

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



To: Board Members

Subject: Agenda Item XVI. Executive Officer's Report

### Discussion of Board's Response to COVID-19 Pandemic and Actions Taken by Other Agencies

The Board continues to dedicate significant resource to its response to the COVID-19 public health crisis; both independently as well as in collaboration with other government agencies.

Subsequent to Governor Newson's March 4, 2020 declaration of emergency, the Board developed and implemented a waiver request process consistent with the provisions of Business and Professions Code (BPC) section 4062. This statute provides the Board the authority to waive provisions of Pharmacy Law or its regulations if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care. Consistent with the Board's policy, President Lippe reviews and makes final determination on all waiver approvals. As previously discussed, some waiver requests cannot be approved, either because they are outside the scope of the Board's jurisdiction or they seek to expand the scope of practice of a licensee.

As the conditions of the pandemic continue to evolve, decisions on waivers only occurs after thoughtful consideration. In general, when making decisions on waivers, the Board makes a decision on balance, in the best interest of Californians. As healthcare locations resume services, openings of previously closed facilities resume, and in recognition of variances in local conditions, some broad waivers have expired. Whether the waiver is extended or expired, notification is sent via the Board's subscriber alert system and the Board's website is updated. Readers are also reminded about the option to request a site-specific waivers.

### Broad Waivers Issued/Extended

The Board currently has eight Broad waivers. Provided below is a brief summary of each waiver and the current expiration date.

- Signature Requirement for Receipt of Delivery of Drugs (BPC section 4059.5) Summary: Waives the signature requirement for the receipt of the delivery of drugs under specified conditions Effective: March 17, 2020 Expires: December 21, 2020 or until the emergency declaration is lifted, whichever is sooner.
- 2. <u>Prescriber Dispensing Medication to Emergency Room Patient (BPC sections 4068(a)(1),</u> 4068(a)(5), and 4068(a)(6))

**Summary**: Waives the prohibition against a prescriber dispensing medications to an emergency room patient under specified conditions.

Effective: March 27, 2020

**Expires**: December 21, 2020, or until the emergency declaration is lifted, whichever is sooner.

3. <u>USP <797> Requirements Related to Use of Personal Protective Equipment (BPC section</u> <u>4126.8)</u>

**Summary**: Waive USP <797> requirements related to the use of PPE, to allow for a PPE mask and gown to be reused by staff performing sterile compounding under specified conditions.

Effective: March 17, 2020

Expires: December 21, 2020

- Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (Title 16, California Code of Regulations, section 1751.5)
   Summary: Allows for the potential waiver of required PPE requirements for compounding performed in a CAI or CACI under specified conditions.
   Effective: April 1, 2020
   Expires: December 28, 2020
- Restoration of Retired or Canceled Pharmacist License BPC section 4200.5(d), Related to Retired Licensees; BPC section 4402(b), Related to Canceled Pharmacist Licenses; and BPC section 4403, Related to Payment of Fees for Reissuance or Renewal of License Summary: Waives conditions for reinstatement of a cancelled or retired pharmacist license.
   Effective: April 3, 2020

Expires: January 1, 2020

6. Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a))

Summary: Waives the requirement for in-person consultation under specified conditions. Effective: April 1, 2020

Expires: December 28, 2020

- <u>Remote Processing (BPC section 4071.1(a))</u> <u>Summary</u>: Waives limitations on the provisions of remote order entry. <u>Effective</u>: March 18, 2020 <u>Expires</u>: October 31, 2020 or until the emergency declaration is lifted, whichever is sooner.
   <u>Staffing Ratio of Pharmacists to Intern Pharmacists and General Supervision –</u>
- Immunizations BPC section 4114

   Summary:
   Authorizes and increase in the ratio of pharmacists to pharmacy technicians if the additional intern is administering immunizations under specified conditions.

   Effective:
   July 23, 2020

   Expires:
   January 18, 2021

Decisions on possible extension of many of these waivers will be agendized for the December 2020 meeting.

