California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

LICENSING COMMITTEE REPORT

Debbie Veale, Licensee Member, Chairperson
Seung Oh, License Member, Vice-Chairperson
Lavanza Butler, Licensee Member
Jignesh Patel, Licensee Member
Jason Weisz, Public Member
Albert Wong, Licensee Member

The Board will receive a summary of the committee's work at its October 20, 2020, meeting, as well as updates for discussion and action as necessary.

a. Approval of the July 8, 2020, Licensing Committee Meeting Minutes

During its meeting, the Committee will review and consider for approval the minutes from its July 8, 2020, meeting. **Attachment 1** includes a copy of the draft minutes.

b. Discussion and Consideration of Proposal to Expand the Authority for Pharmacists to Order and Administer CLIA Waived Tests for Influenza and COVID

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. More recently, on August 25, 2020, the DCA Director issued a waiver to specified professional licensing requirements and amends the scopes of practice of pharmacists and pharmacy technicians to allow them to perform waived, point-of-care tests used to detect SARS-CoV-2. Along with the waiver, guidance was released to inform and educate pharmacies, pharmacists and pharmacy technician of clinical laboratory requirements that apply under the DCA Order. Staff notes that this waiver and guidance document provide a good framework and understanding of what changes would be required in the law to make such authority permanent.

The CDC notes that both the flu and COVID-19 are both respiratory illnesses but are caused by different viruses. As included in the CDC's information, because the flu and COVID-19 are similar, it may be hard to tell the difference between them based on symptoms alone, and testing may be needed to help confirm a diagnosis.

For Committee Discussion and Consideration

As previously discussed by this committee, the authority for pharmacists to order and administer tests resides 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.

It may be appropriate for the committee to consider the benefits to patients in expanding testing authority for pharmacists on a permanent basis for CLIA waived point of care tests for both COVID-19 and influenza. Should the committee believe such expansion of authority is appropriate, the committee should also consider what, if any, additional requirements would be appropriate. To help facilitate such discussion, below are some questions the committee may wish to consider.

1. What, if any, additional training requirements should be required?
2. Should patient referral services be required?
3. How should test results be communicated to the patient and patient's primary care physician?
4. What, if any, space requirements should be required, e.g. designated area away from other patrons?
5. What, if any, personal protective requirements should be required?
6. Should the pharmacy providing such services be required to notify the Board in advance of providing such services?
7. Should the Board specify records requirements.
8. Should the Board require pharmacists to provide patient education as part of the process?

Attachment 2 includes the relevant laws, DCA issued waiver and relevant guidance documents.

c. Discussion and Consideration of Action Taken by the Accreditation Council of Pharmacy Education Related to California Health Sciences University Loss of Accreditation Status

Relevant Law

BPC section 4200 establishes the requirements for a pharmacist license, including graduation from a college of pharmacy or department of pharmacy of a university recognized by the Board, or if the applicant graduated from a foreign pharmacy school, certification by the Foreign Pharmacy Graduate Examination Committee.

CCR section 1719 defines "recognized school of pharmacy" as a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE) or otherwise recognized by the Board.

Background

Through an action by the ACPE, California Health Sciences University (CHSU) pre-accreditation status was withdrawn by the ACPE. Information released by CHSU indicates that the ACPE Board determined that the CHSU program was not sufficiently compliant in three of the 25 standards, and that according the ACPE policy, more time could not be granted for accreditation.

CHSU advised that 44 students accepted for admittance in the fall of 2020 must transition to another California pharmacy school. However, existing students are allowed to continue their education through a "teachout" program.

Attachment 3 is information received from ACPE. As included in the correspondence, ACPE notes that students continuing in the program who successfully complete both the didactic and experiential components of the Doctor of Pharmacy curriculum, will graduate from a program recognized by ACPE as holding candidate status. Such individuals will meet the educational requirements established in Pharmacy Law.

d. Discussion and Consideration of Development of Mandatory Reporting Requirement for Schools of Pharmacy to Notify the Board of Licensees Engaged in Academic Dishonesty as Part of the Students Academics

Background

As part of the Board's July 2020 meeting, members received a presentation on published research examining students' attitudes toward academic dishonesty in California pharmacy schools.

Public comment following the presentation indicated that the findings were troubling. Public comment also suggested that there is a stigma of reporting cheating worldwide and suggested that establishing a mandatory reporting requirement would take away the stigma.

To meet the educational requirements established for graduation, students complete both introductory and advanced pharmacy practice experience. Only individuals licensed by the Board as an intern pharmacist are eligible to complete such experience.

For Committee Consideration and Discussion

During the meeting, members will have the opportunity to discuss the policy regarding establishing such a requirement. Should members agree with the policy, staff will work with counsel to develop a proposal for future consideration by the Committee and Board.

e. Discussion and Consideration of Authorized Duties of a Pharmacy Technician and Possible Expansion to allow for Administration of Influenza Vaccinations by Pharmacy Technicians

Relevant Law

Business and Professions Code section 4115 provides that a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. This section further requires the board to adopt regulations that a pharmacy technician may perform.

Title 16, California Code of Regulations section 1793.2 establishes the nondiscretionary tasks to include removing the drug or drugs from stock; counting, pouring, or mixing

pharmaceuticals, placing the product into the container, affixing the label or labels to the container; and packaging or repackaging.

Background

Existing law provides authority for pharmacists to independently initiate and administer vaccines lists on the routine schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) under specific conditions (BPC 4052.8). Effective January 1, 2021, this authority will be expanded to COVID-19 vaccines that are FDA authorized or FDA approved.

The Committee and Board have previously received public comment requesting an expansion of authorized activities that may be performed by a pharmacy technician, to include administration of influenza shots or vaccines.

