



To: Board Members

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

Consideration of Site-Specific Waivers

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.

Specific to this agenda item, under the respective provisions of current law issuance of a temporary license is limited to 180 days.

For Board Discussion and Consideration

During the meeting members will have the opportunity to consider three recommendations from staff to extend temporary licenses beyond the 180-day period as provided below.

1. California Department of Public Health Alternative Care Site – Sacramento (Sleep Train Arena), HPE, 57779

Summary: The Board issued a license to the above facility as part of California's efforts to increase surge capacity. The license was issued on April 13, 2020, under the provisions BPC Section 4110, for a 180-day. The license expired on November 4, 2020. Subsequent to the expiration as the need to reactivate the surge location became apparent, President Lippe authorized a waiver to BPC section 4110 to allow for the reinstatement of the license for 90-days. The license was reactivated on November 19, 2020, and will expire February 17, 2021.

Recommendation: Board staff recommend extension of the hospital license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

2. LACC No 1 Pharmacy, PHE 57875

Summary: LACC No. 1 is also a COVID-19 surge location. The Board issued the temporary license on August 8, 2020, to this Low-Acuity Continuing Care (LACC) site. On January 11, 2021, President Lippe approved a waiver to BPC section 4110 to extend the temporary license an additional 30-days to allow for the continued use of the surge location until the Board could consider a lengthier extension. This location provides care for patients outside of the traditional brick and mortar hospitals. The site is run under the purview of the City and County of San Francisco Department of Public Health. This pharmacy will not be pursuing a full license.

Recommendation: Board staff recommend extension of the pharmacy license until August 31, 2021, or until the surge location is no longer operating, whichever occurs first.

3. McKesson Medical Surgical, Inc., NPL 1258

Summary: On September 28, 2020, President Lippe approved a waiver of BPC 4161(i)(2) to allow for the issuance of a temporary nonresident 3PL (NPL) license to McKesson Specialty Distribution LLC. In preparation to implement the large-scale distribution of COVID-19 vaccines, the US CDC contracted with McKesson Corporation to distribute COVID-19 vaccines. The waiver and issuance of the temporary license allows McKesson Specialty LLC to operate in the resident state without licensure as a third-party logistics provider in that jurisdiction. Texas is one of the jurisdictions that has not implemented the provisions required under federal law to regulate wholesalers and third-party logistics providers separately.

Recommendation: Board staff recommend extension of the nonresident 3PL license until December 31, 2021, or until such time as either McKesson Medical-Surgical obtains appropriate licensure in the resident state or until changes in California Law are secured, whichever occurs first.