded	2,365	2,090	2,311	2,217	8,983
Sterile Compounding/Outsourcing Received	1,646	1,275	1,214	1,646	5,781
Sterile Compounding/Outsourcing Responded	1,319	808	882	1,140	4,149
Wholesale/Clinic/Hypodermic/3PL Received	1,119	927	922	1,244	4,212
Wholesale/Clinic/Hypodermic/3PL Responded	575	665	751	1,110	3,101
Automated Drug Delivery Systems Received	565	617	365	133	1,680
Automated Drug Delivery Systems Responded	505	277	183	85	1,050
Pharmacist-in-Charge Received	516	763	748	879	2,906
Pharmacist-in-Charge Responded	254	650	556	454	1,914
Change of Permit Received	1,546	909	982	1,023	4,460
Change of Permit Responded	725	446	721	826	2,718
Renewals Received	2,269	1,701	1,934	1,908	7,812
Renewals Responded	1,854	1,480	1,733	1,650	6,717

Telephone Calls Received	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representative	50	0	67	56	173
Advanced Practice Pharmacist	149	229	45	20	443
Pharmacist/Intern	1,257	2,122	92	458	3,929
Pharmacy	226	461	413	581	1,681
Sterile Compounding/Outsourcing	120	111	162	84	477
Wholesale/Clinic/Hypodermic/3PL	280	499	338	246	1,363
Automated Drug Delivery Systems	28	58	48	31	165
Pharmacist-in-Charge	151	234	192	117	694
Change of Permit	119	122	112	92	445
Renewals	1,227	1,559	1,501	1,051	5,338

UPDATE LICENSING RECORDS

Change of Pharmacist-in-Charge	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	504	526	528	459	2,017
Processed	218	556	717	637	2,128
Approved	332	600	747	710	2,389
Pending (Data reflects number of pending at the end of the quarter.)	692	629	416	178	n/a
Change of Designated Representative-in-Charge	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	37	33	56	35	161
Processed	59	28	60	38	185
Approved	70	35	55	42	202
Pending (Data reflects number of pending at the end of the quarter.)	57	50	53	46	n/a
Change of Responsible Manager	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	5	8	7	6	26
Processed	7	8	6	7	28
Approved	7	10	5	9	31
Pending (Data reflects number of pending at the end of the quarter.)	4	2	4	1	n/a
Change of Professional Director	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	1	13	29	25	68
Processed	0	13	55	41	109
Approved	0	1	41	40	82
Pending (Data reflects number of pending at the end of the quarter.)	6	18	42	30	n/a
Change of Permits	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	356	312	297	323	1,288
Processed	9	145	679	629	1,462
Approved	13	301	304	506	1,124
Pending (Data reflects number of pending at the end of the quarter.)	1,724	1,745	1,862	1,717	n/a
Clinic Co-Location	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	0	0	0	0	0
Processed	0	0	0	0	0
Approved	0	0	0	0	0
Pending (Data reflects number of pending at the end of the quarter.)	0	0	0	0	n/a
Discontinuance of Business	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	103	134	97	23	357
Processed	96	191	125	28	440
Approved	91	156	126	27	400
Pending (Data reflects number of pending at the end of the quarter.)	266	249	217	221	n/a
Requests Approved	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Address/Name Changes	3,797	2,883	3,216	2,996	12,892
Off-site Storage	31	649	40	16	736
Transfer of Intern Hours	15	10	7	10	42
License Verification	655	437	589	461	n/a

DISCONTINUED OF BUSINESS

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	3	15	25	14	57
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	0	0
Centralized Hospital Packaging (CHP)	0	0	0	0	0
Clinics (CLN)	7	5	3	0	15
Clinics Government Owned (CLE)	1	3	0	0	4
Drug Room (DRM)	0	0	0	0	0
Drug Room Government Owned (DRE)	0	0	0	0	0
Hospitals (HSP)	0	0	2	0	2
Hospitals Government Owned (HPE)	1	0	1	0	2
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	0	0
Hypodermic Needle and Syringes (HYP)	0	1	0	0	1
Correctional Pharmacy (LCF)	0	0	0	0	0
Outsourcing Facility (OSF)	0	0	0	1	1
Outsourcing Facility Nonresident (NSF)	2	1	0	0	3
Pharmacy (PHY)	36	43	29	31	139
Pharmacy (PHY) Chain	9	51	14	8	82
Pharmacy Government Owned (PHE)	0	0	0	0	0
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	7	5	5	5	22
Sterile Compounding (LSC)	13	8	20	6	47
Sterile Compounding Government Owned (LSE)	5	0	1	0	6
Sterile Compounding Nonresident (NSC)	0	3	2	0	5
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	1	0	0	0	1
Third-Party Logistics Providers Nonresident (NPL)	0	1	2	0	3
Veterinary Food-Animal Drug Retailer (VET)	0	0	1	0	1
Wholesalers (WLS)	10	5	6	1	22
Wholesalers Government Owned (WLE)	0	2	0	0	2
Wholesalers Nonresident (OSD)	7	7	0	2	16
Total	**102**	**150**	**111**	**68**	**431**

LICENSES RENEWED

Individual Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	585	591	667	621	2,464
Designated Representatives Vet (EXV)	23	4	11	25	63
Designated Representatives-3PL (DRL)	77	54	57	66	254
Designated Representatives-Reverse Distributor (DRR)	0	2	0	0	2
Designated Paramedic (DPM)	0	0	0	0	0
Pharmacist (RPH)	5,545	5,386	5,302	5,687	21,920
Advanced Practice Pharmacist (APH)	78	61	68	104	311
Pharmacy Technician (TCH)	7,673	7,299	7,468	8,265	30,705
Total	**13,981**	**13,397**	**13,573**	**14,768**	**55,719**