For Committee Discussion and Consideration

During the meeting members will have the opportunity to discuss this policy issue and determine if such expansion is appropriate. Should the committee agree that such an expansion is appropriate, the committee should consider what conditions are appropriate.

1. What additional training should be required as a precursor to expanding the pharmacist technicians permissible tasks?
   Board staff notes that the American Pharmacist Association provides a six-hour pharmacy-based immunization administration program. The course includes a self-study component combined with a live seminar that teaches hands-on immunization techniques.
2. Should ongoing continuing education be required, if so, what is the appropriate number of hours and frequency?
3. Should the proposal require certification in basic life support?
4. What, if any, additional documentation should be required, e.g. documentation including the identification of the administering pharmacy technician as well as the pharmacist providing supervision?
5. Are all routes of vaccine administration appropriate?
6. Is it appropriate to also allow a pharmacy technician to administer epinephrine?
7. Should the proposal be limited to only patients of a certain age, e.g. 18 and above?
8. Should the proposal include explicit language providing that the supervising pharmacist has delegated the administration function and that the supervising pharmacist reserves the right to not make such a delegation?

Attachment 4 includes a copy of the relevant laws and information on the APhA training program.

f. Discussion and Consideration of Pharmacy Technician Application Requirements and Common Deficiencies

Relevant Law

BPC 4202 establishes the authority for a pharmacy technician to qualify for licensure as a pharmacy technician. Specifically, an individual must either be a high school graduate or possess a general education certificate equivalent as well as satisfy one of four qualification methods:

1. Possess an associate degree in pharmacy technology.
2. Complete a course of training specified by the board in regulation.
3. Graduate from a school of pharmacy recognized by the board.
4. Be certified by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board.

CCR 1793.6 further defines the requirements of a pharmacy technician training program in BPC 4202(a)(2) as follows:

- Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,
- Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
- Any other course that provides a training period of at least 240 hours of instruction covering specific requirements defined in subsection (c) of section 1793.6.

CCR 1793.5 defines the pharmacy technician application requirements and incorporates the pharmacy technician application in the regulation (Form 17A-5 (Rev 10/15). Any revisions to the pharmacy technician application requires the application to go through the regulatory process. The application requirements include:

- Completing the pharmacy technician application (Form 17A-5 (Rev 10/15).
- The applicant's personal information to identify the applicant. BPC 30 requires applicants to provide either their US social security number or individual taxpayer identification number.
- Documentation to support the applicant's qualifications.
- Criminal background check that require submission of fingerprint cards.
- A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) date no earlier than 60 days of the date of application is submitted to the board.
- The applicant shall sign the application under penalty of perjury.

Background

The Board's largest volume of applications received each year are pharmacy technician applications. Historically, these applications have a high deficiency rate at the time of submission. In an effort to address deficiency rates in 2016, the Board created a video detailing the application process. The video is posted on the Board's website and on the department's YouTube channel. Regrettably, the Board continues to receive a large number of deficient applications, about 44% in the last fiscal year. Deficient applications not only impact the processing times but delay the applicant from being issued a license to enter the pharmacy workforce.

Currently, the Board has proposed changes to the application, that are moving through the regulatory process. The Board initiated the rulemaking process on July 27, 2016.

The most common deficiencies at the time of initial application review were:

- The applicant failed to complete the application by answering all the questions, provide a U.S. social security number or individual taxpayer identification number, provide a passport style photo, sign the application, and/or date the application. The applicant is required to complete the application, sign, and date the application within 60 days of the date the application is submitted to the Board.
- The Self-Query Report from the NPDB was not received in a sealed envelope, the applicant's name was transposed on the report, the date of birth or social security number was missing or incorrect, and/or the report was not within 60 days of receipt of the application.
- The high school transcript received does not reflect a graduation date.
- The applicant provided documentation of earning a degree from an accredited post-secondary institution, which did not satisfy section BPC 4202(a) that specifies, the Board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent.
- The applicant failed to submit a copy of the Pharmacy Technician Certification Board Certificate (PTBC) or the National Healthcare Association Pharmacy Technician Certification Program (ExCPT) [BPC 4202(a)(4).
- The appropriate authorized person with the pharmacy technician training program failed to complete the affidavit correctly (BPC 4202(a)(2) and CCR 1793.6(c).

As the Board continues through the Business Modernization process to move towards electronic submission of applications, it is clear allowing pharmacy technician applicants to complete the application online should provide for a more permanent solution to errors caused by incomplete applications.

Additionally, staff continues to work with pharmacy technician programs to make resources available to programs and applicants to assist them in submitting completed applications.

<u>For Committee Discussion and Consideration</u>

During the committee meeting, members will have an opportunity to discuss the pharmacy technician application requirements.

Attachment 5 includes the current relevant laws and the board's approved regulatory changes to CCR 1793.5 and 1793.6 on July 27, 2016.

g. Licensing Statistics

The quarterly licensing statistics for fiscal year 2020/2021, are provided in **Attachment 6.**

As of September 30, 2020, the Board has received 4,751 initial applications, including:

- 1,237 intern pharmacists
- 884 pharmacist exam applications (298 new, 586 retake)
- 60 advanced practice pharmacists
- 1,182 pharmacy technicians
- 89 community pharmacy license applications
- 24 sterile compounding pharmacy license applications (LSC, LSE, SCP, SCE)
- 30 nonresident pharmacy license applications
- 7 hospital pharmacy license applications

As of September 30, 2020, the Board has received 130 requests for temporary site license applications, including:

- 58 community pharmacy license applications
- 17 sterile compounding pharmacy license applications
- 18 nonresident pharmacy license applications
- 6 hospital pharmacy license applications

As of September 30, 2020, the Board has issued 2,693 individual licenses, including:

- 935 intern pharmacists
- 936 pharmacists
- 34 advanced practice pharmacists
- 711 pharmacy technicians

As of September 30, 2020, the Board has issued 131 site licenses without temporary license requests, including:

- 28 automated drug delivery systems
- 25 community pharmacies
- 0 hospital pharmacies

As of September 30, 2020, the Board has issued 102 temporary site licenses, including:

- 49 community pharmacies
- 4 hospital pharmacies

Processing Times

The general application and deficiency mail processing times by license type are provided below reflecting data current as of October 2, 2020. The data reflects the time from when an application or deficiency response is received by the Board through to the time it is reviewed by licensing staff. The standard performance processing time is within 30 days for initial applications and is within 10 days for deficiency mail. The term "Current" means staff is currently processing within 1-5 days for that specific license type.