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### Site Specific Waivers

Site specific waivers continue to be granted. Such waivers typically address a specific challenge at a worksite, that on balance, can be granted without negatively impacting consumers. Members have previously reviewed some site-specific waivers during public meetings and will be considering one such waiver during this meeting. Other site-specific waivers are granted because the entity cannot meet the requirements of the law, e.g., conducting an in-person inspection as required by Business and Professions Code section 4127.2(c).

### DCA Director Waivers

As previously reported, in addition to the Board's waiver process, on March 30, 2020, Governor Newsom signed an Executive Order N 39-20, granting the DCA Director the authority to waive licensing requirements and amend scope of practice and any accompanying regulations to facilitate the continued provision of care to individuals.

On August 25, 2020, the DCA Director issued an order that waives 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 have been working with the administration and CDPH on implementation efforts, including developing a process to issue mobile pharmacy licenses under the provisions of BPC 4062 to pharmacies wishing to provide testing at temporary locations consistent with authorizing provisions found within the purview of Laboratory Field Services with the California Department of Public Health.

### **Temporary Licenses**

As part of Operation Warp Speed, Board staff has issued temporary licenses to wholesalers partnering with the federal government to distribute vaccinations.

### **Operational Changes**

Staff continue to respond to the fluidity of the pandemic by making adjustments to operations to ensure the safety of staff and the public. As previously report, there are several limiting factors that must be addressed long term to sustain this rotational teleworking schedule, most notably more robust and portable computers and a decreased reliance on paper. We continue to complete internal assessments to identify the best methods to make the necessary operational changes to facilitate teleworking while minimizing impacts to processing timeframes.

As reported in July, in partnership with several other state agencies, inspector staff will begin assessing for compliance with the statewide face mask requirement and other physical distancing and protective measures. To date staff have perform about 725 such inspections while conducting onsite inspections.

Executive Officer's Report October 27-28, 2020 Board Meeting Page 3 of 4 Attachment 1 includes a copy of the DCA waiver and supporting guidance documents.

### Update on the Sunset Review Process

Board staff was recently advised that oversight hearings could resume in the near future. However, no potential hearing dates or logistics have yet been finalized. As part of the communication, committee staff have advised that oversight committees will use the sunset reports submitted last year but have requested that relevant updates be provided. In addition, supplemental questions related to COVID-19 have been provided that we require response.

As this supplemental reporting is due December 1, Board staff requests the Board's consideration of a recommendation to delegate authority to the Board President or another member to work with staff to finalize the report to meet the submission deadline. Alternatively, the Board could schedule a meeting the end of November to review the supplemental report.

Attachment 2 Includes a copy of the supplemental questions requested.

### Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

The Board publishes a biannual report of the pass rates for the CPJE and NAPLEX exam. **Attachment 3** includes the aggregate information for examinations administered between May and September. As indicated in the report includes pass rate information for the 1934 exams administered during the reporting period. The overall pass rate for the CPJE is 63.7 percent and is 92.5 percent for the NAPLEX.

This information will also be posted on the website.

# **Attachment 1**



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

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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 <u>State of Emergency</u> 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 <u>N-39-20</u>, 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. Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests Department of Consumer Affairs pg. 2

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
το	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 <sup>1</sup>

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

<sup>&</sup>lt;sup>1</sup> 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 <u>Laboratory Field Services (LFS) released guidelines</u> 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.



Important Information for California State Board of Pharmacy Licensees Related to COVID-19 Testing Page 3

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 <u>LFSCOVID@cdph.ca.gov</u>. LFS has also posted FAQs for laboratories: <u>https://www.cdph.ca.gov/Programs/OSPHLD/LFS/Pages/COVID-19.aspx</u>.

### 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:

- <u>FAQs</u> 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): <u>https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html</u>
- Guidance on COVID-19 for Pharmacy Personnel: <u>https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-</u> <u>19/GuidanceforPharmacies.aspx</u>
- Guidance on Resource Requests for Health Care Providers: <u>https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-</u> <u>19/ResourceRequestingforHealthCareProviders.aspx</u>
- Guidance on Expanded Access to Testing: <u>https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-</u> <u>19/Expanding-Access-to-Testing-Updated-Interim-Guidance-on-</u> <u>Prioritization-for-COVID-19-Laboratory-Testing-0501.aspx</u>



Important Information for California State Board of Pharmacy Licensees Related to COVID-19 Testing Page 4

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

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

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

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

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.



