



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VII. Discussion and Consideration of Requests to Waive Pharmacy Law Provisions Consistent with the Authority of Business and Professions Code section 4062

Background

In light of Governor Gavin Newsom's declaration of emergency and the national declaration of emergency, and consistent with Business and Professions Code (BPC) section 4062, the California State Board of Pharmacy (Board) or the Board president through delegated authority has been issuing waivers of Pharmacy Law or its regulations adopted pursuant to it, if in the board's opinion the waiver will add in the protection of public health or the provisions of care. In general, waivers are limited in duration as determined by the Board, or by the Board president as delegated by the Board, unless the waiver resulted in the issuance or renewal of a license.

During its March 2020 meeting, the Board considered several waivers and approved several waivers. Additionally, the Board voted to extend the president's authority to issue waivers for up to 90-days. Further, subsequent to the March meeting, the DCA Director was given authority to grant waivers under specified conditions.

Waivers approved may be broad in application or license specific. To date, the Board has granted over 150 waivers.

For Board Discussion and Consideration

During this meeting, members will have the opportunity to consider three waivers issued by the President Lippe that will otherwise expire before the Board's June 2020 meeting.

Stanford Health, Waiver of Title 16, California Code of Regulation (CCR) Sections 1735.1 (af), 1735.6(e) & 1751.8(c)

On March 9, 2020, President Lippe approved a limited waiver to Stanford Health to allow for the compounding of a medium risk investigational drug in a noncompliant hazardous compounding environment. The facility is enrolled in a study conducted by the National Institutes for Health to evaluate the potential treatment of the infection. Under the approved waiver Stanford Health is granted limited authority to compound the investigational drug.

The facility indicates that equipment is on order. It is anticipated that the equipment should be operation in August 2020.

**PETNet, Waiver of Business and Professions Code section 4126.8 & Title 16, CCR
Section 1751.5**

On March 20, 2020, President Lippe approved a limited waiver to PETNet to exclude employees from donning new garb when compounding staff enter the current demarcated processing area where a hot-cell is located. Use of such a device requires no direct interventions into the PEC by the compounding staff to process or compound the patient doses from the manufactured radiopharmaceuticals. A picture of a hot-cell is provided in **Attachment 1**. Approval of the waiver was granted in light of the limited supply of PPE.

**CAP Rx, Inc, Waiver of Business and Professions Code section 4126.8 & Title 16, CCR
Section 1735.1(x)**

On March 12, 2020, President Lippe approved limited waiver to allow for an alternative use of PPE by staff performing hazardous non-sterile compounding under the following conditions:

1. The pharmacist-in-charge has made a determination that the current and potential stock of masks, chemotherapy gloves, and/or shoe covers on hand is insufficient to maintain the single-use provisions established in USP 795.
2. The pharmacy has developed a policy that details the conditions under which a mask may be reused. Such policies shall be consistent with standards of practice used during emergency situations.
3. Documented training is provided to all staff on the policy.
4. Master formulas are evaluated to determine if changes are necessary to the criteria for establishing beyond use dating.
5. Documentation is maintained indicating the duration of time the pharmacy is operating under the waiver approval.

Approval of the waiver was granted in light of the limited supply of PPE.

Attachment 1

A hardcopy of the picture may be made available upon request to
Debbie.Damoth@dca.ca.gov.