Staff has been working diligently and adjusting the application review process during the pandemic in order to review applications electronically. All applications are received by mail and deficiency items are sent via email or mail. Regrettably as we transition internally processes for teleworking some application processing times have been negatively impacted.

Premises Application Types	Application Processing Times as of 6/26/2020	Application Processing Times as of 10/2/2020	Deficiency Mail Processing Times as of 6/26/2020	Deficiency Mail Processing Times as of 10/2/2020
Pharmacy	21	28	8	10
Nonresident Pharmacy	7	14	12	10
Sterile Compounding	23	28	22	22
Nonresident Sterile Compounding	Current	22	19	21
Outsourcing	Current	Current	Current	Current
Nonresident Outsourcing	11	17	Current	Current
Hospital Satellite Compounding Pharmacy	Current	Current	Current	Current
Hospital	30	2	Current	Current
Clinic	23	22	Current	10
Wholesaler	15	23	9	Current
Nonresident Wholesaler	Current	24	9	Current
Third-Party Logistics Provider	Current	Current	Current	Current
Nonresident Third-Party Logistics Provider	Current	8	Current	Current
Automated Drug Delivery System	10	8	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 6/26/2020	Application Processing Times as of 10/2/2020	Application Processing Times as of 6/26/2020	Application Processing Times as of 10/2/2020
Exam Pharmacist	11	24	Current	7
Pharmacist Initial Licensure	Current	Current	Current	n/a
Advanced Practice Pharmacist	Current	Current	Current	Current
Intern Pharmacist	Current	42	Current	9
Pharmacy Technician	23	51	10	Current
Designated Representative	Current	Current	Current	Current
Designated Represenatives-3PL	Current	Current	Current	Current
Designated Representatives-Reverse Distributor	Current	Current	Current	Current
Designated Paramedic	Current	Current	Current	Current

IX. Future Committee Meeting Dates

- January 27, 2021
- April 21, 2021
- July 14, 2021
- October 27, 2021

Attachment 1

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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 2

Relevant Law

4052. Furnishing to Prescriber; Permitted Procedures by Pharmacist

(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.

4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility

(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.

4052.2. Permitted Pharmacist Procedures in Health Care Facility; Home Health Agency or Clinic with Physician Oversight

(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.

4052.4. Skin Puncture by Pharmacist; Conditions Permitting
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.

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.

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.

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.

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DEPARTMENT OF CONSUMER AFFAIRS

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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

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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.

Attachment 3

Relevant Laws

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed a version of the California Practice Standards and Jurisprudence Examination for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure and the applicant meets either of the following requirements:

(A) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and holds an active pharmacist license in another state or territory of the United States.

(B) Has passed the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

1719. Recognized Schools of Pharmacy.

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200 of the Business and Professions Code.

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION
190 S. LaSalle Street, Suite 2850 Chicago, Illinois 60603-3499 | www.acpe-accredit.org
P: 312/664-3575 | F: 866/228-2631 | E: gboyer@acpe-accredit.org

October 9, 2020

Debi Mitchell
Senior Licensing Manager
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Dear Ms Mitchell:

I am writing in response to your October 5, 2020, inquiry regarding the remaining students enrolled in the Doctor of Pharmacy program at the California Health Sciences University (CHSU) College of Pharmacy (COP). Below please find my response to each of your three questions.

1. *As a result of the ACPE withdrawing CHSU's candidate status, please confirm ACPE considers the current students enrolled in the PharmD program at CHSU graduating in the next three years to fall within ACPE's "Candidate status" and to be eligible for licensure.*

ACPE Response: After three unsuccessful attempts to advance from Candidate Status to Accredited Status, ACPE withdrew its Preaccreditation Status from the Doctor of Pharmacy program offered by CHSU. Candidate Status is the second of the two phases of Preaccreditation Status, each of which must be completed before Accredited Status can be awarded. As a consequence of this action to withdraw Preaccreditation Status, any new students matriculating into the program would be entering a program with no status with ACPE. No new P1 class matriculated in fall 2020.

To protect those students currently enrolled at the time status was withdrawn (e.g., the students in the P2, P3, and P4 classes), the College must provide for their continued instruction and development via a Teachout plan. CHSU has elected to provide this Teachout itself. Thus, all students in the current P2, P3, and P4 classes who successfully complete both the didactic and experiential components of the Doctor of Pharmacy curriculum, will graduate from a program recognized by ACPE as holding Candidate Status. Historically, all State Boards of Pharmacy have recognized graduates of programs in Candidate Status as eligible for licensure.

2. *Please confirm how ACPE is ensuring that CHSU is providing a quality program?*
3. *Please confirm how ACPE is going to monitor the "Teachout" phase for these students….?*

ACPE Response to Questions 2 & 3: ACPE will continue its periodic monitoring of the CHSU Doctor of Pharmacy program. Such monitoring includes requested interim reports from the program, review of annual monitoring data, and on-site or virtual evaluations.