# LABORATORY FIELD SERVICES

# Guidance for Pharmacies, Pharmacists, and Pharmacy Technicians Performing Waived, Point-of-Care COVID-19 Tests

On August 25, 2020, the Director of the Department of Consumer Affairs issued an Order, DCA-20-45, that waives 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, the virus that causes COVID-19 disease. This DCA Order, among other requirements, requires pharmacies where such testing is performed to obtain a California Clinical Laboratory Registration from Laboratory Field Services (LFS) and a federal CLIA Certificate of Waiver, and to comply with applicable SARS-CoV-2 reporting requirements. DCA-20-45 supersedes the previous Department of Consumer Affairs Order issued on May 12, 2020, and the subsequent extension granted on July 7, 2020. A Guidance for Pharmacies, Pharmacists and Pharmacy Technicians Ordering, Collecting Specimens for, and Performing COVID-19 Tests with general information on the Order is available on the DCA website.

In order to inform and educate pharmacies, pharmacists, and pharmacy technicians of the clinical laboratory requirements that apply under the DCA Order, LFS provides the following general information on the laboratory registration/certification process and testing personnel and reporting requirements.

### **State Registration and Federal CLIA Certification Requirements**

- DCA-20-45 requires that a pharmacy performing waived, point-of-care testing for SARS-CoV-2 must obtain a California Clinical Laboratory Registration and a federal CLIA Certificate of Waiver.
  - Pursuant to DCA-20-45, for the duration of the California state of emergency, a pharmacy is authorized to perform waived, point-of-care tests used to detect the presence of SARS-CoV-2 authorized by the FDA.
  - DCA-20-45 does not affect pharmacists' authority to perform other waived tests not related to SARS-CoV-2, such as blood glucose, hemoglobin, A1c, or cholesterol tests.
- To obtain a California Clinical Laboratory Registration:
  - The pharmacy must complete and submit to LFS the following State application form, with the application fee, for new laboratory registration applications:
    - LAB 155 Application for Clinical Laboratory Registration (PDF)
      - Pursuant to DCA-20-45, the pharmacy is not required to identify a laboratory director on the state laboratory registration application.
- To obtain a CLIA Certificate of Waiver:
  - The pharmacy must complete and submit to LFS the following federal application form:
    - CMS 116 CLIA application (PDF)
      - Pursuant to DCA-20-45, the pharmacist-in-charge is required to be identified as the laboratory director on the federal application.
      - CLIA will bill the applicant separately for the application fee.

• For more information about the application process, please contact LFS at LFSCOVID@cdph.ca.gov. Please submit forms to the same email address, to ensure that they are received as COVID-19 applications. LFS will process applications sent to this email within 10 days of receipt of a complete application.

### State Registration Requirements for Mobile Units and Temporary Testing Sites

- In general, Business and Professions Code section 1265(d) requires a separate registration for each laboratory location where testing is performed.
- However, for the duration of the California state of emergency, a pharmacy that performs waived COVID-19 tests at locations other than at the pharmacy site may be exempt from the separate registration requirement if certain criteria are met.
  - **Temporary Testing Site:** A pharmacy operating a temporary testing site is exempt from the separate registration requirement if all of the following conditions are met:
    - The pharmacy identifies a designated primary site or "home base" where personnel, testing equipment, supplies, and reagents are stored, and records and files are maintained.
    - The pharmacy notifies LFS of the temporary testing site locations.
    - No equipment, supplies, and reagents are stored permanently at the temporary site.
    - A temporary testing site may include the following: diagnostic screening health fairs, skilled nursing facilities, and other locations conducive to waived, point-of-care testing.
  - **Mobile Units Providing Laboratory Testing:** A pharmacy that operates a mobile laboratory unit is exempt from the separate registration requirement for all testing locations if the following conditions are met:
    - The mobile unit is a self-contained operational laboratory with its own personnel, equipment, and records. Typically, the mobile unit is a vehicle such as an ambulance or van.
    - The laboratory equipment must be permanently located within the mobile unit.
    - The mobile unit is not used solely for transport of the equipment from one testing site to another.
    - The mobile unit must be affiliated with a home base. If testing occurs at the home base, the home base and the mobile unit must maintain separate State registrations and CLIA certificates.

