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Department of Consumer Affairs Gavin Newsom, Governor

Business, Consumer Services and Housing Agency



To: Board Members

Subject: Agenda Item IX Discussion on Draft Policy Statement Related to Implementation of Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Relevant Law

On October 8, 2023, Governor Newsom signed <u>Assembly Bill 1286</u>, the Board's patient safety measure. The measure creates a mandatory requirement that community pharmacies report medication errors that occur in the outpatient setting to an entity approved by the Board. Further, the measure updates minimum staffing requirements and authority for the pharmacist-in-charge, updates professional conduct codes, establishes authority for the issuance of a cease and desist under specified conditions, expands authority for pharmacy technicians to perform expanded duties under specified conditions, and updates the renewal requirements for surgical clinics.

Background

During the October 19, 2023, Enforcement and Compounding Committee and the November 1-2, 2023, Board Meeting, members discussed various activities the Board will undertake to implement the measure.

During respective discussion at both meetings, members noted that the medication error report requirements do not become effective until after the Board approved an entity to receive such reports. The Board agreed that an alert should be released regarding the medication error reporting requirement.

The Board also considered correspondence received indicating that a delay in implementation is necessary surrounding the staffing requirements. The Board noted that each case needs to be assessed individually based on its unique facts and that pharmacies should begin taking the necessary steps for compliance. Staff note that prior public comment suggested that the application processing time was over 90 days for pharmacy technicians. Although processing times fluctuate, staff notes that processing time for pharmacy technician applications is under 30 days for completed applications. The processing times for processing deficiency items is also less than 30 days.

For Member Consideration and Discussion

Following this memo is a draft statement to provide licensees and interested stakeholders with the Board's policy related to implementation of AB 1286. Should members agree that release of a statement is appropriate, the following motion could be used.

MOTION: Approve the policy statement [insert either as drafted or consistent with the Board's discussion].

Draft Statement Re: Assembly Bill 1286 Implementation

The California State Board of Pharmacy provides licensees and interested stakeholders with the following information on its policy relating to implementation of provisions contained within Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023).

Assembly Bill 1286 establishes a requirement for the reporting of medication errors that occur in the outpatient setting to an entity approved by the Board under specified conditions. The Enforcement and Compounding Committee will begin its evaluation of entities in the coming months. During this intervening period, reporting of such errors is not required nor will it be retroactive. It is anticipated that reporting of such errors will only be expected after approval of such an entity with an appropriate transition period for implementation. Interested stakeholders are encouraged to participate in relevant public meetings.

Assembly Bill 1286 also establishes a self-assessment process for surgical clinics. Development of the self-assessment form will be undertaken by the Enforcement and Compounding Committee. Upon development and approval of the self-assessment form, the Board will advise licensees and make the form available on its website. During this intervening period, completion of the self-assessment form requirement will be delayed. Interested stakeholders are encouraged to participate in relevant public meetings.

Several additional provisions contained in Assembly Bill 1286 become effective January 1, 2024. The Board encourages licensees to begin taking the necessary steps for compliance immediately. The Board recognizes that despite good faith efforts, there may be delays in achieving compliance by January 1, 2024. During the implementation period, the Board will consider actions taken to secure compliance when areas of non-compliance are identified through the inspection or investigation process. The Board encourages licensees to maintain documentation of actions taken to achieve compliance and to present such information to the Board upon request.

November 20, 2023