



October 19, 2020

Debbie Veale, R.Ph.
Chair, Licensing Committee
California Board of Pharmacy
2720 Gateway Oaks Dr, Ste. 100
Sacramento, CA 95833

RE: Comments on Agenda Item IV

Dear Ms. Veale,

The California Pharmacists' Association (CPhA) is writing to you today to provide comments on Agenda Item IV of the Licensing Committee's report on October 20, 2020 relating to the expansion of authority for pharmacists to order and administer CLIA-waived testing for Influenza and COVID-19.

CPhA worked diligently with the National Association of Chain Drug Stores and the California Retailers Association since late April/early May to get Governor Gavin Newsom to issue an executive order to permit pharmacists and pharmacy technicians to perform "end-to-end" COVID testing. This resulted in such an executive order and ensuing Pharmacy Law Waiver from the Department of Consumer Affairs (DCA) allowing this to occur.

CPhA is happy to see the Board taking an interest in making this authority permanent for pharmacists, as well as adding CLIA-waived testing for influenza. CPhA is eager to work with the Board on this proposal but would also like to provide some insight into some of the questions being discussed:

1. What, if any, additional training requirements should be required?

CPhA's website contains a plethora of information on COVID-19 as it relates to pharmacists. Within that information, CPhA has highlighted the training on specimen collection that is offered, free of charge, by the American Pharmacists Association (APhA) to any who are interested. Additionally, other pharmacy groups currently offer the same type of training, also free of charge. Lastly, the manufacturers of the testing include instructions on how to process the specimens. CPhA believes this to be sufficient accessibility to necessary training that pharmacists would need. CLIA-waived tests, by definition, are simple laboratory tests that carry an insignificant risk of erroneous result and employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. CLIA-waived tests are also carry no reasonable risk of harm to the patient even if the test was incorrectly performed.

2. Should patient referral services be required?

3. How should test results be communicated to the patient and patient's primary care physician?

These two questions are similar in nature. CPhA would support the same type of requirement of referral services outlined in California Code of Regulations 1746.3(c)(7) wherein the pharmacist, with patient consent, can notify the patient's primary care provider of any test performed on the patient into a patient record system shared

with the primary care provider, as permitted by the patient and the primary care provider. In the event there is no primary care provider, or chooses not to give notification consent, the pharmacist should provide the patient with written record of the test as well as information to consult an appropriate healthcare provider of the patient's choice. This would be in addition to required reporting by any local health department or the state's Department of Public Health (CDPH).

4. What, if any, space requirements should be required, e.g. designated area away from other patrons?

CPhA, has concerns with specific space requirements being written into regulation or statute when conducting COVID testing or influenza testing. If a pharmacy has decided to set up a drive through station, how would any space requirements be reasonably enforced? Additionally, any space requirements would depend on the route of administration if the testing is for an infectious agent. CPhA would recommend the Board allow the professional judgement of the pharmacist to determine what space is needed for safe and appropriate testing.

5. What, if any, personal protective requirements should be required?

CPhA has always advocated for appropriate personal protective equipment (PPE) for pharmacists in their practice settings. The COVID-19 pandemic has, unfortunately, made some PPE very difficult to obtain, given various government stockpiling activities at the state and federal levels. CPhA would caution the Board on overly prescriptive PPE requirements being written into statute or regulation that would inadvertently cause less testing to occur when there is a shortage of PPE and instead allow pharmacists to use their professional judgement, in conjunction with recommendations from the Centers for Disease Control and Prevention and CDPH, to determine what PPE is necessary to carry out the testing.

6. Should the pharmacy providing such services be required to notify the Board in advance of providing such services?

The current DCA Guidance on COVID-19 testing by pharmacists contain reporting requirements for pharmacists in that they must register with CDPH to perform waived tests AND comply with disease reporting requirements applicable to laboratories and health care providers, including reporting through the state's CalREDIE system. CPhA doesn't believe that a requirement to notify the Board in advance of providing these services provide a tangible public benefit other than creating extra steps for pharmacists that would be unnecessary and duplicative in nature. If the Board wanted information on pharmacies or pharmacists providing these services, they could work with CDPH to obtain this without adding requirements in law. Additionally, any pharmacist or pharmacy that is under a collaborative practice agreement (CPA) to provide these types of testing is already required to submit a copy of their CPA to the Board.

7. Should the Board specify records requirements?


Consistent with other pharmacists' services allowed in statute and regulation (CCR 1746.1, 1746.2, and 1746.3), CPhA would support a requirement to maintain documentation of testing for three years from date of testing in a readily retrievable format.

8. Should the Board require pharmacists provide patient education as part of the process?

CCR 1707.2 requires pharmacists' duty to consult when there is a patient request, in the professional judgement of a pharmacist, when the patient receives a drug not previously dispensed, or if the patient receives a drug in a different dosage. CPhA believes that this is consistent with the pharmacy standard of practice and any further requirements to this would be overly onerous and unnecessary.

CPhA appreciates the Board's willingness to explore a permanent authority for pharmacists to conduct COVID and influenza testing. CPhA also appreciates opportunity to provide comment on this agenda item. Should you have any questions about these comments, please don't hesitate to contact me at dmartinez@cpha.com or at (916) 779-4519. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Martinez', with a stylized flourish at the end.

Danny Martinez
Director, Regulatory Affairs and Policy Development
California Pharmacists Association