### **Specimen Collection Activities Authorized Pursuant to DCA-20-45**

Pursuant to DCA-20-45, both a pharmacist and a pharmacy technician may collect specimens for COVID-19 tests. However, the respective scopes of practice vary.

- Pharmacists: Under the terms of the DCA Order, a pharmacist
  - Is authorized to collect specimens for a COVID-19 test of any complexity level (waived, moderate, or high-complexity).
  - May collect specimens using any method of collection.
  - Must be competent and trained to collect the specimen and specimen collection must be consistent with the test's FDA Emergency Use Authorization (EUA).
- Pharmacy Technicians: By contrast, under the terms of the DCA Order, a pharmacy technician:
  - Is limited to collecting specimens in a pharmacy under the direct supervision and control of a supervising pharmacist.
  - Is limited to collecting specimens for waived tests and is limited to the following collection methods: nasal swab, nasopharyngeal swab, and throat swab.
  - Must be competent and trained to collect the specimen and the specimen collection must be consistent with the test's FDA EUA.

### State Testing Personnel Requirements for DCA-20-45 Testing Pharmacies

• Pursuant to DCA-20-45, both a pharmacist and a pharmacy technician may perform waived, point-of-care tests for SARS-CoV-2 that are FDA-authorized. The pharmacist and pharmacy technician may perform these

waived tests absent the supervision of a qualified laboratory director only if all conditions and requirements in the DCA Order are met.

- The pharmacist and pharmacy technician must be competent and trained to perform the waived test.
- Test performance must be consistent with the waived test's FDA EUA.
- While a pharmacist may perform waived, point-of-care COVID-19 tests independent of a laboratory director, a pharmacy technician is limited to performing testing in a pharmacy and must do so under the direct supervision and control of a supervising pharmacist pursuant to Business and Professions Code section 4115 (a).
- *Note:* The temporary suspension and waiver effectuated by DCA-20-45 does not affect the separate suspension of the certification and licensure requirements under the Governor's March 12, 2020, Executive Order N-25-20 (PDF). Pharmacists or pharmacy technicians who elect to perform COVID-19 tests outside of the parameters of DCA-20-45 and who do not meet existing laboratory personnel licensure or certification requirements may otherwise perform analysis of samples to test for SARS-CoV-2 if they meet the federal requirements of 42 C.F.R. section 493.1389 for high-complexity testing personnel.

### State Reporting Requirements Applicable to Ordering Pharmacists and Testing Pharmacies

- A pharmacist who orders a COVID-19 test of any complexity level (waived, moderate, or high-complexity) is required to comply with the infectious disease reporting requirements applicable to health care providers outlined in 17 CCR section 2500.
  - Laboratory Field Services advises pharmacists ordering COVID-19 tests for patients to contact their local public health department and the California Reportable Disease Information Exchange (CalREDIE) program at CDPH to discuss options for reporting patient data and test results in compliance with regulations.
- In addition, a pharmacy that performs waived, point-of-care COVID-19 tests pursuant to the authority and conditions established in DCA-20-45 is required to comply with the infectious disease reporting requirements applicable to laboratories outlined in 17 CCR section 2505.
  - A pharmacy that has a California clinical laboratory registration and federal CLIA certificate of waiver to test for SARS-CoV-2 must report all positive and non-positive (negative, indeterminate, and specimen unsatisfactory) test results from the waived, point-of-care, FDA-authorized test for SARS-CoV-2 through the CalREDIE Electronic Laboratory Reporting system (ELR) within eight hours from the time the laboratory notifies the health care provider or other person authorized to receive the report.
    - Pharmacies unable to report results via ELR can submit results in a .CSV file or use the CalREDIE Manual Lab Reporting Module instead. For information about this reporting option, please contact calrediehelp@cdph.ca.gov.
  - A pharmacy must report data on patients' **race and ethnicity** for all COVID-19 test results. Pharmacies should ensure that requisition forms include this information and are encouraged to work with healthcare providers to ensure that demographic information is collected during patient intake so that it can be included when results are reported through the CalREDIE system.
  - For more information about the ELR and reporting requirements, please visit the CDPH CalREDIE ELR webpage.
  - Pharmacies are requested to use the encoding guidelines for ELR messages for SARS-CoV-2. The LOINC codes are pre-release codes, developed for special use. These codes, as well as future updates, can be found at the LOINC website.
  - $\circ~$  In addition, pharmacies are requested to use the following SNOMED codes:
    - 260373001 Detected
    - 260415000 Not detected
    - 419984006 Inconclusive
    - 125154007 Specimen unsatisfactory