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These are the same approaches ACPE uses to monitor all of the 141 programs holding status with ACPE. Such monitoring will continue until the final cohort (the current P2 class) completes its course of instruction in spring 2024. If deficiencies are identified during any of these monitoring activities that compromise compliance with the Standards for the students remaining in the program, the College will be required to take the necessary steps to address the concerns.

Yours truly,

J. Gregory Boyer, Ph.D.
Associate Executive Director, and
Director Professional Degree Program Accreditation

Attachment 4

Relevant Laws

4115. Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratio

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against

any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.
(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).
(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.
(i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:
(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.
(2) Sealing emergency containers for use in the health care facility.
(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

1793.2. Duties of a Pharmacy Technician.
"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:
(a) removing the drug or drugs from stock;
(b) counting, pouring, or mixing pharmaceuticals;
(c) placing the product into a container;
(d) affixing the label or labels to the container;
(e) packaging and repackaging.
Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Share:

Pharmacy-Based Immunization Administration by Pharmacy Technicians

Activity Preview

Originally developed by Washington State University (WSU) and recently revised through a partnership between WSU and the American Pharmacists Association (APhA), the APhA/WSU *Pharmacy-Based Immunization Administration by Pharmacy Technicians* training program explores the expanding role of the pharmacy technician by providing additional skills training to administer immunizations. This two-part program emphasizes a health care team collaboration between pharmacists and technicians which seeks to improve population health by increasing immunization rates in states that allow technicians to immunize.

Composed of an online self-study component combined with a live seminar that teaches hands-on immunization techniques, this program will provide a total of six hours of continuing education for technicians and pharmacists.

Activity Type: Practice-based
Target Audience: Technicians in all practice settings and pharmacists
Learning Level: Level 3

Learning Objectives

Self-Study Learning Objectives:

- Describe proper technique when drawing up and administering immunizations
- Recognize commonly used vaccines and their corresponding routes of administration
- Distinguish proper needle length selection based on vaccine and patient age and size
- Identify proper documentation procedures
- Recall vaccine storage requirements
- Describe safety measures to avoid accidental needle stick injuries
- Recognize appropriate actions to take in emergency situations

Live Seminar Learning Objectives:

- Demonstrate a successful technique when administering an intramuscular and subcutaneous injection.
- Demonstrate appropriate distraction techniques during immunization administration.
- Demonstrate the use of universal precautions as they pertain to blood borne pathogens
- Explain the procedures for managing a vaccine reaction emergency

This ACPE activity does not provide a certification in this topic but rather advanced professional training which upon successful completion the learner will be able to download a certificate of achievement.

Accreditation Information

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The *Pharmacy-Based Immunization Administration by Pharmacy Technicians* training program is approved for a total of 6.0 contact hours of continuing pharmacy education (CPE) credit (0.6 CEUs). The ACPE Universal Activity Numbers (UAN) for this activity are listed below.

Successful completion of the self-study component involves passing the self-study assessment with a grade of 70% or higher and will result in 2 contact hours of CPE credit (0.2 CEUs). ACPE UAN: 0202-0000-20-124-H06-T/0202-0000-20-124-H06-P

Successful completion of the live seminar component involves attending the full live seminar, successfully completing the injection technique assessment, and completing the online assessment and evaluation. Successful completion of this component will result in 4 contact hours of CPE credit (0.4 CEU). ACPE UAN: 0202-0000-20-125-H06-T/0202-0000-20-125-H06-P

Practice Topics

Tools and resources to support your practice.

- Patient Care
- Payment
- Immunization Center
- Opioid Resource Center

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To obtain 6.0 contact hours of CPE credit 0.6 CEUs) for the *Pharmacy-Based Immunization Administration by Pharmacy Technicians* training program, the learner must complete all components listed above, and CLAIM credit for each component. Participants will need to have a valid APhA (pharmacist.com) username and password, as well as a CPE Monitor account to claim credit. After credit has been claimed, please visit CPE monitor for your transcript. The Certificate of Achievement will be available online upon successful completion of the necessary activity requirements on the participant's My Training page.

APhA continuing pharmacy education policy provides you with two opportunities to successfully complete the continuing pharmacy education assessment. Please note that you will not be permitted to submit the assessment a third time. The current policy of the APhA Education Department is not to release the correct answers to any of our CPE tests. This policy is intended to maintain the integrity of the CPE activity and the assessment.

Release Date: January 20, 2020

Expiration Date: January 20, 2023 - PLEASE NOTE: NO Home Study credit granted after this date; Live Credit can only be granted within 60 days from the day of the seminar attended.

Development

APhA/WSU's Pharmacy-Based Immunization Administration by Pharmacy Technicians training program was developed jointly by the American Pharmacists Association and Washington State University. Copyright © 2020 by the American Pharmacists Association/Washington State University.

System Requirements

Computer and Internet access are required to complete this activity. Please visit our website to view the Technology System Requirements in order to have a positive learning experience.

Additional Resources

If you are looking for some additional resources, try visiting our Pharmacist Immunization Center.

Join or Renew your Membership

Don't miss out on all the great benefits an APhA membership has to offer. Become a member today and see what APhA can do for you.

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Attachment 5

Relevant Law – Pharmacy Technician

4202. Pharmacy Technician: License Requirements for Education, Experience; Board Regulations; Criminal Background Check; Discipline

(a) The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy recognized by the board.

(4) Is certified by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board.

(b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(e) Once an individual is licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.

1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) is:

(a)

the following:

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

1793.5. Pharmacy Technician Application.

The “Pharmacy Technician Application” (Form 17A-5 (Rev. 10/15)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

Title 16. Board of Pharmacy
Proposed Regulation Text

Changes to the adopted emergency regulation text are as follows: underline for added text and strikethrough for deleted text.