Site Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	12	497	16	80	605
Automated Drug Delivery System EMS (ADE)	0	0	0	0	0
Automated Patient Dispensing System 340B Clinic (ADC)	0	0	0	0	0
Centralized Hospital Packaging Government Owned (CHE)	0	0	0	1	1
Centralized Hospital Packaging (CHP)	3	1	3	0	7
Clinics (CLN)	302	255	263	236	1,056
Clinics Government Owned (CLE)	138	96	53	70	357
Drug Room (DRM)	6	4	7	6	23
Drug Room Government Owned (DRE)	1	9	0	0	10
Hospitals (HSP)	53	131	113	82	379
Hospitals Government Owned (HPE)	28	25	2	20	75
Hospital Satellite Sterile Compounding (SCP)	1	0	0	1	2
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	1	1	2
Hypodermic Needle and Syringes (HYP)	38	70	73	59	240
Correctional Pharmacy (LCF)	1	56	0	2	59
Outsourcing Facility (OSF)	1	5	0	0	6
Outsourcing Facility Nonresident (NSF)	3	1	1	7	12
Pharmacy (PHY)	1,105	2,010	1,601	1,525	6,241
Pharmacy Government Owned (PHE)	82	25	4	17	128
Remote Dispensing Pharmacy (PHR)	0	0	0	0	0
Pharmacy Nonresident (NRP)	60	168	152	106	486
Sterile Compounding (LSC)	135	244	148	155	682
Sterile Compounding Government Owned (LSE)	71	5	2	32	110
Sterile Compounding Nonresident (NSC)	9	19	11	21	60
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0
Third-Party Logistics Providers (TPL)	7	5	8	7	27
Third-Party Logistics Providers Nonresident (NPL)	21	25	8	14	68
Veterinary Food-Animal Drug Retailer (VET)	3	4	6	3	16
Wholesalers (WLS)	114	90	101	109	414
Wholesalers Government Owned (WLE)	7	3	1	1	12
Wholesalers Nonresident (OSD)	154	155	144	155	608
Total	**2,355**	**3,903**	**2,718**	**2,710**	**11,686**

CURRENT LICENSES - Data reflects number of licenses at the end of the quarter.

Individual Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Designated Representatives (EXC)	2,933	2,914	2,919	2,903
Designated Representatives Vet (EXV)	67	66	67	67
Designated Representatives-3PL (DRL)	319	335	339	345
Designated Representatives-Reverse Distributor (DRR)	2	2	3	4
Designated Paramedic (DPM)	0	0	3	3
Intern Pharmacist (INT)	7,700	7,171	6,959	6,954
Pharmacist (RPH)	47,023	47,670	47,876	47,891
Advanced Practice Pharmacist (APH)	574	624	670	765
Pharmacy Technician (TCH)	70,150	69,796	69,534	69,559
Total	**128,768**	**128,578**	**128,370**	**128,491**

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD)	794	952	899	910
Automated Drug Delivery System EMS (ADE)	0	0	1	1
Automated Patient Dispensing System 340B Clinic (ADC)	1	1	1	1
Centralized Hospital Packaging Government Owned (CHE)	2	2	3	2
Centralized Hospital Packaging (CHP)	8	8	8	8
Clinics (CLN)	1,245	1,246	1,257	1,301
Clinics Government Owned (CLE)	468	550	641	880
Drug Room (DRM)	22	22	22	22
Drug Room Government Owned (DRE)	10	10	10	10
Hospitals (HSP)	385	387	388	389
Hospitals Government Owned (HPE)	83	82	81	82
Hospital Satellite Sterile Compounding (SCP)	3	3	4	4
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	1	1
Hypodermic Needle and Syringes (HYP)	299	299	299	300
Correctional Pharmacy (LCF)	60	60	61	61
Outsourcing Facility (OSF)	5	5	5	4
Outsourcing Facility Nonresident (NSF)	22	22	22	24
Pharmacy (PHY)	6,442	6,389	6,400	6,399
Pharmacy Government Owned (PHE)	130	130	134	135
Remote Dispensing Pharmacy (PHR)	0	0	0	1
Pharmacy Nonresident (NRP)	552	558	577	581
Sterile Compounding (LSC)	753	754	744	746
Sterile Compounding Government Owned (LSE)	117	114	114	113
Sterile Compounding Nonresident (NSC)	72	69	66	68
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	1
Third-Party Logistics Providers (TPL)	29	30	30	33
Third-Party Logistics Providers Nonresident (NPL)	74	78	80	84
Veterinary Food-Animal Drug Retailer (VET)	21	21	21	21
Wholesalers (WLS)	539	537	539	545
Wholesalers Government Owned (WLE)	14	14	14	14
Wholesalers Nonresident (OSD)	761	769	780	789
Total	**12,912**	**13,113**	**13,203**	**13,530**
Total Population of Licenses	**141,680**	**141,691**	**141,573**	**142,021**

CALIFORNIA STATE BOARD OF PHARMACY - THREE YEAR COMPARISON

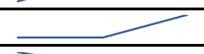
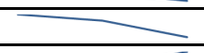
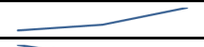
APPLICATIONS RECEIVED