#### Resources

More information about testing in pharmacies:

- DCA Order DCA-20-45 Waiving Restrictions on Pharmacies, Pharmacists and Pharmacy Technicians Relating to Ordering, Collecting Specimens for, and Performing COVID-19 Tests August 25, 2020 (PDF)
- Guidance for Pharmacies, Pharmacists and Pharmacy Technicians Ordering, Collecting Specimens for, and Performing COVID-19 Tests (PDF)
- Information about applying for California Clinical Laboratory Registration and CLIA certification is available on the LFS Facility Registration webpage.
- Information about reporting requirements and enrollment in CalREDIE is available on the CalREDIE webpage.

Page Last Updated : September 21, 2020

# **Attachment 2**

#### Board Actions and Responses to COVID-19.

- 1. In response to COVID-19, has the board implemented teleworking policies for employees and staff?
  - a. How have those measures impacted board operations? If so, how?
- 2. In response to COVID-19, has the board utilized any existing state of emergency statutes?
  - a. If so, which ones, and why?
- 3. Pursuant to the Governor's Executive Orders N-40-20 and N-75-20, has the board worked on any waiver requests with the Department?
  - a. Of the above requests, how many were approved?
  - b. How many are pending?
  - c. How many were denied?
  - d. What was the reason for the outcome of each request?
- 4. In response to COVID-19, has the board taken any other steps or implemented any other policies regarding licensees or consumers?
- 5. Has the board recognized any necessary statutory revisions, updates or changes to address COVId-19 or any future State of Emergency Declarations?

# **Attachment 3**



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# California State Board of Pharmacy CPJE Statistics May 2020 – September 2020

The charts below display data for all candidates who took the CPJE examination between May 2020 to September 2020, inclusive.

The board also displays NAPLEX scores associated with any candidate who took the CPJE during this time period and was reported to the board, regardless of when the NAPLEX may have been taken (it could have occurred outside the fivemonth reporting period noted above). Typically, the board reports CPJE performance data at six-month intervals.

### CPJE Overall Pass Rates

Pass/Fail	Frequency	Percent	
Fail	703	36.3	
Pass	1231	63.7	
Total	1934	100.0	

# NAPLEX Overall Pass Rates

Pass/Fail	Frequency	Percent	
Fail	93	7.5	
Pass	1150	92.5	
Total	1243	100.0	

# **CPJE Pass Rates – Location by Number**

Location	Fail	Pass	Total
California	335	780	1115
Other US	327	386	713
Foreign	41	64	105
Unclassified	0	1	1
Total	703	1231	1934

### **CPJE Pass Rates – Location by Percent**

Location	Fail	Pass
California	30.0	70.0
Other US	45.9	54.1
Foreign	39.0	61.0
Unclassified	0	100.0

# NAPLEX Pass Rates – Location by Number

Location	Fail	Pass	Total
California	45	582	627
Other US	31	500	531
Foreign	17	67	84
Unclassified	0	1	1
Total	93	1150	1243