Proposal to amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 7/2020)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:
   (1) Information sufficient to identify the applicant.
   (2) A description of the applicant's qualifications and supporting documentation for those qualifications.
   (3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).
   (4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5,~~ 114.5, 115.4, 115.5, 4005, ~~4007, 4038,~~ 4115, and 4202, ~~4207 and 4400,~~ Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402~~ and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Proposal to amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services

for which the applicant possesses a certificate of completion, or

(c)(1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(~~1~~A) Knowledge and understanding of different pharmacy practice settings.

(~~2~~B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(~~3~~C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(~~4~~D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(~~5~~E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(~~6~~F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(~~7~~G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115,~~ and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Proposal to add §1793.65 to Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, 2021.

Note: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

Attachment 6

CALIFORNIA STATE BOARD OF PHARMACY
QUARTERLY LICENSING STATISTICS FISCAL YEAR 2020/2021

APPLICATIONS RECEIVED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	92				92
Designated Representatives Vet (EXV)	0				0
Designated Representatives-3PL (DRL)	27				27
Designated Representatives-Reverse Distributor (DRR)	1				1
Designated Paramedic (DPM)	0				0
Intern Pharmacist (INT)	1,237				1,237
Pharmacist Exam Applications	298				298
Pharmacist Retake Exam Applications	586				586
Pharmacist Initial License Application (RPH)	935				935
Advanced Practice Pharmacist (APH)	60				60
Pharmacy Technician (TCH)	1,182				1,182
Total	**4,418**	**0**	**0**	**0**	**4,418**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	50				50
Automated Drug Delivery System EMS (ADE)	0				0
Automated Patient Dispensing System 340B Clinic (ADC)	0				0
Centralized Hospital Packaging Government Owned (CHE)	0				0
Centralized Hospital Packaging (CHP)	1				1
Clinics (CLN)	26				26
Clinics Government Owned (CLE)	19				19
Drug Room (DRM)	0				0
Drug Room Government Owned (DRE)	0				0
Hospitals (HSP)	6				6
Hospitals Government Owned (HPE)	1				1
Hospital Satellite Sterile Compounding (SCP)	0				0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0				0
Hypodermic Needle and Syringes (HYP)	4				4
Correctional Pharmacy (LCF)	0				0
Outsourcing Facility (OSF)	0				0
Outsourcing Facility Nonresident (NSF)	1				1
Pharmacy (PHY)	84				84
Pharmacy (PHY) Chain	5				5
Pharmacy Government Owned (PHE)	4				4
Remote Dispensing Pharmacy (PHR)	2				2
Pharmacy Nonresident (NRP)	30				30
Sterile Compounding (LSC)	23				23
Sterile Compounding Government Owned (LSE)	1				1
Sterile Compounding Nonresident (NSC)	5				5
Surplus Medication Collection Distribution Intermediary (SME)	0				0
Third-Party Logistics Providers (TPL)	4				4
Third-Party Logistics Providers Nonresident (NPL)	8				8
Veterinary Food-Animal Drug Retailer (VET)	0				0
Wholesalers (WLS)	20				20
Wholesalers Government Owned (WLE)	0				0
Wholesalers Nonresident (OSD)	30				30
Total	**324**	**0**	**0**	**0**	**324**

Applications Received with Temporary License Requests	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0				0
Hospitals - Temp (HSP)	6				6
Hospital Satellite Sterile Compounding - Temp (SCP)	0				0
Outsourcing Facility - Temp (OSF)	0				0
Outsourcing Facility Nonresident - Temp (NSF)	0				0
Pharmacy - Temp (PHY)	58				58
Remote Dispensing Pharmacy - Temp (PHR)	1				1
Pharmacy Nonresident - Temp (NRP)	18				18
Sterile Compounding - Temp (LSC)	17				17
Sterile Compounding Nonresident - Temp (NSC)	1				1
Third-Party Logistics Providers - Temp (TPL)	3				3
Third-Party Logistics Providers Nonresident - Temp (NPL)	7				7
Veterinary Food-Animal Drug Retailer - Temp (VET)	0				0
Wholesalers - Temp (WLS)	6				6
Wholesalers Nonresident - Temp (OSD)	13				13
Total	**130**	**0**	**0**	**0**	**130**

LICENSES ISSUED

Individual Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	57				57
Designated Representatives Vet (EXV)	2				2
Designated Representatives-3PL (DRL)	18				18
Designated Representatives-Reverse Distributor (DRR)	0				0
Designated Paramedic (DPM)	0				0
Intern Pharmacist (INT)	935				935
Pharmacist (RPH)	936				936
Advanced Practice Pharmacist (APH)	34				34
Pharmacy Technician (TCH)	711				711
Total	**2,693**	**0**	**0**	**0**	**2,693**

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	28				28
Automated Drug Delivery System EMS (ADE)	0				0
Automated Patient Dispensing System 340B Clinic (ADC)	0				0
Centralized Hospital Packaging Government Owned (CHE)	0				0
Centralized Hospital Packaging (CHP)	0				0
Clinics (CLN)	18				18
Clinics Government Owned (CLE)	18				18
Drug Room (DRM)	0				0
Drug Room Government Owned (DRE)	0				0
Hospitals (HSP)	0				0
Hospitals Government Owned (HPE)	0				0
Hospital Satellite Sterile Compounding (SCP)	0				0
Hospital Satellite Sterile Compounding Government Owned (SCE)	1				1
Hypodermic Needle and Syringes (HYP)	1				1
Correctional Pharmacy (LCF)	0				0
Outsourcing Facility (OSF)	0				0
Outsourcing Facility Nonresident (NSF)	1				1
Pharmacy (PHY)	25				25
Pharmacy Government Owned (PHE)	1				1
Remote Dispensing Pharmacy (PHR)	2				1
Pharmacy Nonresident (NRP)	4				4
Sterile Compounding (LSC)	10				10
Sterile Compounding Government Owned (LSE)	1				1
Sterile Compounding Nonresident (NSC)	0				0
Surplus Medication Collection Distribution Intermediary (SME)	0				0
Third-Party Logistics Providers (TPL)	0				0
Third-Party Logistics Providers Nonresident (NPL)	1				1
Veterinary Food-Animal Drug Retailer (VET)	0				0
Wholesalers (WLS)	5				5
Wholesalers Government Owned (WLE)	0				0
Wholesalers Nonresident (OSD)	15				15
Total	**131**	**0**	**0**	**0**	**130**