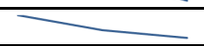
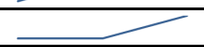
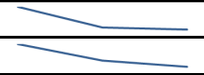
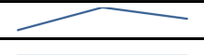
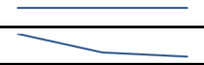
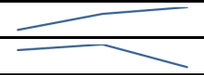
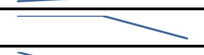
Designated Representatives Vet (EXV)	2	10	7	250%	
Designated Representatives-3PL (DRL)	82	91	85	4%	
Designated Representatives-Reverse Distributor (DRR)	0	2	2	n/a	
Designated Paramedic (DPM)	0	0	3	n/a	
Intern Pharmacist (INT)	2,395	2,212	2,015	-16%	
Pharmacist Exam Appllications	3,543	3,389	2,417	-32%	
Pharmacist Retake Exam Applications (exam applications)	n/a	n/a	1,333	n/a	
Pharmacist (initial licensing applications)	2,019	2,022	1,958	-3%	
Advanced Practice Pharmacist (APH)	258	246	199	-23%	
Pharmacy Technician (TCH)	5,420	5,338	4,422	-18%	
Total	**14,168**	**13,711**	**12,785**	**-10%**	

Automated Drug Delivery System EMS (ADE)	n/a	0	1	n/a	
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	1	0	n/a	
Centralized Hospital Packaging Government Owned (CHE)	0	0	2	n/a	
Centralized Hospital Packaging (CHP)	2	5	1	-50%	
Clinics (CLN)	93	209	122	31%	
Clinics Government Owned (CLE)	12	116	515	4192%	
Drug Room (DRM)	0	0	0	0%	
Drug Room Government Owned (DRE)	1	0	0	-100%	
Hospitals (HSP)	22	52	30	36%	
Hospitals Government Owned (HPE)	3	4	3	0%	
Hospital Satellite Sterile Compounding (SCP)	3	5	2	-33%	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	2	2	100%	
Hypodermic Needle and Syringes (HYP)	20	12	6	-70%	
Correctional Pharmacy (LCF)	3	1	0	-100%	
Outsourcing Facility (OSF)	1	2	1	0%	
Outsourcing Facility Nonresident (NSF)	9	8	12	33%	
Pharmacy (PHY)	375	466	334	-11%	
Pharmacy (PHY) Chain	604	33	38	-94%	
Pharmacy Government Owned (PHE)	6	6	7	17%	
Remote Dispensing Pharmacy (PHR)	0	0	4	n/a	
Pharmacy Nonresident (NRP)	136	168	124	-9%	
Sterile Compounding (LSC)	105	153	100	-5%	
Sterile Compounding Government Owned (LSE)	8	9	12	50%	
Sterile Compounding Nonresident (NSC)	18	17	10	-44%	
Surplus Medication Collection Distribution Intermediary (SME)	0	1	0	0%	
Third-Party Logistics Providers (TPL)	4	10	7	75%	
Third-Party Logistics Providers Nonresident (NPL)	19	16	22	16%	
Veterinary Food-Animal Drug Retailer (VET)	0	3	0	0%	
Wholesalers (WLS)	83	70	56	-33%	
Wholesalers Government Owned (WLE)	2	0	0	-100%	
Wholesalers Nonresident (OSD)	133	101	102	-23%	
Total	**1,662**	**2,065**	**1,838**	**11%**	

Applications Received with Temporary License Requests	**FY 17/18**	**FY 18/19**	**FY 19/20**	**% CHANGE FY 17/18 to FY 19/20**	**TREND LINES**
Drug Room -Temp (DRM)	0	0	0	n/a	
Hospitals - Temp (HSP)	16	41	25	56%	
Hospital Satellite Sterile Compounding - Temp (SCP)	0	5	1	n/a	
Outsourcing Facility - Temp (OSF)	0	1	1	n/a	
Outsourcing Facility Nonresident - Temp (NSF)	3	3	6	100%	
Pharmacy - Temp (PHY)	178	878	265	49%	
Remote Dispensing Pharmacy - Temp (PHR)	0	0	1	n/a	
Pharmacy Nonresident - Temp (NRP)	55	98	81	47%	
Sterile Compounding - Temp (LSC)	37	78	51	38%	
Sterile Compounding Nonresident - Temp (NSC)	11	12	4	-64%	
Third-Party Logistics Providers - Temp (TPL)	1	5	4	300%	
Third-Party Logistics Providers Nonresident - Temp (NPL)	7	5	7	0%	
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	1	0	0%	
Wholesalers - Temp (WLS)	35	28	37	6%	
Wholesalers Nonresident - Temp (OSD)	36	31	30	-17%	
Total	**379**	**1,186**	**513**	**35%**	
Total Applications Received	**16,209**	**16,962**	**15,136**	**-7%**	

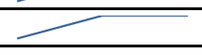
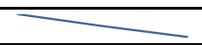
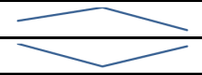
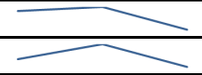
LICENSES ISSUED

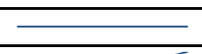
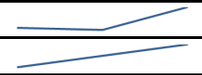
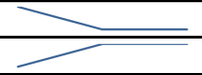
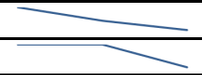
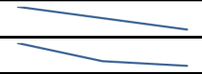
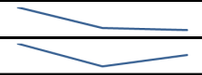
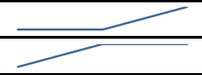
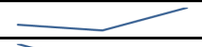
Designated Representatives Vet (EXV)	2	4	6	200%	
Designated Representatives-3PL (DRL)	64	64	87	36%	
Designated Representatives-Reverse Distributor (DRR)	0	2	2	n/a	
Designated Paramedic (DPM)	0	0	3	n/a	
Intern Pharmacist (INT)	2,208	2,030	1,931	-13%	
Pharmacist (RPH)	2,065	2,025	1,917	-7%	
Advanced Practice Pharmacist (APH)	204	216	253	24%	
Pharmacy Technician (TCH)	5,278	4,926	4,644	-12%	
Total	**10,208**	**9,533**	**9,192**	**-10%**	

