california **pharmacists** association

April 23, 2020

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

Dear Governor Newsom:

On behalf of the California Pharmacists Association, we write to assist in your efforts to combat the COVID-19 pandemic and to get California back to work.

Suggested Action: In order to contribute to the state's goal of increasing access to COVID-19 tests for all Californians, CPhA requests from the Governor the following to remove barriers for pharmacists:

1. Issue an Executive Order that clarifies, under B&P Code 4052, pharmacists may order and administer COVID-19 tests as authorized by US Department of Health & Human Services.

2. Within the Executive Order, include Advance Practice Pharmacists (APh), licensed under B&P Code 4052.6, may perform patient assessments and participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

3. Waive B&P Code 1206.6 to remove "only blood glucose, hemoglobin A1c, or cholesterol" to allow for flexibility on types of FDA approved or authorized CLIA-waived tests, such as COVID-19 tests, that can be performed in a community pharmacy setting.

4. Direct DHCS and DMHC to authorize pharmacists to submit claims using CMS defined CPT Codes for COVID-19 testing.

Current Standard of Practice: California Pharmacists and intern pharmacists have been involved in the screening and management of various health conditions through the use of laboratory tests. Pharmacists currently perform fingersticks to use CLIA-waived tests, such as glucometers, A1c meters, lipid panels, INR tests, HIV tests, and Hepatitis C tests. Pharmacists are heavily involved in community outreach and large health screening and education events, often conducting these CLIA-waived tests. Under collaborative practice agreements, pharmacists have also been involved in the use of other CLIA-waived tests that use nasal or oral swabs as the procedure for specimen collection, such as influenza and strep throat. Pharmacists have also been involved in ordering and interpreting laboratory tests, such as metabolic panels, liver function tests, renal function tests, and various serology tests (titers for measles, Hepatitis B, etc).

In addition to these specific skills, pharmacists are highly trained healthcare providers with 6-8 years of higher education training and earn Doctor of Pharmacy (Pharm.D.) degrees; with some completing 1-3 years of post-graduate (residency or fellowship) training. Pharmacists also complete at least 1,500 internship hours before completing state and national licensing examinations.

Pharmacists proved during the H1N1 epidemic to be a key access point for improving community health and will be a readily deployable workforce for COVID-19 screening, prevention, and management. There are over 47,000 registered pharmacists, 7,000 intern pharmacists, 69,000 pharmacy technicians, and 6,300 pharmacies ready to serve the residents of California. Finally, pharmacists are accessible community-based healthcare providers, with nearly all U.S. residents nationwide (91%) residing within 5 miles of a community pharmacy and an estimated 4,000 visits to pharmacies per week.

Pharmacies as Registered Laboratories: The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establishes quality standards for laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results. CLIA requires that any facility examining human specimens for diagnosis, prevention, treatment of a disease or for assessment of health must register with the federal Centers for Medicare & Medicaid Services (CMS) and obtain CLIA certification. CLIA certification is also administered through state agencies. In California, this is overseen by Laboratory Field Services (LFS) at the California Department of Public Health (CDPH).

If any facility (including, but not limited to clinical laboratories, hospitals, medical offices, and pharmacies) performs laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease, then it is considered a laboratory under CLIA and generally must apply and obtain a certificate from the CLIA program that corresponds to the type and complexity of tests performed.

There are 5 types of CLIA certifications, including: Certificate of Waiver (COW), Certificate for Provider-Performed Microscopy Procedures (PPM), Certificate of Registration, Certificate of Compliance (COC), and Certificate of Accreditation (COA). COW and PPM allow for the facilities to perform waived tests. Certificate of Registration, COC, and COA allow for facilities to perform non-waived (moderate and/or high complexity) tests. California pharmacies are currently able to secure registration with the CLIA Certificate of Waiver.

FDA Approval or Authorization of Tests: The Food and Drug Administration (FDA) is responsible for approving medical devices and diagnostic tests. When a diagnostic test receives FDA approval, they are also issued a complexity category of high, moderate, or waived. Waived tests are simple, nontechnical tests that must use unprocessed specimens (whole blood or oral fluid), be easy to use, and have little risk of an incorrect result. Waived tests are usually also performed as point-of-care tests (POCT) or home use.

In February 2020, the Department of Health & Human Services (HHS) and FDA enacted its emergency use authorization (EUA) to expand the immediate availability of diagnostic tests for the detection and/or diagnosis of the novel coronavirus, including serology tests. The EUA allows for manufacturers and commercial laboratories developing tests to use its guidance to bypass the standard regulatory and approval process during the public health emergency.

Tests can be developed and marketed prior to or without an EUA under these policies. When tests have not yet been issued an EUA, they are considered to be high complexity tests. When a test has been issued an EUA, it can be authorized for use in high or moderate complexity settings or in waived settings. The FDA further clarifies that if a test is authorized for use in "patient care settings", then that test is considered to be CLIA waived for the duration of the emergency declaration, and that patient care settings with a CLIA COW or COC may conduct those tests.

Pharmacists' Authority: On April 8, 2020, the HHS Office of the Assistant Secretary for Health (OASH) released Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act, which authorizes "licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized." The guidance also noted that pharmacists ordering and administering tests pharmacists "will qualify as 'covered persons' under the PREP Act," which provides liability immunity for any loss related to countermeasures to COVID-19.

The relevant CA Business and Professions Codes (BPC) pertaining to pharmacist authority that should apply to COVID-19 screening and prevention are the following:

BPC 4052.4 allows pharmacists to perform skin punctures (fingersticks) when using (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.

BPC 1206.5 and 1206.6 specifies which qualified individuals may serve as the laboratory director for a CLIA waived application; this may include a pharmacist under certain situations.

BPC 4052, 4052.1, and 4052.6 authorizes pharmacists and advanced practice pharmacists to perform patient assessment and order and interpret drug therapy-related tests (i.e. COVID-19 vaccines based on serology); with certain restrictions for pharmacists who are not licensed as advanced practice pharmacists.

BPC 4052.6 also authorizes specifically licensed advanced practice pharmacists to participate in the evaluation and management of disease and health conditions in collaboration with other healthcare providers.

Payment for COVID-19 Tests: CMS guidance for the implementation of the Families First Coronavirus Response Act (the FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) indicates that group health plans and health insurance issuers are generally required to provide benefits for certain items and services related to diagnostic testing for the detection of SARS-CoV-2 or the diagnosis of COVID-19 when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period. CMS also states that health plans and issuers are required to reimburse any provider (including out-of-network providers) of COVID-19 diagnostic testing.

Sincerely,

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