Site Temporary Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Drug Room -Temp (DRM)	0				0
Hospitals - Temp (HSP)	4				4
Hospital Satellite Sterile Compounding - Temp (SCP)	0				0
Outsourcing Facility - Temp (OSF)	1				1
Outsourcing Facility Nonresident - Temp (NSF)	1				1
Pharmacy - Temp (PHY)	49				49
Remote Dispensing Pharmacy - Temp (PHR)	2				2
Pharmacy Nonresident - Temp (NRP)	17				17
Sterile Compounding - Temp (LSC)	11				11
Sterile Compounding Nonresident - Temp (NSC)	1				1
Third-Party Logistics Providers - Temp (TPL)	0				0
Third-Party Logistics Providers Nonresident - Temp (NPL)	1				1
Veterinary Food-Animal Drug Retailer - Temp (VET)	0				0
Wholesalers - Temp (WLS)	4				4
Wholesalers Nonresident - Temp (OSD)	11				11
Total	**102**	**0**	**0**	**0**	**102**

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)	178			
Designated Representatives Vet (EXV)	2			
Designated Representatives-3PL (DRL)	42			
Designated Representatives-Reverse Distributor (DRR)	2			
Designated Paramedic (DPM)	0			
Intern Pharmacist (INT)	410			
Pharmacist (exam not eligible)	1,343			
Pharmacist (exam eligible)	1,456			
Advanced Practice Pharmacist (APH)	85			
Pharmacy Technician (TCH)	1,499			
Total	**5,017**	**0**	**0**	**0**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD)	163			
Automated Drug Delivery System EMS (ADE)	0			
Automated Patient Dispensing System 340B Clinic (ADC)	0			
Centralized Hospital Packaging Government Owned (CHE)	1			
Centralized Hospital Packaging (CHP)	5			
Clinics (CLN)	95			
Clinics Government Owned (CLE)	29			
Drug Room (DRM)	1			
Drug Room Government Owned (DRE)	0			
Hospitals (HSP)	19			
Hospitals Government Owned (HPE)	3			
Hospital Satellite Sterile Compounding (SCP)	2			
Hospital Satellite Sterile Compounding Government Owned (SCE)	0			
Hypodermic Needle and Syringes (HYP)	5			
Correctional Pharmacy (LCF)	0			
Outsourcing Facility (OSF)	0			
Outsourcing Facility Nonresident (NSF)	5			
Pharmacy (PHY)	150			
Pharmacy Government Owned (PHE)	4			
Remote Dispensing Pharmacy (PHR)	3			
Pharmacy Nonresident (NRP)	132			
Sterile Compounding (LSC)	84			
Sterile Compounding - Government Owned (LSE)	10			
Sterile Compounding Nonresident (NSC)	11			
Surplus Medication Collection Distribution Intermediary (SME)	0			
Third-Party Logistics Providers (TPL)	4			
Third-Party Logistics Providers Nonresident (NPL)	46			
Veterinary Food-Animal Drug Retailer (VET)	1			
Wholesalers (WLS)	46			
Wholesalers Government Owned (WLE)	1			
Wholesalers Nonresident (OSD)	91			
Total	**911**	**0**	**0**	**0**

Applications Pending with Temporary Licenses Issued - Pending Full License	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Drug Room -Temp (DRM)	0			
Hospitals - Temp (HSP)	4			
Hospital Satellite Sterile Compounding - Temp (SCP)	0			
Outsourcing Facility - Temp (OSF)	1			
Outsourcing Facility Nonresident - Temp (NSF)	3			
Pharmacy - Temp (PHY)	99			
Remote Dispensing Pharmacy - Temp (PHR)	2			
Pharmacy Nonresident - Temp (NRP)	36			
Sterile Compounding - Temp (LSC)	11			
Sterile Compounding Nonresident - Temp (NSC)	2			
Third-Party Logistics Providers - Temp (TPL)	1			
Third-Party Logistics Providers Nonresident - Temp (NPL)	0			
Veterinary Food-Animal Drug Retailer - Temp (VET)	0			
Wholesalers - Temp (WLS)	4			
Wholesalers Nonresident - Temp (OSD)	9			
Total	**172**	**0**	**0**	**0**

APPLICATIONS WITHDRAWN

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	233				233
Designated Representatives Vet (EXV)	1				1
Designated Representatives-3PL (DRL)	70				70
Designated Representatives-Reverse Distributor (DRR)	1				1
Designated Paramedic (DPM)	0				0
Intern Pharmacist (INT)	3				3
Pharmacist (exam applications)	239				239
Advanced Practice Pharmacist (APH)	9				9
Pharmacy Technician (TCH)	7				7
Total	**563**	**0**	**0**	**0**	**563**