### NAPLEX Pass Rates – Location by Percent

Location	Fail	Pass
California	7.2	92.8
Other US	5.8	94.2
Foreign	20.2	79.8
Unspecified	0	100.0

### CPJE Pass Rates – Gender by Number

Gender Fail P		Pass	Total
Female	419	807	1226
Male	284	424	708
Total	703	1231	1934

### **CPJE Pass Rates – Gender by Percent**

Gender	Fail	Pass
Female	34.2	65.8
Male	40.1	59.9

### NAPLEX Pass Rates – Gender by Number

Gender	Fail	Pass	Total
Female	59	717	776
Male	34	433	467
Total	93	1150	1243

# NAPLEX Pass Rates – Gender by Percent

Gender	Fail	Pass
Female	7.6	92.4
Male	7.3	92.7

# CPJE Pass Rates – California School of Pharmacy by Number

CA School	Fail	Pass	Total
UCSF	21	91	112
UOP	66	135	201
USC	36	135	171
Western	34	79	113
Loma Linda	22	36	58
UCSD	6	43	49
Touro U	32	54	86
Cal Northstate	25	79	104
Keck	23	35	58
West Coast U	15	17	32
Chapman	24	48	72
CA Health Sci U	27	20	47
Marshall B			
Ketchum	4	8	12
Total	335	780	1115

# CPJE Pass Rates – California School of Pharmacy by Percent

CA School	Fail	Pass
UCSF	18.8	81.2
UOP	32.8	67.2
USC	21.1	78.9
Western	30.1	69.9
Loma Linda	37.9	62.1
UCSD	12.2	87.8
Touro U	37.2	62.8
Cal Northstate	24.0	76.0
Keck	39.7	60.3
West Coast U	46.9	53.1
Chapman	33.3	66.7
CA Health Sci U	57.4	42.6
Marshall B		
Ketchum	33.3	66.7

### NAPLEX Pass Rates – California School of Pharmacy by Number

CA School	Fail	Pass	Total
UCSF	0	48	48
UOP	6	109	115
USC	5	65	70
Western	3	54	57
Loma Linda	3	35	38
UCSD	0	32	32
Touro U	3	53	56
Cal Northstate	8	49	57
Keck	6	33	39
West Coast U	1	21	22
Chapman	3	52	55
CA Health Sci U	6	28	34
Marshall B			
Ketchum	1	3	4
Total	45	582	627

# NAPLEX Pass Rates – California School of Pharmacy by Percent

CA School	Fail	Pass
UCSF	0	100.0
UOP	5.2	94.8
USC	7.1	92.9
Western	5.3	94.7
Loma Linda	7.9	92.1
UCSD	0	100.0
Touro U	5.4	94.6
Cal Northstate	14.0	86.0
Keck	15.4	84.6
West Coast U	4.5	95.5
Chapman	5.5	94.5
CA Health Sci U	17.6	82.4
Marshall B	25.	75.0
Ketchum		

# CPJE Pass Rates – School of Pharmacy by Number

	F . 1	Dava	Talal
School	Fail	Pass	Total
Auburn	1	0	1
Samford	1	1	2
U of AZ	2	14	16
U of AR	1	0	1
UCSF	21	91	112
U of Pacific	66	135	201
USC	36	135	171
U of CO	11	15	26
U of Conn	0	1	1
Howard DC	1	0	1
FL A&M	1	1	2
U of FL	3	5	8
Mercer	5	3	8
U of GA	3	3	6
Idaho SU	1	0	1
U of IL Chi	7	7	14
Butler U	1	2	3
Purdue	3	2	5
Drake	2	2	4
U of IA	2	5	7
U of KS	1	1	2
U of KY	3	2	5
NE LA U	1	1	2
Xavier	1	0	1
U of MD	8	4	12

