

Supporting California's COVID-19 Response: Pharmacist Testing and Immunization

Presented by:

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COVID-19 Testing

- April 8 2020: OASH issued guidance pursuant to the PREP Act (42 U.S.C. § 247d-6d) and the HHS' PREP Act Declaration (Mar. 10, 2020) authorizing pharmacists to 'order and administer COVID-19 tests, including serology tests, that the FDA has authorized,' thus, qualifying pharmacists as "covered persons" for the purposes of PREP Act immunity.
- April- May 2020: CPhA and NACDS worked with the Board of Pharmacy and the DCA staff to issue the waivers of law under Governor Newsom's Executive Order to authorize pharmacists to perform (i.e. order and administer) COVID-19 testing under state law.
 - Currently, there are about 3 COVID-19 test sites available per 100,000 people and over 18,200 community pharmacists in the chain and independent setting that could potentially be performing (i.e. ordering and administering) COVID-19 testing.
- May 14: The DCA issued a pharmacy law waiver that temporarily allows pharmacists to independently order COVID-19 tests for patients as well as conduct collection of specimens from patients. However, there are still some barriers for pharmacists to administer COVID-19 tests.

The Problem

- Pharmacists can only participate in administering COVID-19 tests under CA state law, aside from specimen collection, by contracting with a laboratory director specifically to oversee COVID testing.
 - Some COVID-19 tests are classified as CLIA-waived tests, which requires a CLIA-waiver certificate to order and administer. In some states, pharmacists may order and administer tests when done under a pharmacy's CLIA-waiver certificate. However, it is our understanding that CDPH is currently denying CLIA waiver-certificates to pharmacies.
 - More so, even if pharmacies were issued CLIA-waiver certificates, pharmacists may not be able to administer tests:
 - **BPC 1206.5:** Pharmacists can only perform CLIA-waived tests under the overall operation and administration of a laboratory director.
 - *Exception- Community pharmacists can independently perform CLIA tests involving blood glucose, hemoglobin A1C, and cholesterol.*
 - **BPC 1209:** Definition of Laboratory Directors
 - Pharmacists currently are not authorized to be laboratory directors.
 - The requirement is cost-prohibitive and difficult, especially for smaller community pharmacies.

Clarification of Federal Guidance

- On May 19th, HHS' Office of the General Counsel issued an advisory opinion, which states that the PREP Act and associated federal action (i.e. Apr. 8th guidance) preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 test.
- *See* 42 U.S.C. § 247d-6d(b)(8)(A); *see also* Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, *available at* <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>.

Proposed Solution

- Governor Newsom should sign an Executive Order removing existing lab barriers that prevent pharmacists from conducting the full COVID-19 testing process.
 - Despite Governor Newsom's repeated support for increased testing and tracing to safely re-open California, CDPH has actively prevented increased testing capacity in California by excluding pharmacies.
- The Board of Pharmacy and the DCA should enhance advocacy efforts and continue conversations with the Administration authorizing pharmacists to administer COVID-19 tests.
 - Currently, 40+ other states allow pharmacies to perform such CLIA-waived tests and California pharmacists should have the ability to do so too.

COVID-19 Vaccination

- Pharmacies are essential community vaccination destinations.
- According to a CDC Pandemic Vaccine Model, **80% national vaccination coverage** can be achieved **7 weeks earlier** when pharmacies are deployed.
 - In 2009, CDC distributed ~ 5.5 million doses to 10 pharmacy chains (10,700+ retail stores) in 3 months.
 - * This accounted for **23% of all vaccines distributed during that same time period.**
- Pharmacies and pharmacists stand ready to support the nation's COVID-19 pandemic vaccine response.

The Problem

- Vaccine candidates will most likely be authorized by FDA and eventually included in the CDC ACIP-recommended Immunization Schedule.
- California pharmacists currently are not authorized to administer vaccines outside of the ACIP-recommended list.
 - California permits community pharmacists to vaccinate for all ACIP-recommended vaccines to patients 3 years and older.
- This **delays access** for California residents to receive the COVID-19 vaccine.

Proposed Solution

To fully leverage pharmacies and pharmacists to best support COVID-19 pandemic response, consider the following:

- The Governor should issue an Executive Order authorizing pharmacists to independently order and administer ***any FDA-authorized vaccines*** to people of ***all ages***.
- The Board of Pharmacy and the DCA should work with state partners and stakeholders to:
 - Expand access to influenza and pneumonia vaccinations.
 - Permit safe and effective delivery of vaccines by pharmacists at pharmacies and other convenient locations.

QUESTIONS?

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