Site Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	3				3
Automated Drug Delivery System EMS (ADE)	0				0
Automated Patient Dispensing System 340B Clinic (ADC)	0				0
Centralized Hospital Packaging Government Owned (CHE)	0				0
Centralized Hospital Packaging (CHP)	0				0
Clinics (CLN)	1				1
Clinics Government Owned (CLE)	0				0
Drug Room (DRM)	0				0
Drug Room Government Owned (DRE)	0				0
Hospitals (HSP)	0				0
Hospitals Government Owned (HPE)	0				0
Hospital Satellite Sterile Compounding (SCP)	0				0
Hospital Satellite Sterile Compounding Government Owned (SCE)	1				1
Hypodermic Needle and Syringes (HYP)	0				0
Correctional Pharmacy (LCF)	0				0
Outsourcing Facility (OSF)	0				0
Outsourcing Facility Nonresident (NSF)	0				0
Pharmacy (PHY)	9				9
Pharmacy Government Owned (PHE)	2				2
Remote Dispensing Pharmacy (PHR)	0				0
Pharmacy Nonresident (NRP)	0				0
Sterile Compounding (LSC)	1				1
Sterile Compounding - Government Owned (LSE)	0				0
Sterile Compounding Nonresident (NSC)	0				0
Surplus Medication Collection Distribution Intermediary (SME)	0				0
Third-Party Logistics Providers (TPL)	0				0
Third-Party Logistics Providers Nonresident (NPL)	3				3
Veterinary Food-Animal Drug Retailer (VET)	0				0
Wholesalers (WLS)	1				1
Wholesalers Government Owned (WLE)	0				0
Wholesalers Nonresident (OSD)	1				1
Total	**22**	**0**	**0**	**0**	**22**

APPLICATIONS DENIED

Individual Applications	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	0				0
Designated Representatives Vet (EXV)	0				0
Designated Representatives-3PL (DRL)	0				0
Designated Representatives-Reverse Distributor (DRR)	0				0
Designated Paramedic (DPM)	0				0
Intern Pharmacist (INT)	0				0
Pharmacist (exam application)	1				1
Pharmacist (exam eligible)	0				0
Advanced Practice Pharmacist (APH)	0				0
Pharmacy Technician (TCH)	1				1
Total	**2**	**0**	**0**	**0**	**2**

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

RESPOND TO STATUS INQUIRIES

Email Inquiries	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representative Received	1,123				1,123
Designated Representative Responded	1,018				1,018
Advanced Practice Pharmacist Received	110				110
Advanced Practice Pharmacist Responded	110				110
Pharmacist/Intern Received	2,473				2,473
Pharmacist/Intern Responded	1,796				1,796
Pharmacy Technician Received	1,215				1,215
Pharmacy Technician Responded	1,193				1,193
Pharmacy Received	2,013				2,013
Pharmacy Responded	1,799				1,799
Sterile Compounding/Outsourcing Received	1,196				1,196
Sterile Compounding/Outsourcing Responded	630				630
Wholesale/Clinic/Hypodermic/3PL Received	1,014				1,014
Wholesale/Clinic/Hypodermic/3PL Responded	803				803
Automated Drug Delivery Systems Received	180				180
Automated Drug Delivery Systems Responded	112				112
Pharmacist-in-Charge Received	686				686
Pharmacist-in-Charge Responded	542				542
Change of Permit Received	1,285				1,285
Change of Permit Responded	891				891
Renewals Received	1,986				1,986
Renewals Responded	1,727				1,727

Telephone Calls Received	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representative	62				62
Advanced Practice Pharmacist	16				16
Pharmacist/Intern	991				991
Pharmacy	480				480
Sterile Compounding/Outsourcing	121				121
Wholesale/Clinic/Hypodermic/3PL	232				232
Automated Drug Delivery Systems	40				40
Pharmacist-in-Charge	117				117
Change of Permit	118				118
Renewals	853				853
Reception	17,184				17,184

UPDATE LICENSING RECORDS

Change of Pharmacist-in-Charge	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Received	441				441
Processed	469				469
Approved	457				457
Pending (Data reflects number of pending at the end of the quarter.)	175				n/a
Change of Designated Representative-in-Charge	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	28				28
Processed	24				24
Approved	23				23
Pending (Data reflects number of pending at the end of the quarter.)	53				n/a
Change of Responsible Manager	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	6				6
Processed	5				5
Approved	5				5
Pending (Data reflects number of pending at the end of the quarter.)	2				n/a
Change of Professional Director	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	24				24
Processed	31				31
Approved	17				17
Pending (Data reflects number of pending at the end of the quarter.)	47				n/a
Change of Permits	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	238				238
Processed	268				268
Approved	178				178
Pending (Data reflects number of pending at the end of the quarter.)	1,799				n/a
Clinic Co-Location	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	0				0
Processed	0				0
Approved	0				0
Pending (Data reflects number of pending at the end of the quarter.)	0				n/a
Discontinuance of Business	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	92				92
Processed	92				92
Approved	79				79
Pending (Data reflects number of pending at the end of the quarter.)	237				n/a
Intern Pharmacist Extensions	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Received	31				31
Processed	25				25
Completed	13				13
Pending (Data reflects number of pending at the end of the quarter.)	28				n/a
Requests Approved	**July - Sept**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total FYTD**
Address/Name Changes	3,351				3,351
Off-site Storage	94				94
Transfer of Intern Hours	5				5
License Verification	514				514

