

July 7, 2020

The Honorable Gavin Newsom
Governor, State of California
State Capitol
Sacramento, CA 95814

Dear Governor Newsom,

The California Pharmacists Association (CPhA) and the National Association of Chain Drug Stores (NACDS) would like to thank you for your support in allowing pharmacists to independently order and perform COVID-19 test specimen collection. We truly believe this will only help increase the goal of increased testing statewide for COVID-19. However, as discussed below, barriers remain that are still preventing pharmacists from performing end-to-end COVID-19 testing services in California.

As you may remember, on April 8, 2020, the U.S Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) issued a declaration “*authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized*” (OASH Guidance). OASH made this authorization pursuant to Secretary Alex Azar’s March 10, 2020 declaration made under the Public Readiness and Emergency Preparedness (PREP) Act. Furthermore, on May 19th, HHS’ Office of the General Counsel issued an advisory opinion (OGC Advisory Opinion), which stated that the PREP Act and associated OASH Guidance preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 test. On May 14th, around the same time as the aforementioned federal action, the California Department of Consumer Affairs (DCA) issued a pharmacy law waiver that allows pharmacists to independently order COVID-19 tests and perform specimen collection. However, the authority to actually perform end-to-end COVID-19 testing, outside of specimen collection, remained unchanged under current California law.

California law requires any entity who performs end-to-end COVID-19 testing to obtain a valid Clinical Laboratory Improvement Amendments (CLIA) certificate (either a Certificate of Registration or a Certificate of Waiver). Important to pharmacies and their pharmacists seeking to perform end-to-end COVID-19 testing, some COVID-19 tests are classified as “CLIA-waived” tests, which requires a pharmacy to obtain a CLIA-Certificate of Waiver (CLIA-waiver certificate) to perform. To obtain a valid CLIA-waiver certificate in California, however, the entity applying must have a valid “laboratory director” under Business and Professions Code 1206.5. More so, Business and Professions Code 1209 lists who is eligible to be a laboratory director, but pharmacists are not listed. Thus, the requirement to obtain a CLIA-waiver certificate with a laboratory director and the further exclusion of pharmacists as laboratory directors act as barriers that prevent pharmacists from conducting the full end-to-end COVID-19 testing process.

We urge California to remove these barriers for several reasons. First, the OASH Guidance and OGC Advisory Opinion place California’s CLIA-waiver certificate requirements at odds with federal action on COVID-19 testing. Specifically, the requirement to obtain a CLIA-waiver with a laboratory director and

the exclusion of pharmacists as laboratory directors may be viewed as state requirements that prohibit or effectively prohibit a pharmacist from ordering and administering a COVID-19 test.

Second, the only exception to California's CLIA-waiver law, as it is applied to pharmacists, is listed in Business and Professions Code 1206.6 that does not require the use of a laboratory director for purposes of performing CLIA-waived tests on hemoglobin A1C, and cholesterol. This exception is relevant to COVID-19 testing because the baseline skillset of patient assessment, specimen collection, and interpretation of test results required to perform a hemoglobin A1C or cholesterol test is similar to that required for other CLIA-waived point-of-care tests, including COVID-19. States such as New York have similar laboratory restrictions in place for limited healthcare professionals to perform tests. However, given pharmacists' ability to increase access to COVID-19 testing, New York waived existing burdensome laboratory barriers to allow New York pharmacists to conduct full COVID-19 testing services.

Third, for the last couple of weeks, we have seen California's COVID-19 rates exceed previously estimated projections. While testing is available in some areas, testing is currently limited to hospitals and clinics and often have longer than expected wait times, sometimes ranging as long as 3-5 days. Currently, there are about 3 COVID-19 test sites available per 100,000 people in California. Thus, it is critical for California to leverage the 18,200+ community pharmacists in the chain and independent setting the full authority to perform COVID-19 testing to increase the state's ability to more effectively conduct contact tracing to address infection rates.


As such, we strongly urge you to issue an Executive Order that waives existing CLIA-waiver certificate requirements that prevent pharmacists from conducting the full end-to-end COVID-19 testing process. Specifically, the Executive Order should waive the provisions of Business and Professions Code 1206.5 that pharmacies and their pharmacists will have the ability to exponentially increase COVID-19 testing in all of California. For your consideration, please see the attached draft Executive Order.

Thank you for your immediate attention to this matter. Should you have any questions, please don't hesitate to contact us at (916) 779-1400 for CPhA or (817) 442-1155 for NACDS.