Automated Drug Delivery System EMS (ADE)	n/a	0	1	n/a	
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	1	0	n/a	
Centralized Hospital Packaging Government Owned (CHE)	0	0	1	n/a	
Centralized Hospital Packaging (CHP)	3	0	0	-100%	
Clinics (CLN)	49	93	202	312%	
Clinics Government Owned (CLE)	10	122	531	5210%	
Drug Room (DRM)	0	0	0	n/a	
Drug Room Government Owned (DRE)	0	1	0	0%	
Hospitals (HSP)	3	3	1	-67%	
Hospitals Government Owned (HPE)	3	1	0	-100%	
Hospital Satellite Sterile Compounding (SCP)	0	3	1	n/a	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	1	n/a	
Hypodermic Needle and Syringes (HYP)	6	25	6	0%	
Correctional Pharmacy (LCF)	1	0	1	0%	
Outsourcing Facility (OSF)	2	3	0	-100%	
Outsourcing Facility Nonresident (NSF)	15	5	4	-73%	
Pharmacy (PHY)	243	150	118	-51%	
Pharmacy Government Owned (PHE)	4	6	5	25%	
Remote Dispensing Pharmacy (PHR)	0	0	0	n/a	
Pharmacy Nonresident (NRP)	68	35	28	-59%	
Sterile Compounding (LSC)	34	50	57	68%	
Sterile Compounding Government Owned (LSE)	7	8	4	-43%	
Sterile Compounding Nonresident (NSC)	6	11	2	-67%	
Surplus Medication Collection Distribution Intermediary (SME)	0	0	1	n/a	
Third-Party Logistics Providers (TPL)	1	3	5	400%	
Third-Party Logistics Providers Nonresident (NPL)	5	7	16	220%	
Veterinary Food-Animal Drug Retailer (VET)	1	1	0	-100%	
Wholesalers (WLS)	53	30	31	-42%	
Wholesalers Government Owned (WLE)	1	0	0	-100%	
Wholesalers Nonresident (OSD)	59	60	63	7%	
Total	**574**	**618**	**2,087**	**264%**	

Hospitals - Temp (HSP)	11	46	10	-9%	
Hospital Satellite Sterile Compounding - Temp (SCP)	0	0	0	n/a	
Outsourcing Facility - Temp (OSF)	0	0	0	n/a	
Outsourcing Facility Nonresident - Temp (NSF)	2	2	3	50%	
Pharmacy - Temp (PHY)	135	241	245	81%	
Remote Dispensing Pharmacy - Temp (PHR)	0	0	0	n/a	
Pharmacy Nonresident - Temp (NRP)	43	89	77	79%	
Sterile Compounding - Temp (LSC)	35	64	35	0%	
Sterile Compounding Nonresident - Temp (NSC)	4	12	7	75%	
Third-Party Logistics Providers - Temp (TPL)	1	4	3	200%	
Third-Party Logistics Providers Nonresident - Temp (NPL)	6	3	7	17%	
Veterinary Food-Animal Drug Retailer - Temp (VET)	0	1	0	n/a	
Wholesalers - Temp (WLS)	20	26	24	20%	
Wholesalers Nonresident - Temp (OSD)	25	29	34	36%	
Total	**282**	**519**	**445**	**58%**	
Total Licenses Issued	**11,064**	**10,670**	**11,724**	**6%**	

PENDING APPLICATIONS

Designated Representatives Vet (EXV)	1	6	5	400%	
Designated Representatives-3PL (DRL)	100	111	103	3%	
Designated Representatives-Reverse Distributor (DRR)	0	2	2	n/a	
Designated Paramedic (DPM)	0	0	0	n/a	
Intern Pharmacist (INT)	232	170	113	-51%	
Pharmacist (exam applications)	1,272	1,505	1,120	-12%	
Pharmacist (eligible)	2,487	1,848	2,417	-3%	
Advanced Practice Pharmacist (APH)	174	196	71	-59%	
Pharmacy Technician (TCH)	1,176	1,341	1,091	-7%	
Total	**5,769**	**5,569**	**5,301**	**-8%**	

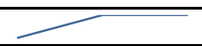
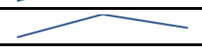
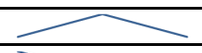
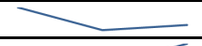
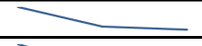
Automated Drug Delivery System EMS (ADE)	n/a	0	0	n/a	
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	0	0	n/a	
Centralized Hospital Packaging Government Owned (CHE)	0	0	1	n/a	
Centralized Hospital Packaging (CHP)	2	5	4	100%	
Clinics (CLN)	80	185	91	14%	
Clinics Government Owned (CLE)	11	43	28	155%	
Drug Room (DRM)	0	0	0	n/a	
Drug Room Government Owned (DRE)	1	0	0	-100%	
Hospitals (HSP)	8	7	20	150%	
Hospitals Government Owned (HPE)	0	1	2	100%	
Hospital Satellite Sterile Compounding (SCP)	3	2	2	-33%	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	2	2	n/a	
Hypodermic Needle and Syringes (HYP)	24	11	2	-92%	
Correctional Pharmacy (LCF)	1	1	0	-100%	
Outsourcing Facility (OSF)	3	2	1	-67%	
Outsourcing Facility Nonresident (NSF)	15	7	5	-67%	
Pharmacy (PHY)	693	189	150	-78%	
Pharmacy Government Owned (PHE)	3	1	2	-33%	
Remote Dispensing Pharmacy (PHR)	0	0	3	n/a	
Pharmacy Nonresident (NRP)	91	128	128	41%	
Sterile Compounding (LSC)	69	93	84	22%	
Sterile Compounding Government Owned (LSE)	7	6	10	43%	
Sterile Compounding Nonresident (NSC)	22	8	9	-59%	
Surplus Medication Collection Distribution Intermediary (SME)	0	1	0	n/a	
Third-Party Logistics Providers (TPL)	9	8	0	-100%	
Third-Party Logistics Providers Nonresident (NPL)	49	53	43	-12%	
Veterinary Food-Animal Drug Retailer	0	1	1	100%	
Wholesalers (WLS)	43	48	37	-14%	
Wholesalers Government Owned (WLE)	1	1	1	0%	
Wholesalers Nonresident (OSD)	120	112	89	-26%	
Total	**1,255**	**1,510**	**859**	**-32%**	

