



April 22, 2020

Kimberly Kirchmeyer, Director
California Department of Consumer Affairs
1625 N Market Blvd.
Sacramento, CA 95834

Re: Executive Order N-39-20 – Request for Pharmacy Law Waivers

Dear Director Kirchmeyer,

The California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) write to request critical waivers and guidance that will enable pharmacies to ensure patients have access to necessary medications and services during the COVID-19 pandemic.

CRA and NACDS applaud your leadership and Governor Newsom’s actions to protect the health and safety of Californians during the declared COVID-19 State of Emergency. As millions of Californians shelter in place to “flatten the curve” and mitigate the spread of COVID-19, the healthcare system has had to adapt to serve patients. Many pharmacy services and operations must be modified to protect patient and pharmacy worker safety and to preserve access to necessary care. We appreciate recent waivers approved by the Board of Pharmacy, including waivers of requirements related to Duty to Consult (Title 16, California Code of Regulations, section 1707.2(a)), Inventory Reconciliation Report of Controlled Substances (Title 16, California Code of Regulations, section 1715.65(c)), and the Staffing Ratio of Pharmacists to Intern Pharmacists (BPC section 4114(b)) – just to name a few. While these waivers are essential, the following additional pharmacy requirements must be waived or modified in order to provide vital services in light of the COVID-19 outbreak:

Community POCT COVID-19 Testing

On April 8, the U.S. Department of Health and Human Services (HHS) authorized pharmacists to order and conduct testing for COVID-19, including serology tests.¹ We respectfully request that the state immediately authorize COVID-19 testing by pharmacists to drive the health of our communities, and restore the health of the state’s economy. As the Governor and other experts have acknowledged, more testing for

¹ See <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>.

COVID-19 in California is desperately needed. The U.S. Food and Drug Administration (FDA) has just recently authorized several Point-of-Care (POC) Tests that determine if someone has an active infection of and EAU for a few serologic assays. Community pharmacists are frontline, essential healthcare professionals and are educated and trained to provide POC tests. In fact, since 2016 the Accreditation Council for Pharmacy Education (ACPE) has included point-of-care testing skills as part of *the Doctor of Pharmacy curriculum*, ensuring students graduate ready to provide patients with needed care. In 40 states across the nation, pharmacists provide POC tests for flu, strep, HIV and/or Hepatitis C et al.

Importantly, as of the date of this letter, the following **nineteen (19) states** have already authorized pharmacists to provide COVID-19 testing. States with emergency testing authority for pharmacies are: Colorado, Iowa, Idaho, Illinois, Kentucky, Louisiana, Michigan, Missouri, North Carolina, North Dakota, Nevada, Ohio, Pennsylvania, Tennessee, Washington, Wisconsin and Texas. Also, Texas provides for pharmacy testing under a protocol, Pennsylvania provided testing authorization (is in the process of removing CLIA waiver barrier), and many more states are actively engaged in similar emergency efforts. Given the nature of this unprecedented crisis along with the substantial benefits which will flow to the state, *we urge you to authorize registered pharmacists (not just Advanced Practice Pharmacists) to order and perform COVID-19 tests to help protect Californians and reopen the state's economy in accordance with Governor's Newsom vision.*

COVID-19 Treatment: In 17 states across the country, pharmacists are authorized to test and treat for flu and strep (Tamiflu and identified antibiotics). The private sector and the federal government are working together to develop and test potential treatments. When these treatments become available, it will be critical to accelerate the availability of these medications to Californians. In fact, two (2) states (Kentucky and Michigan) specifically enacted forward leaning, emergency orders authorizing pharmacists to test and treat for COVID-19 in accordance with CDC or other protocols. To this end, *we also seek authorization to test and treat for COVID-19 as forthcoming treatments are authorized by FDA.* This authorization will enable patients to receive prompt, accessible and efficient screening and treatment to reduce the spread of COVID-19.

Authorization to Administer COVID-19 Immunization

Across the nation, in all 50 states, pharmacies administer vaccines to drive public health of communities. One out of three adult Americans received their annual flu vaccine at a community pharmacy. In the 2009 H1N1 pandemic, and in other disasters and emergencies, pharmacies have actively engaged in emergency response efforts, using strong local presence to administer vaccines to patients quickly and safely. Community pharmacies are proud to be part of the Centers for Disease Control and Prevention's (CDC's) Pandemic Immunization Plan. To this end, in anticipation for the FDA-authorized or approved COVID-19 immunization, *we urge you to take a critical important, forward leaning preparedness step, authorizing pharmacists the ability to administer an FDA-authorized and FDA-approved COVID-19 vaccine(s) to people of all ages without needless administrative restrictions.*

Spot or Product Shortage: Therapeutic Substitutions

During this public health crisis, access to medication is more important than ever. We request that pharmacists temporarily be given the authority to substitute therapeutic alternatives when there is a shortage of a particular drug. Pharmacists should be able to conduct therapeutic interchange when and if spot or product shortages arise. Distribution and system challenges in COVID-19 “hot zones” confirm the need to ensure continuity of patient care in this unprecedented crisis. For example, albuterol or levalbuterol inhalers are in short supply immediately. If a patient needs an albuterol or levalbuterol inhaler immediately that is not available currently, pharmacists should be able to automatically substitute and change the prescription to another available therapeutically alternative product (a different albuterol or levalbuterol inhaler).

