July 24, 2020

The Honorable Steve Glazer
Chair, Senate Business, Professions & Economic Development Committee
State Capitol, Room 5108
Sacramento, CA 95814

Re: **AB 1710 (Wood) Pharmacy Practice: Vaccines - SUPPORT**

Dear Chairman Glazer,

The California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS) write to express our support for AB 1710 (Wood), which will expand and expedite access to the COVID-19 vaccine once it is available, in addition to other FDA-approved vaccines, by leveraging pharmacists throughout the state.

As we prepare for the widespread availability of a COVID-19 vaccine, it will be critical to ensure that pharmacists are able to independently initiate and administer the vaccine. Pharmacies are often the most easily reachable access point to healthcare services for California patients. This is especially true during the COVID-19 pandemic, as we work to protect patients, alleviate some of the overwhelming demand placed on institutional settings, and mitigate the spread of the virus.

AB 1710 will allow pharmacists to independently initiate and administer vaccines approved by the U.S. Food and Drug Administration (FDA) or recommended by the federal Advisory Committee on Immunization Practices (ACIP). We strongly support AB 1710 as it is currently drafted. However, in order to further broaden access to the vaccine for priority groups once it is available, we recommend that AB 1710 be amended to use the language "FDA-authorized vaccines." This language would be inclusive of both vaccines under investigation by FDA and vaccines approved by FDA. Current law allows pharmacists to independently initiate and administer vaccines that are part of the ACIP recommended routine immunization schedules, are in compliance with ACIP vaccine recommendations, and that the federal Centers for Disease Control (CDC) publishes for individuals aged three and older. Expanding existing pharmacist immunization authority will enhance access and protection of Californians as soon as a viable COVID-19 vaccine has been developed.

Generally, once the FDA approves vaccinations, ACIP reviews the vaccinations and recommends them to the CDC. This process can often take six months or longer from when a vaccination receives FDA approval. AB 1710 will allow the COVID-19 vaccine to be deployed once it is FDA-approved, ensuring Californians have access to it quickly and in-turn reopening the economy more swiftly. Without this bill, pharmacists will be unable to administer the vaccination until it has been recommended by ACIP, which will delay access to the vaccine for Californians by at least six months and possibly longer.

Also, just as COVID-19 test kits first were released as FDA-authorized, it is likely COVID-19 vaccines would follow a similar course of action. Under normal circumstances, a vaccine would move forward

via a lengthy application and review process before being approved by the FDA.[i] However, in the event of a public health emergency such as the current COVID-19 global pandemic, the anticipated COVID-19 vaccine could first be introduced via an expedited route, the Emergency Use Authorization (EUA).[ii] Additionally, the FDA recently issued guidance that COVID-19 vaccines, still undergoing investigational review, may be considered for expedited distribution via EUA to a limited population upon demonstration of safety and effectiveness of the vaccine.[iii] The FDA also made it explicitly clear that despite the accelerated process, the rigorous, scientific review processes and standards will still be maintained to confirm such aspects.[iv] Thus, upon determination of safety and appropriateness, primarily healthy individuals, such as first responders and hospital personnel who meet all the eligibility requirements, would be eligible for the FDA-authorized vaccine.

Because the agency's approval process can be bureaucratic and protracted, it could take up to a year to secure final FDA approval from the initial agency EUA. Thus, leveraging pharmacists and pharmacy staff to independently initiate and administer FDA-authorized vaccines in the meantime will still broaden immediate and convenient access for priority groups to receive this service throughout California.

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 155,000 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.

For the reasons listed above, we support AB 1710 (Wood). Please do not hesitate to contact Jennifer Snyder or Lindsay Gullahorn with Capitol Advocacy at jsnyder@capitoladvocacy.com or lgullahorn@capitoladvocacy.com if you have any questions.

Sincerely,

Rachel Michelin
President
California Retailers Association

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

cc: The Honorable Jim Wood, Author
Members, Senate Business, Professions & Economic Development Committee

[i] The approval processes consist of investigational new drug application, clinical trials, Biologics License Application (BLA), usability testing, etc. https://www.cdc.gov/vaccines/basics/test-approve.html
[ii] https://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-Authorization-Toolkit/Comparing-Emergency-Use-Authorization-to-Investigational-New-Drug---Investigational-Device-Exemption-Protocols-Fact-Sheet/
[iii] The EUA would be issued after confirmed safety and effectiveness review, but before completion of the formal review process. https://www.fda.gov/media/139638/download
[iv] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid