

Executive Office

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Order Waiving Restrictions on Pharmacists Independently Initiating and Furnishing Paxlovid to Individual Patients - AMENDED

On March 4, 2020, the Governor proclaimed a <u>State of Emergency</u> to exist in California as a result of the impacts of COVID-19 to make additional resources available, formalize emergency actions already underway across multiple state agencies and departments, and help the state prepare to respond to an increasing number of individuals requiring medical care and hospitalization as a result of a broader spread of COVID-19.

Pursuant to the Governor's Executive Order N-39-20, during the State of Emergency, the Director of the California Department of Consumer Affairs may waive any statutory or regulatory professional licensing requirements and amend scopes of practice pertaining to individuals licensed pursuant to Division 2 of the Business and Professions Code, including pharmacists.

On September 14, 2021, the Secretary of the federal Department of Health and Human Services issued the Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (the Declaration). In relevant part, the Declaration authorized licensed pharmacists to independently order and administer any COVID-19 therapeutic, subject to certain conditions, including compliance with any federal Food and Drug Administration (FDA) authorization.

On July 6, 2022, the FDA amended the <u>Emergency Use Authorization</u> (EUA) for Paxlovid, an orally-administered COVID-19 therapeutic drug. The amended EUA expressly permits licensed pharmacists to independently order Paxlovid for individual patients under certain conditions.

Pursuant to the Governor's Executive Order, and consistent with the Declaration and amended EUA, the Director waives Business and Professions Code sections 4051, 4052, 4052.1, 4052.2, and 4052.8, to the extent those provisions prohibit pharmacists from independently initiating and furnishing Paxlovid for individual patients, subject to the following conditions:

- The drug is ordered and furnished in accordance with the FDA EUA, including the following:
 - Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and,

- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction;
- The drug is ordered and furnished in accordance with the <u>Fact Sheet for Healthcare Providers</u>, including the following:
 - The pharmacist should refer an individual patient for clinical evaluation (e.g., telehealth, in-person visit) with a physician, advanced practice registered nurse, or physician assistant licensed or authorized to prescribe drugs, if any of the following apply:
 - Sufficient information is not available to assess renal and hepatic function;
 - Sufficient information is not available to assess for a potential drug interaction;
 - Modification of other medications is needed due to a potential drug interaction; or
 - Paxlovid is not an appropriate therapeutic option based on the authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible;
- The pharmacist maintains documentation for each patient furnished Paxlovid sufficient to demonstrate compliance with the requirements of the EUA; and
- The pharmacist complies with all applicable federal and state recordkeeping and reporting requirements, including medication error and adverse event reporting requirements of the EUA.

Pharmacists acting within the scope of this Order may independently initiate and furnish Paxlovid to individual patients, as specified above.

This order is effective immediately but may be amended as circumstances require.

Dated: July 11, 2022

Amended: August 4, 2022

Signature	on	File	

Kimberly Kirchmeyer Director