School	Fail	Pass	Total
MA Col Pharm	10	20	30
NE-MA	3	9	12
Ferris	0	2	2
U of MI	6	4	10
Wayne SU	2	2	4
U of MN	4	6	10
St. Louis Col of PH	4	0	4
UMKC	1	2	3
U of MT	0	2	2
Creighton	5	12	17
U of NE	0	2	2
	6		11
Rutgers U of NM	2	5 3	5
Western Midwestern II Chiegge	34	79	113
Midwestern U Chicago	13	14	27
A&M Schwartz	5	4	9
St. Johns	4	5	9
SUNY-Buff	1	2	3
	4	4	8
UNC	5	4	9
ND SU	1	0	1
OH Northern U	1	2	3
OH State U	4	4	8
U of Cinn	1	2	3
U of Toledo	0	2	2
SW OK State	1	1	2 2
U of OK	2	0	2
OR State U	1	4	5
Duquesne	1	0	1
PhI C of Pharm	3	2	5
Temple	6	2	8
U of Pitt	0	3 3	3
U of RI	4		7
Med U of SC	2	2	4
U of SC	1	1	2
U of TN	1	2	3
U of Hous	1	2	3
U of TX	4	5	9
U of UT	1	7	8
Med C of VA	2	2	4
U of WA	4	11	15
WA State U	6	13	19
WVU	0	1	1
U of WI-Mad	4	5	9

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School	Fail	Pass	Total
U of WY	1	0	1
Campbell U	0	1	1
Nova Southeastern	6	5	11
Wilkes University	1	2	3
Texas Tech	4	2	6
Bernard J Dunn	2	1	3
Midwestern AZ	15	7	22
Nevada College of Pharm	25	47	72
Loma Linda U	22	36	58
UCSD	6	43	49
MA School of Pharm -	1 /	0	0.4
Worcester	16	8	24
Palm Beach Atlantic University	0	2	2
Lake Erie Col	10	5	15
	32	54	86
U of Charleston	0	2	2
South U School of Pharm	0	1	1
Hampton U (VA)	1	0	1
Pac U of Or	7	9	16
U of Incarnate Word	2	1	3
Sullivan U	4	0	4
Cal Northstate	25	79	104
Unclassified	0	1	1
Other/FG	41	64	105
U of HI - Hilo	6	10	16
NE Ohio Universities	1	0	1
Texas A&M	1	1	2
Thomas Jefferson U	0	1	1
Belmont U	4	1	5
Harding U	4	0	4
Husson U	1	0	1
Appalachian College of	0	2	
Pharm Chianna Still	2	3	5
Chicago St U	3	1	4
U of New England	2	3	5
Regis University	1		3 2
Notre Dame of MD	2	0	
Concordia U Coll Pharm	2	0	2
Rosalind Franklin U	1	2	3
Western NE U	1	0	1
U of Saint Joseph	3	2	5
Roosevelt U Drachadarian	4	2	6
Presbyterian	1	1	2
D'Youville	1	0	1
Touro New York	0	1	1

School	Fail	Pass	Total
South College	3	1	4
Manchester U	1	5	6
SIUE	0	1	1
Marshall U School Pharm	1	2	3
<b>KECK GRAD INST SCHL PHARM</b>	23	35	58
CA Health Sci U	27	20	47
Fairleigh Dickinson	2	1	3
Cedarville U	0	2	2
U of the Sciences	1	2	3
UNTX Col of Pharm	0	2	2
WEST CST UNIV COL PHARM	15	17	32
CHAPMAN U SCHL PHARM	24	48	72
Marshall B Ketchum U	4	8	12
Total	703	1231	1934

# CPJE Pass Rates – Country by Number

		_	
Country	Fail	Pass	Total
Armenia	0	1	1
Belgium	0	1	1
Bulgaria	1	0	1
Brazil	0	1	1
Canada	1	0	1
Switzerland	0	1	1
Egypt	10	22	32
Spain	1	0	1
United Kingdom	0	6	6
India	4	5	9
Iraq	0	4	4
Iran	2	3	5
Italy	0	1	1
Jordan	5	4	9
Lebanon	1	2	3
Nigeria/New			
Guinea	1	1	2
Philippines	11	7	18
Pakistan	1	0	1
Poland	1	0	1
Sudan	0	1	1
Syria	2	4	6
Ukranian	0	1	1
USA	662	1166	1828
Total	703	1231	1934