DISCONTINUED OF BUSINESS

discontinued by date of closure

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	13				13
Automated Drug Delivery System EMS (ADE)	0				0
Automated Patient Dispensing System 340B Clinic (ADC)	0				0
Centralized Hospital Packaging Government Owned (CHE)	0				0
Centralized Hospital Packaging (CHP)	0				0
Clinics (CLN)	3				3
Clinics Government Owned (CLE)	0				0
Drug Room (DRM)	0				0
Drug Room Government Owned (DRE)	0				0
Hospitals (HSP)	2				2
Hospitals Government Owned (HPE)	1				1
Hospital Satellite Sterile Compounding (SCP)	0				0
Hospital Satellite Sterile Compounding Government Owned (SCE)	0				0
Hypodermic Needle and Syringes (HYP)	1				1
Correctional Pharmacy (LCF)	0				0
Outsourcing Facility (OSF)	0				0
Outsourcing Facility Nonresident (NSF)	0				0
Pharmacy (PHY)	19				19
Pharmacy (PHY) Chain	8				8
Pharmacy Government Owned (PHE)	0				0
Remote Dispensing Pharmacy (PHR)	0				0
Pharmacy Nonresident (NRP)	4				4
Sterile Compounding (LSC)	3				3
Sterile Compounding Government Owned (LSE)	1				1
Sterile Compounding Nonresident (NSC)	0				0
Surplus Medication Collection Distribution Intermediary (SME)	0				0
Third-Party Logistics Providers (TPL)	0				0
Third-Party Logistics Providers Nonresident (NPL)	2				2
Veterinary Food-Animal Drug Retailer (VET)	0				0
Wholesalers (WLS)	1				1
Wholesalers Government Owned (WLE)	0				0
Wholesalers Nonresident (OSD)	2				2
Total	**60**	**0**	**0**	**0**	**60**

LICENSES RENEWED

Individual Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Designated Representatives (EXC)	495				495
Designated Representatives Vet (EXV)	12				12
Designated Representatives-3PL (DRL)	82				82
Designated Representatives-Reverse Distributor (DRR)	0				0
Designated Paramedic (DPM)	0				0
Pharmacist (RPH)	4,846				4,846
Advanced Practice Pharmacist (APH)	99				99
Pharmacy Technician (TCH)	6,975				6,975
Total	**12,509**	**0**	**0**	**0**	**12,509**

Site Licenses Renewed	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun	Total FYTD
Automated Drug Delivery System (ADD)	21				21
Automated Drug Delivery System EMS (ADE)	0				0
Automated Patient Dispensing System 340B Clinic (ADC)	0				0
Centralized Hospital Packaging Government Owned (CHE)	2				2
Centralized Hospital Packaging (CHP)	3				3
Clinics (CLN)	400				400
Clinics Government Owned (CLE)	116				116
Drug Room (DRM)	3				3
Drug Room Government Owned (DRE)	5				5
Hospitals (HSP)	53				53
Hospitals Government Owned (HPE)	44				44
Hospital Satellite Sterile Compounding (SCP)	2				2
Hospital Satellite Sterile Compounding Government Owned (SCE)	0				0
Hypodermic Needle and Syringes (HYP)	59				59
Correctional Pharmacy (LCF)	2				2
Outsourcing Facility (OSF)	1				1
Outsourcing Facility Nonresident (NSF)	2				2
Pharmacy (PHY)	1,027				1,027
Pharmacy Government Owned (PHE)	59				59
Remote Dispensing Pharmacy (PHR)	1				1
Pharmacy Nonresident (NRP)	69				69
Sterile Compounding (LSC)	139				139
Sterile Compounding Government Owned (LSE)	69				69
Sterile Compounding Nonresident (NSC)	10				10
Surplus Medication Collection Distribution Intermediary (SME)	1				1
Third-Party Logistics Providers (TPL)	4				4
Third-Party Logistics Providers Nonresident (NPL)	20				20
Veterinary Food-Animal Drug Retailer (VET)	3				3
Wholesalers (WLS)	123				123
Wholesalers Government Owned (WLE)	5				5
Wholesalers Nonresident (OSD)	174				174
Total	**2,417**	**0**	**0**	**0**	**2,417**

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)	2,849			
Designated Representatives Vet (EXV)	67			
Designated Representatives-3PL (DRL)	351			
Designated Representatives-Reverse Distributor (DRR)	4			
Designated Paramedic (DPM)	3			
Intern Pharmacist (INT)	7,039			
Pharmacist (RPH)	48,587			
Advanced Practice Pharmacist (APH)	851			
Pharmacy Technician (TCH)	68,637			
Total	**128,388**	**0**	**0**	**0**

Site Licenses	July - Sept	Oct-Dec	Jan-Mar	Apr-Jun
Automated Drug Delivery System (ADD)	930			
Automated Drug Delivery System EMS (ADE)	1			
Automated Patient Dispensing System 340B Clinic (ADC)	1			
Centralized Hospital Packaging Government Owned (CHE)	2			
Centralized Hospital Packaging (CHP)	8			
Clinics (CLN)	1,311			
Clinics Government Owned (CLE)	898			
Drug Room (DRM)	22			
Drug Room Government Owned (DRE)	10			
Hospitals (HSP)	392			
Hospitals Government Owned (HPE)	79			
Hospital Satellite Sterile Compounding (SCP)	4			
Hospital Satellite Sterile Compounding Government Owned (SCE)	2			
Hypodermic Needle and Syringes (HYP)	300			
Correctional Pharmacy (LCF)	61			
Outsourcing Facility (OSF)	4			
Outsourcing Facility Nonresident (NSF)	25			
Pharmacy (PHY)	6,378			
Pharmacy Government Owned (PHE)	136			
Remote Dispensing Pharmacy (PHR)	3			
Pharmacy Nonresident (NRP)	589			
Sterile Compounding (LSC)	744			
Sterile Compounding Government Owned (LSE)	112			
Sterile Compounding Nonresident (NSC)	68			
Surplus Medication Collection Distribution Intermediary (SME)	1			
Third-Party Logistics Providers (TPL)	32			
Third-Party Logistics Providers Nonresident (NPL)	84			
Veterinary Food-Animal Drug Retailer (VET)	20			
Wholesalers (WLS)	530			
Wholesalers Government Owned (WLE)	14			
Wholesalers Nonresident (OSD)	807			
Total	**13,568**	**0**	**0**	**0**
Total Population of Licenses	**141,956**	**0**	**0**	**0**