The number of temporary applications pending issuance is reflected in the number reported for the primary license type.

Applications Pending with Temporary Licenses Issued - Pending Full License*	FY 17/18	FY 18/19	FY 19/20	% CHANGE FY 17/18 to FY 19/20	TREND LINES
Drug Room -Temp (DRM)	n/a	n/a	0	n/a	
Hospitals - Temp (HSP)	n/a	n/a	3	n/a	
Hospital Satellite Sterile Compounding - Temp (SCP)	n/a	n/a	0	n/a	
Outsourcing Facility - Temp (OSF)	n/a	n/a	0	n/a	
Outsourcing Facility Nonresident - Temp (NSF)	n/a	n/a	2	n/a	
Pharmacy - Temp (PHY)	n/a	n/a	126	n/a	
Remote Dispensing Pharmacy - Temp (PHR)	n/a	n/a	0	n/a	
Pharmacy Nonresident - Temp (NRP)	n/a	n/a	45	n/a	
Sterile Compounding - Temp (LSC)	n/a	n/a	9	n/a	
Sterile Compounding Nonresident - Temp (NSC)	n/a	n/a	3	n/a	
Third-Party Logistics Providers - Temp (TPL)	n/a	n/a	1	n/a	
Third-Party Logistics Providers Nonresident - Temp (NPL)	n/a	n/a	0	n/a	
Veterinary Food-Animal Drug Retailer - Temp (VET)	n/a	n/a	0	n/a	
Wholesalers - Temp (WLS)	n/a	n/a	7	n/a	
Wholesalers Nonresident - Temp (OSD)	n/a	n/a	3	n/a	
Total	**0**	**0**	**199**	**n/a**	
Total Licenses Pending	**7,024**	**7,079**	**6,359**	**-9%**	

* Temporary pending full license not collected FY 17/18-18/19

WITHDRAWN APPLICATIONS

Designated Representatives Vet (EXV)	0	1	1	n/a	
Designated Representatives-3PL (DRL)	4	9	6	50%	
Designated Representatives-Reverse Distributor (DRR)	0	0	0	n/a	
Designated Paramedic (DPM)	0	0	0	n/a	
Intern Pharmacist (INT)	5	56	5	0%	
Pharmacist (Exam)*	764	12	179	-77%	
Advanced Practice Pharmacist (APH)	1	0	69	6800%	
Pharmacy Technician (TCH)	540	128	63	-88%	
Total	**1,333**	**258**	**338**	**-75%**	

Automated Drug Delivery System EMS (ADE)	n/a	0	0	n/a	
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	0	0	n/a	
Centralized Hospital Packaging Government Owned (CHE)	1	0	0	-100%	
Centralized Hospital Packaging (CHP)	2	1	2	0%	
Clinics (CLN)	2	9	3	50%	
Clinics Government Owned (CLE)	4	1	31	675%	
Drug Room (DRM)	0	0	0	n/a	
Drug Room Government Owned (DRE)	0	0	0	n/a	
Hospitals (HSP)	2	0	4	100%	
Hospitals Government Owned (HPE)	0	0	0	n/a	
Hospital Satellite Sterile Compounding (SCP)	0	1	0	n/a	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	n/a	
Hypodermic Needle and Syringes (HYP)	1	2	9	800%	
Correctional Pharmacy (LCF)	2	0	0	-100%	
Outsourcing Facility (OSF)	0	0	1	100%	
Outsourcing Facility Nonresident (NSF)	2	6	4	100%	
Pharmacy (PHY)	45	592	31	-31%	
Pharmacy Government Owned (PHE)	0	0	0	n/a	
Remote Dispensing Pharmacy (PHR)	0	0	0	n/a	
Pharmacy Nonresident (NRP)	29	6	8	-72%	
Sterile Compounding (LSC)	1	9	15	1400%	
Sterile Compounding Government Owned (LSE)	2	2	1	-50%	
Sterile Compounding Nonresident (NSC)	4	5	1	-75%	
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	n/a	
Third-Party Logistics Providers (TPL)	1	3	5	400%	
Third-Party Logistics Providers Nonresident (NPL)	2	1	13	550%	
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	n/a	
Wholesalers (WLS)	7	3	8	14%	
Wholesalers Government Owned (WLE)	0	0	0	n/a	
Wholesalers Nonresident (OSD)	10	15	31	210%	
Total	**117**	**656**	**267**	**128%**	
Total Applications Withdrawn	**1,450**	**914**	**605**	**-58%**	

* FY 17/18 There were 764 Pharmacist (exam) applications withdrawn as a result of redirection of staff to identify abandoned applications