Additional Requests to Assist Pharmacies Respond to the COVID-19 Pandemic

- Waive verbal authorization to dispense faxed Schedule II-V prescription drugs and create an exception for follow-up paper prescriptions to an emergency oral Schedule II prescription called into a pharmacy. This waiver would be consistent with March 27, 2020 Drug Enforcement Administration (DEA) guidance for Schedule II prescription drugs that extended the timeframe from 7 days to 15 days for prescribers to provide the follow-up prescription to the pharmacy after a prescriber issues an emergency oral Schedule II prescription to a pharmacist.
- Ensure prescriptions can be faxed (no paper delivery) to ensure pharmacist safety and reduce exposure to contaminated paper.
- Allow a 90-day supply to be dispensed on the initial fill, waiving requirement for initial 30-day fill.
- Authorize pharmacists to treat patients for minor ailments to advance health and avoid surges on hospitals and urgent clinics. Please see Appendix B for exemplar statutory language.
- Allow pharmacy staff, including technicians, a grace period for all licensure and Board requirements, including but not limited to CPR certification and Continuing Education requirements. Due to the COVID-19 State of Emergency, CPR recertification classes are not available.
- Waive the requirement for proof of delivery (POD) or signature for mail-order prescriptions.
- Allow pharmacy technicians and pharmacy technician trainees to perform certain nonjudgmental technical duties associated with the preparation and distribution of prescription drugs, such as accepting prescriptions transferred from another pharmacy as well as initiating and receiving refill authorization requests.
- Allow non-pharmacist personnel to receive deliveries. The Board of Pharmacy recently approved a waiver of the signature requirement for the delivery of drugs (BPC Section 4059.5), which applies as long as the delivery personnel confirm that the employee accepting the delivery is a pharmacist and certain other requirements are met. This is an important waiver but we request that additional employees can receive deliveries, e.g. store clerks or other personnel.

(See Appendix A for Model Pharmacy Waiver Language).

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, restaurants, convenience stores, supermarkets and grocery stores, chain drug, and specialty retail such as auto, vision, jewelry, hardware and home stores. CRA works on behalf of California's retail industry, which currently operates over 400,000 retail establishments with a gross domestic product of \$330 billion annually and employs over 3 million people—one fourth of California's total employment.

The National Association of Chain Drug Stores represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and health care affordability.

We appreciate your consideration of the suggestions outlined above, which will save more lives and help mitigate the COVID-19 pandemic in California. Please do not hesitate to contact Jennifer Snyder or Lindsay Gullahorn with Capitol Advocacy at (916) 444-0400 if you have any questions.

Sincerely,



Rachel Michelin
President
California Retailers Association



Steve C. Anderson, IOM, CAE
President & Chief Executive Officer
National Association of Chain Drug
Stores

cc: Governor Gavin Newsom
Dr. Bradley Gilbert, Director, Department of Health Care Services
Greg Lippe, President, Board of Pharmacy
Anne Sodergren, Executive Officer, Board of Pharmacy

Appendix A: Model Pharmacy Waiver Language

Proposed Executive Order: For the purposes of preparing for, conducting to and mitigating any effect of COVID-19 testing, the Governor grants pharmacy personnel the requisite authority needed to carry out end-to-end COVID-19 testing. Likewise, for the purpose of preparing for, responding to, and mitigating any effect of COVID-19, the provisions of [CODE], statute and rules promulgated thereunder, that if applied, would operate to limit distribution, dispensing, or administration of otherwise legitimate prescription drugs, vaccines authorized by FDA or medical devices in a manner that could hinder, prevent, or delay mitigation of any health-related condition, are suspended for a period of 60 days, and automatically extended unless withdrawn during the pandemic. This paragraph does not affect any law governing distribution, dispensation, or administration of any controlled substance as that term is defined in [STATUTE].

Appendix B: Model Statutory Language

Pulled from Idaho Statute

"Practice of pharmacy" means:

...

(5) The prescribing of:

- a. Dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
- b. Agents for active immunization when prescribed for susceptible persons six (6) years of age or older for the protection from communicable disease;
- c. Opioid antagonists pursuant to section 54-1733B, Idaho Code;
- d. Epinephrine auto-injectors pursuant to sections 54-1733C and 54-1733D, Idaho Code;
- e. Tobacco cessation products pursuant to section 54-1733E, Idaho Code;
- f. Tuberculin purified protein derivative products pursuant to section 54-1733F, Idaho Code; and
- g. **Drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:**
 - i. **Do not require a new diagnosis;**
 - ii. **Are minor and generally self-limiting;**
 - iii. **Have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or**
 - iv. **In the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.**