STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

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

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Order Waiving Restrictions on Pharmacies, Pharmacists and Pharmacy Technicians Relating to Ordering, Collecting Specimens for, and Performing 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, including pharmacists and pharmacy technicians. This authority allows the Director to waive restrictions on the practice of licensees and the activities that licensees may undertake.

In addition, pursuant to the Governor's Executive Order N-75-20, the Department of Consumer Affairs, in consultation with the Department of Public Health, may amend scopes of practice to allow pharmacists and pharmacy technicians to conduct any aspect of any point-of-care test for the presence of SARS-CoV-2 that is deemed or classified as CLIA waived and, to that end, may waive any provision of the Business and Professions Code, or any other provision of law, to the extent that provision would prevent or in any way restrict any pharmacist or pharmacy technician from conducting any aspect of any such test.

Business and Professions Code section 1206.5, subdivision (a) provides that no person may perform a clinical laboratory test classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), unless the test is performed under the overall operation and administration of a laboratory director. Business and Professions Code section 1209, subdivision (a)(2) specifies who may serve as a laboratory director in relation to waived tests, and section 1265, subdivision (b) requires clinical laboratory registration applicants to include the name of the laboratory director on an application for registration.

The Director waives Business and Professions Code section 1206.5, subdivision (a), section 1209, subdivision (a)(2), and section 1265, subdivision (b) to the extent they prohibit a pharmacy, pharmacist or pharmacy technician from performing on

individual patients point-of-care clinical laboratory tests or examinations for the presence of the virus SARS-CoV-2 that are deemed or classified as CLIA waived ("waived COVID-19 tests"), and without a laboratory director. The waiver is subject to the following conditions:

- Testing is limited to waived COVID-19 tests authorized by the United States Food and Drug Administration ("FDA") and is performed consistent with the provisions of any applicable Emergency Use Authorization issued by the FDA;
- The pharmacy complies with any other applicable federal requirements, including CLIA certificate of waiver requirements. For purposes of CLIA, the person identified as responsible for directing and supervising testing oversight and decision making is the pharmacist-in-charge, as defined in Business and Professions Code section 4036.5;
- The pharmacy is registered by the California Department of Public Health under Business and Professions Code section 1265 (which, notwithstanding subdivision (b) of that section, shall not require the pharmacy to identify a laboratory director);
- Pharmacists must comply with disease reporting requirements applicable to health care providers ordering tests for the presence of the virus SARS-CoV-2, pursuant to California Code of Regulations, title 17, section 2500;
- Pharmacies must comply with the disease reporting requirements applicable to laboratories testing for COVID-19 pursuant to California Code of Regulations, title 17, section 2505; and,
- The pharmacy, pharmacist or pharmacy technician complies with such other requirements as the California Department of Public Health, in consultation with the Department of Consumer Affairs, may impose that are not inconsistent with this Order.

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 and interpret only certain tests, subject to certain conditions. Business and Professions Code section 4052.1, subdivision (a)(2) authorizes pharmacists to order certain laboratory tests, subject to certain conditions. Business and Professions Code section 4052.4 authorizes pharmacists to perform routine patient assessment procedures, including certain laboratory tests that are classified as CLIA waived.

Pursuant to Executive Orders N-39-20 and N-75-20, the Director waives Business and Professions Code section 4051, subdivision (b), section 4052, subdivision (a)(12), and section 4052.4, to the extent those provisions would otherwise prohibit pharmacists from ordering or otherwise authorizing any CLIA category of test for the presence of the virus SARS-CoV-2 in individual patients, or prohibit pharmacists from performing and interpreting the results of waived COVID-19 tests, without coordination with the patient's primary care provider or diagnosing prescriber. The Director also waives Business and Professions Code section 4052.1, subdivision (a)(2) to the extent it would prohibit pharmacists from ordering or otherwise authorizing any CLIA category of test for the presence of the virus SARS-CoV-2 in individual patients, outside of a licensed health facility and in accordance with its policies and procedures, and without the concurrence of the facility administrator.

Business and Professions Code sections 4051, 4052, 4052.1, and 4052.4, as specified, 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 any category of test for the presence of the virus SARS-CoV-2.

The waiver of sections 4051, 4052, 4052.1, and 4052.4, as specified, is subject to the following conditions:

- The test is authorized by the FDA; and,
- The pharmacist is competent and trained to collect the specimen and perform the test, and the specimen is collected and the test is performed consistent with the provisions of any applicable Emergency Use Authorization issued by the FDA.

Pharmacists acting within the scope of this Order may order and collect specimens for all CLIA categories of tests for the presence of the virus SARS-CoV-2, and they may order, collect specimens for, perform, and interpret results for authorized waived COVID-19 tests.

Business and Professions Code section 4038 provides that a pharmacy technician assists pharmacists in a pharmacy in the performance of pharmacy-related duties. Business and Professions Code section 4115, subdivision (a), and California Code of Regulations, title 16, section 1793.2, provide that pharmacy technicians may perform packaging, manipulative, repetitive, or other nondiscretionary tasks while assisting, and while under the direct supervision and control of, a pharmacist.

Pursuant to Executive Orders N-39-20 and N-75-20, the Director waives Business and Professions Code sections 4038 and 4115, subdivision (a), and California Code of

Regulations, title 16, section 1793.2, to the extent they would prohibit a pharmacy technician in a pharmacy from performing waived COVID-19 tests, or physically collecting through the use of nasal, nasopharyngeal, or throat swabs specimens necessary to perform waived COVID-19 tests. The waiver is subject the following condition:

- The pharmacy technician is competent and trained to collect the specimen and perform the test, and the specimen is collected and the test is performed consistent with the provisions of any applicable Emergency Use Authorization issued by the FDA.

Pharmacy technicians acting within the scope of this Order may collect specimens through the use of nasal, nasopharyngeal, or throat swabs for, and perform, authorized waived COVID-19 tests. Pharmacy technicians acting within the scope of this Order remain subject to the direct supervision and control of a supervising pharmacist, pursuant to Business and Professions Code section 4115, subdivision (a).

On May 12, 2020, the Director of the Department of Consumer Affairs issued an Order Waiving Restrictions on Pharmacists Ordering and Collecting Specimens for COVID-19 Tests. On July 7, 2020, the Director extended the May 12, 2020, Order until September 9, 2020.

The May 12, 2020, Order and the July 7, 2020, extension are hereby withdrawn and superseded by this Order.

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

Dated: August 25, 2020

Signature on File

Kimberly Kirchmeyer
Director