Sincerely,



SUSAN BONILLA
Chief Executive Officer
California Pharmacists Association



STEVEN C. ANDERSON, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores



Rachel Michelin
President
California Retailers Association

CC:

CHHS Secretary Mark Ghaly

CDPH Director Sonia Angell

DCA Director Kimberly Kirchmeyer

BOP Executive Officer Anne Sodergren

Richard Figueroa, Office of the Governor

EXECUTIVE DEPARTMENT
STATE OF CALIFORNIA

EXECUTIVE ORDER _____

WHEREAS on March 12, 2020, I issued Executive Order N-25-20 which suspended California Code of Regulations, Title 17, Section 1079 and Business and Professions Code Section 1206.5 AS TO all persons who meet the requirements under the Clinical Laboratory Improvement Amendments (“CLIA”) of Section 353 of the Public Health Service Act for high complexity testing and who are performing analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in any certified public health laboratory or licensed clinical laboratory; and

WHEREAS on May 12, 2020, the Department of Consumer Affairs issued an Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests to allow greater access to testing; and

WHEREAS I have determined that there is a continued need for expanded testing capability within the State that cannot be currently met by existing resources, and in particular for laboratories where testing can be performed and qualified personnel who are authorized to perform such testing; and

WHEREAS point-of-care laboratory tests that are deemed “waived” under CLIA have been determined to be simple and to have a low risk of erroneous results when performed in a manner consistent with the manufacturer’s instructions by appropriately trained personnel; and

WHEREAS licensed pharmacists who have received training on CLIA-waived point-of-care testing for SARS-CoV-2 have sufficient education and experience to serve as laboratory directors for a registered laboratory performing only such testing, and to serve as waived laboratory supervisors for a registered laboratory performing only such testing; and

WHEREAS licensed pharmacists and pharmacy technicians who have received training on CLIA-waived point-of-care testing for SARS-CoV-2, who follow the manufacturer’s instructions for such testing, and who perform such testing under the supervision required under Business and Professions Code Division 2, Chapter 3 and the related regulations will pose a minimal risk of erroneous results; and

NOW, THEREFORE, I, GAVIN NEWSOM, Governor of the State of California, in accordance with the authority vested in me by the State Constitution and statues of the State of California, and in particular, Government Code sections 8567, 8571 and 8572, do hereby issues the following order to become effective immediately:

IT IS HEREBY ORDERED THAT:

1. Licensed pharmacists who have received training on CLIA-waived point-of-care testing for SARS-CoV-2 are hereby authorized to serve as laboratory directors for registered laboratories performing only such testing at any site within the State, including without limitation licensed pharmacies, employer sites, long-term care facilities and community locations. Any statute, regulation or rule that is inconsistent with this authority is hereby waived to the extent necessary to effectuate this Section 1, including without limitation the qualification requirements of Business and Professions Code Section 1209(a)**Error! Reference source not found..**

2. Licensed pharmacists who have received training on CLIA-waived point-of-care testing for SARS-CoV-2 are hereby authorized to serve as waived laboratory supervisors for purposes of California Code of Regulations, Title 17, Section 1036.3, for registered laboratories performing only such testing at any site within the State, including without limitation licensed pharmacies, employer sites, long-term care facilities and community locations. Any statute, regulation or rule that is inconsistent with this authority is hereby waived to the extent necessary to effectuate this Section 2, including without limitation any qualification requirements of California Code of Regulations, Title 17, Section 1036.3(a)**Error! Reference source not found.**
3. In addition to and not in lieu of the suspension of the certification and licensure requirements of California Code of Regulations, Title 17, Section 1079 and Business and Professions Code Section 1206.5 in Executive Order N-25-20, the certification and licensure requirements of California Code of Regulations, Title 17, Section 1079 and Business and Professions Code Section 1206.5 are hereby suspended as to licensed pharmacists and pharmacy technicians who (a) are performing CLIA-waived point-of-care testing for SARS-CoV-2, (b) have been appropriately trained in the performance of the applicable test, (c) are performing the test in a public health laboratory or an appropriately licensed or registered clinical laboratory at any site within the State, including without limitation licensed pharmacies, employer sites, long-term care facilities and community locations, and (d) who are performing the applicable tests in accordance with the test manufacturers' instructions.

IT IS FURTHER ORDERED that as soon as hereafter possible, this Order be filed in the Office of the Secretary of State and that widespread publicity and notice be given of this Order.

This Order is not intended to, and does not, create any rights or benefits, substantive or procedural, enforceable at law or in equity, against the State of California, its agencies, department, entities, officers, employees, or any other person.

IN WITNESS WHEREOF I have hereunto set my hand and caused the Great Seal of the State of California to be affixed this __ day of _____, 2020.

GAVIN NEWSOM
Governor of California

ATTEST:

ALEX PADILLA
Secretary of State