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

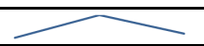
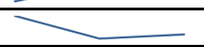
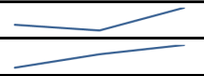
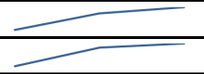
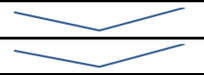
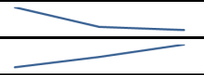
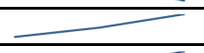
DENIED APPLICATIONS

Designated Representatives-3PL (DRL)	0	0	0	n/a	
Designated Paramedic (DPM)	0	0	0	n/a	
Designated Representatives-Reverse Distributor (DRR)	0	0	0	n/a	
Intern Pharmacist (INT)	5	11	1	-80%	
Pharmacist (exam applications)	8	5	4	-50%	
Pharmacist (eligible)	0	2	0	n/a	
Advanced Practice Pharmacist (APH)	0	0	0	n/a	
Pharmacy Technician (TCH)	37	32	27	-27%	
Total	**50**	**50**	**32**	**-36%**	

Centralized Hospital Packaging (CHP)	0	0	0	n/a	
Clinics (CLN)	0	1	0	n/a	
Clinics Government Owned (CLE)	0	0	0	n/a	
Drug Room (DRM)	0	0	0	n/a	
Drug Room Government Owned (DRE)	0	0	0	n/a	
Hospitals (HSP)	0	0	0	n/a	
Hospitals Government Owned (HPE)	0	0	0	n/a	
Hospital Satellite Sterile Compounding (SCP)	0	0	0	n/a	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	0	n/a	
Hypodermic Needle and Syringes (HYP)	0	0	0	n/a	
Hypodermic Needle and Syringes Government Owned (HYE)	0	0	0	n/a	
Correctional Pharmacy (LCF)	0	0	0	n/a	
Outsourcing Facility (OSF)	2	1	1	-50%	
Outsourcing Facility Nonresident (NSF)	4	1	1	-75%	
Pharmacy (PHY)	14	6	11	-21%	
Pharmacy Government Owned (PHE)	0	0	0	n/a	
Remote Dispensing Pharmacy (PHR)	0	0	0	n/a	
Pharmacy Nonresident (NRP)	4	0	0	-100%	
Sterile Compounding (LSC)	1	1	2	100%	
Sterile Compounding Government Owned (LSE)	0	0	0	n/a	
Sterile Compounding Nonresident (NSC)	0	0	0	n/a	
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	n/a	
Third-Party Logistics Providers (TPL)	0	0	0	n/a	
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	n/a	
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	n/a	
Wholesalers (WLS)	1	1	1	0%	
Wholesalers Government Owned (WLE)	0	0	0	n/a	
Wholesalers Nonresident (OSD)	0	2	0	n/a	
Total	**26**	**13**	**16**	**-38%**	
Total Applications Denied	**76**	**63**	**48**	**-37%**	

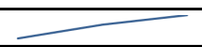
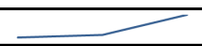
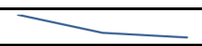
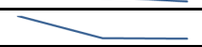
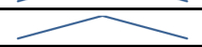
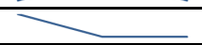
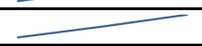
The number of temporary applications denied is reflected in the number reported for the primary license type.

RESPOND TO STATUS INQUIRIES

Designated Represenative Responded	447	2,015	704	57%	
Advanced Practice Pharmacist Received*	n/a	172	760	n/a	
Advanced Practice Pharmacist Responded*	n/a	396	519	n/a	
Pharmacist/Intern Received	8,775	6,082	6,542	-25%	
Pharmacist/Intern Responded	6,452	3,584	7,515	16%	
Pharmacy Technician Received	4,914	4,303	4,598	-6%	
Pharmacy Technician Responded	4,016	3,875	4,435	10%	
Pharmacy Received	6,365	7,630	8,515	34%	
Pharmacy Responded	6,183	8,186	8,983	45%	
Sterile Compounding/Outsourcing/CHP Received	4,614	5,560	5,781	25%	
Sterile Compounding/Outsourcing/CHP Responded	4,075	3,791	4,149	2%	
Wholesale/Clinic/Hypodermic/3PL Received	4,071	3,755	4,212	3%	
Wholesale/Clinic/Hypodermic/3PL Responded	3,447	3,149	3,101	-10%	
Automated Drug Delivery System (ADD) Received	n/a	779	1,680	n/a	
Automated Drug Delivery System (ADD) Responded	n/a	375	1,050	n/a	
Change of PIC/DRIC/RMG and DOB Received	1,681	2,313	2,906	73%	
Change of PIC/DRIC/RMG and DOB Responded	1,311	1,534	1,914	46%	
Change of Permit Received	5,559	6,247	4,460	-20%	
Change of Permit Responded	4,515	4,121	2,718	-40%	
Renewals Received	5,389	6,369	7,812	45%	
Renewals Responded	4,412	5,061	6,717	52%	
* FY 17/18 Advanced Practice Pharmacist emails are included in the Pharmacist/Intern.					

Advanced Practice Pharmacist	n/a	120	443	n/a	
Pharmacist/Intern	425	1,417	3,929	824%	
Pharmacy	907	1,177	1,681	85%	
Sterile Compounding/Outsourcing/CHP	411	367	477	16%	
Wholesale/Clinic/Hypodermic/3PL	570	428	1,363	139%	
Automated Drug Delivery System (ADD) Received	n/a	n/a	165	n/a	
Change of PIC/DRIC/RMG and DOB	655	440	694	6%	
Change of Permit	787	869	445	-43%	
Renewals	7,784	7,763	5,338	-31%	
The board did not collected the data separately for the items identified as "n/a".					

