



Oregon

Tina Kotek, Governor

Oregon Board of Pharmacy

800 NE Oregon St., Suite 150

Portland, OR, 97232

Phone: 971-673-0001

Fax: 971-673-0002

pharmacy.board@bop.oregon.gov

www.oregon.gov/pharmacy

February 5, 2024

Via Email

Senator Deb Patterson

sen.debpaterson@oregonlegislature.gov

Re: 2024 SB 1506

Dear Madame Chair Senator Patterson,

Our agency received a fiscal impact request for 2024 SB 1506-1 and during our analysis on the impact to our agency we identified amendments in Sections 4 and Section 5 that would maximize the bill's intended positive impact on public health, welfare, and safety.

SECTION 4.

(2) When testing for SARS-CoV-2, a pharmacist may use:

(a) A screening procedure that can be safely performed by a pharmacist; or

(b) A test that:

(A) Guides the pharmacist's clinical decision-making;

(B) Is determined by the Centers for Medicare and Medicaid Services to qualify as a waived test under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a) or federal regulations adopted pursuant to the Clinical Laboratory Improvement Amendments of 1988; and

(C) Is approved by the board by rule for use under this section.

Does the current wording in section (2)(a), which uses "or," intend to allow pharmacists to prescribe SARS-CoV-2 antivirals based solely on a screening procedure (e.g., symptoms)? If this is your intent, to support our agency, we believe section (2)(a) should be amended to end with "and" to require pharmacists to perform both a screening procedure and a test before prescribing.

Currently there are only four [CLIA waived SARS-CoV-2 tests](#).¹ There are 65 COVID tests authorized by the U.S. Food & Drug Administration (FDA) under an Emergency Use Authorization (EUA).² For context, [HHS Guidance](#) in the *Public Readiness and Emergency Preparedness Act (PREP Act)* authorizes *licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized*.³ We recommend amending (2)(b)(B) to include "or tests that the FDA has authorized?" This change would explicitly allow pharmacists following the protocol in (1) to utilize the wider range of FDA-authorized COVID tests, including those under EUA, expanding access to testing without compromising safety or quality standards.

1- U.S. Food & Drug Administration. (2024, February 2). Database of SARS-CoV-2 CLIA Waived Tests. Retrieved from

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Results.cfm?Analyte_Name=SARS-CoV-2&Clia_Complexity=waived&SortColumn=dad&san=1&PAGENUM=10

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.



Oregon

Tina Kotek, Governor

Oregon Board of Pharmacy

800 NE Oregon St., Suite 150

Portland, OR, 97232

Phone: 971-673-0001

Fax: 971-673-0002

pharmacy.board@bop.oregon.gov

www.oregon.gov/pharmacy

2- U.S. Food and Drug Administration. (2023, March 24). In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2. Retrieved from <https://www.fda.gov/medical-devices/emergency-use-authorizations/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2>

3- U.S. Department of Health & Human Services. (2020, April 8). Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act. Retrieved from <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

SECTION 5. ORS 689.005 is amended to read:

(29) "Practice of pharmacy" means:

(p) The testing and treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pursuant to section 4 of this 2024 Act and rules adopted by the board pursuant to section 4 of this 2024 Act.

To align with existing language in [ORS 689](#),⁴ and ensure consistency, we recommend members of the legislature amend (29)(p) to mirror the structure and phrasing used in ORS 689.005(29)(L)(m) and (n). This revision would result in the following wording: "The testing for and prescribing, dispensing and administering of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antiviral therapies, pursuant to section 4 of this 2024 Act and rules adopted by the Board pursuant to section 4 of this 2024 Act."

4- Oregon State Legislature. (1979, June 21). Chapter 689 — Pharmacists; Drug Outlets. https://www.oregonlegislature.gov/bills_laws/ors/ors689.html

Thank you for allowing me to share our agency's feedback on SB 1506. Please let me know if I or my team can provide additional information.

Best Regards,

Jamal T. Fox, MPA

The Oregon Board of Pharmacy serves to promote and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.