UPDATE LICENSING RECORDS

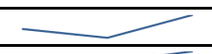
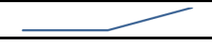
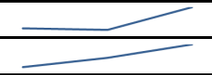
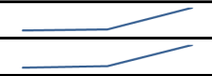
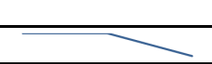
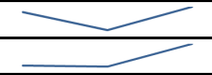
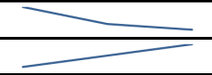
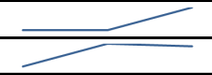
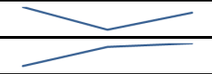
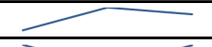
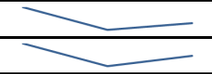
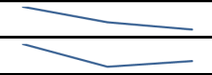
Processed	2,001	2,368	2,128	6%	
Approved	2,037	2,169	2,389	17%	
Pending	452	534	178	-61%	
Processed	114	155	185	62%	
Approved	101	113	202	100%	
Pending	48	90	46	-4%	
Processed	18	19	28	56%	
Approved	16	22	31	94%	
Pending	12	5	1	-92%	
Processed	n/a	n/a	111	n/a	
Approved	n/a	n/a	82	n/a	
Pending	n/a	n/a	30	n/a	
* Implemented tracking FY 19/20					
Processed	1,720	1,511	1,462	-15%	
Approved	1,618	1,126	1,124	-31%	
Pending	930	1,374	1,717	85%	
Processed	0	1	0	n/a	
Approved	0	1	0	n/a	
Pending	1	0	0	-100%	
Processed	357	428	507	42%	
Approved	327	390	459	40%	
Pending	199	256	227	14%	
Off-site Storage	170	169	736	333%	
Transfer of Intern Hours	74	40	42	-43%	
License Verification	2,234	2,489	2,112	-5%	

DISCONTINUED OF BUSINESS

Site Licenses	FY 17/18	FY 18/19	FY 19/20	% CHANGE FY 17/18 to FY 19/20	TREND LINES
Automated Drug Delivery System (ADD)	n/a	n/a	57	n/a	n/a
Automated Drug Delivery System EMS (ADE)	n/a	n/a	0	n/a	n/a
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	n/a	0	n/a	n/a
Centralized Hospital Packaging Government Owned (CHE)	n/a	n/a	0	n/a	n/a
Centralized Hospital Packaging (CHP)	n/a	n/a	0	n/a	n/a
Clinics (CLN)	n/a	n/a	15	n/a	n/a
Clinics Government Owned (CLE)	n/a	n/a	4	n/a	n/a
Drug Room (DRM)	n/a	n/a	0	n/a	n/a
Drug Room Government Owned (DRE)	n/a	n/a	0	n/a	n/a
Hospitals (HSP)	n/a	n/a	2	n/a	n/a
Hospitals Government Owned (HPE)	n/a	n/a	2	n/a	n/a
Hospital Satellite Sterile Compounding (SCP)	n/a	n/a	0	n/a	n/a
Hospital Satellite Sterile Compounding Government Owned (SCE)	n/a	n/a	0	n/a	n/a
Hypodermic Needle and Syringes (HYP)	n/a	n/a	1	n/a	n/a
Correctional Pharmacy (LCF)	n/a	n/a	0	n/a	n/a
Outsourcing Facility (OSF)	n/a	n/a	1	n/a	n/a
Outsourcing Facility Nonresident (NSF)	n/a	n/a	3	n/a	n/a
Pharmacy (PHY)	n/a	n/a	139	n/a	n/a
Pharmacy (PHY) chain	n/a	n/a	82	n/a	n/a
Pharmacy Government Owned (PHE)	n/a	n/a	0	n/a	n/a
Remote Dispensing Pharmacy (PHR)	n/a	n/a	0	n/a	n/a
Pharmacy Nonresident (NRP)	n/a	n/a	22	n/a	n/a
Sterile Compounding (LSC)	n/a	n/a	47	n/a	n/a
Sterile Compounding Government Owned (LSE)	n/a	n/a	6	n/a	n/a
Sterile Compounding Nonresident (NSC)	n/a	n/a	5	n/a	n/a
Surplus Medication Collection Distribution Intermediary (SME)	n/a	n/a	0	n/a	n/a
Third-Party Logistics Providers (TPL)	n/a	n/a	1	n/a	n/a
Third-Party Logistics Providers Nonresident (NPL)	n/a	n/a	3	n/a	n/a
Veterinary Food-Animal Drug Retailer (VET)	n/a	n/a	1	n/a	n/a
Wholesalers (WLS)	n/a	n/a	22	n/a	n/a
Wholesalers Government Owned (WLE)	n/a	n/a	2	n/a	n/a
Wholesalers Nonresident (OSD)	n/a	n/a	16	n/a	n/a
Total	**0**	**0**	**431**	**n/a**	**n/a**

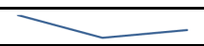
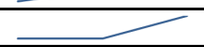
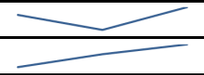
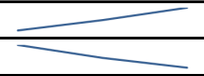
* The Board did not start reporting Licenses discontinued by date of closure until FY 19/20

LICENSES RENEWED

Designated Representatives Vet (EXV)	58	55	63	9%	
Designated Representatives-3PL (DRL)	202	228	254	26%	
Designated Representatives-Reverse Distributor (DRR)	0	0	2	n/a	
Designated Paramedic (DPM)	0	0	0	n/a	
Pharmacist (RPH)	20,663	20,573	21,920	6%	
Advanced Practice Pharmacist (APH)	91	180	311	242%	
Pharmacy Technician (TCH)	30,151	30,172	30,705	2%	
Total	**53,641**	**53,760**	**55,719**	**4%**	
Automated Drug Delivery System EMS (ADE)	n/a	n/a	0	n/a	
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	n/a	0	n/a	
Centralized Hospital Packaging Government Owned (CHE)	1	1	1	0%	
Centralized Hospital Packaging (CHP)	8	8	7	-13%	
Clinics (CLN)	1,035	968	1,056	2%	
Clinics Government Owned (CLE)	233	228	357	53%	
Drug Room (DRM)	24	20	23	-4%	
Drug Room Government Owned (DRE)	10	9	10	0%	
Hospitals (HSP)	390	356	379	-3%	
Hospitals Government Owned (HPE)	108	83	75	-31%	
Hospital Satellite Sterile Compounding (SCP)	0	1	2	100%	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	2	100%	
Hypodermic Needle and Syringes (HYP)	216	243	240	11%	
Correctional Pharmacy (LCF)	60	56	59	-2%	
Outsourcing Facility (OSF)	0	5	6	100%	
Outsourcing Facility Nonresident (NSF)	3	16	12	300%	
Pharmacy (PHY)	6,242	6,188	6,241	0%	
Pharmacy Government Owned (PHE)	140	125	128	-9%	
Remote Dispensing Pharmacy (PHR)	0	0	0	n/a	
Pharmacy Nonresident (NRP)	449	442	486	8%	
Sterile Compounding (LSC)	709	680	682	-4%	
Sterile Compounding Government Owned (LSE)	143	97	110	-23%	
Sterile Compounding Nonresident (NSC)	70	52	60	-14%	
Surplus Medication Collection Distribution Intermediary (SME)	1	1	0	-100%	
Third-Party Logistics Providers (TPL)	19	16	27	42%	
Third-Party Logistics Providers Nonresident (NPL)	52	49	68	31%	
Veterinary Food-Animal Drug Retailer (VET)	18	18	16	-11%	
Wholesalers (WLS)	456	427	414	-9%	
Wholesalers Government Owned (WLE)	15	11	12	-20%	
Wholesalers Nonresident (OSD)	601	614	608	1%	
Total	**11,003**	**10,714**	**11,686**	**6%**	
Total Licenses Renewed	**64,644**	**64,474**	**67,405**	**4%**	

Licenses identified as "n/a" were not in effect or eligible for renewal during the fiscal year.

CURRENT LICENSE POPULATION

Designated Representatives Vet (EXV)	69	66	67	-3%	
Designated Representatives-3PL (DRL)	286	300	347	21%	
Designated Representatives-Reverse Distributor (DRR)	0	2	4	n/a	
Designated Paramedic (DPM)	0	0	3	n/a	
Intern Pharmacist (INT)	6,800	6,541	6,943	2%	
Pharmacist (RPH)	45,988	47,085	47,926	4%	
Advanced Practice Pharmacist (APH)	334	550	803	140%	
Pharmacy Technician (TCH)	71,360	70,126	69,233	-3%	
Total	**127,841**	**127,579**	**128,211**	**0%**	
Automated Drug Delivery System EMS (ADE)	n/a	0	1	n/a	
Automated Patient Dispensing System 340B Clinic (ADC)	n/a	1	1	n/a	
Centralized Hospital Packaging Government Owned (CHE)	2	2	2	0%	
Centralized Hospital Packaging (CHP)	9	8	8	-11%	
Clinics (CLN)	1,109	1,147	1,301	17%	
Clinics Government Owned (CLE)	242	357	880	264%	
Drug Room (DRM)	23	22	22	-4%	
Drug Room Government Owned (DRE)	9	10	10	11%	
Hospitals (HSP)	383	385	389	2%	
Hospitals Government Owned (HPE)	85	83	82	-4%	
Hospital Satellite Sterile Compounding (SCP)	0	3	4	n/a	
Hospital Satellite Sterile Compounding Government Owned (SCE)	0	0	1	n/a	
Hypodermic Needle and Syringes (HYP)	293	297	300	2%	
Correctional Pharmacy (LCF)	58	60	61	5%	
Outsourcing Facility (OSF)	2	5	4	100%	
Outsourcing Facility Nonresident (NSF)	18	23	24	33%	
Pharmacy (PHY)	6,520	6,455	6,399	-2%	
Pharmacy Government Owned (PHE)	126	130	135	7%	
Remote Dispensing Pharmacy (PHR)	0	0	1	n/a	
Pharmacy Nonresident (NRP)	554	553	581	5%	
Sterile Compounding (LSC)	756	750	746	-1%	
Sterile Compounding Government Owned (LSE)	119	119	113	-5%	
Sterile Compounding Nonresident (NSC)	77	70	68	-12%	
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	0%	
Third-Party Logistics Providers (TPL)	23	26	33	43%	
Third-Party Logistics Providers Nonresident (NPL)	65	68	84	29%	
Veterinary Food-Animal Drug Retailer (VET)	20	21	21	5%	
Wholesalers (WLS)	540	530	545	1%	
Wholesalers Government Owned (WLE)	16	14	14	-13%	
Wholesalers Nonresident (OSD)	750	754	789	5%	
Total	**11,800**	**11,894**	**13,530**	**15%**	
Total Licenses Renewed	**139,641**	**139,473**	**141,741**	**2%**	
Licenses identified as "n/a" were not in effect during the fiscal year.					