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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

**To: Board Members**

**Subject: Agenda Item V. Discussion and Consideration of Statutory Proposal to Establish Requirement for Reporting Medication Errors**

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Background

Currently, reporting of medication errors is voluntary. There are different sources for reporting errors including the US Food and Drug Administration's MedWatch Reporting Program and ISMP Medication Errors Reporting Program (MERP).

Prior Committee Discussions

As part of its evaluation of medication errors and workforce issues, the Committee has discussed reporting requirements for medication errors and research available. During the September meeting members discussed the issue of medication errors in the community pharmacy setting and that estimates suggest there could be over five million dispensing errors a year in California.

Members previously discussed several policy questions related to the issue of medication error reporting and determined the following:

1. Should the Board establish a mandatory reporting requirement for medication errors?
2. If yes, what would be the appropriate entity to receive such reports?
3. Should the reporting requirement be limited in duration?
4. Should the Board establish a standardized reporting form?

As reported at the October Board Meeting, members determined it is appropriate for the Board to establish a mandatory reporting requirement and requested that staff present additional information.

More recently, during its November meeting, members resumed consideration of the issue including approaches taken to implement medication error reporting, two mandatory and one voluntary.

Pennsylvania Patient Safety Authority (PSA) is an independent state agency that collects reports of patient safety events from Pennsylvania healthcare facilities. According to information on its website, Pennsylvania is the only state that requires healthcare facilities to report all incidents of harm (serious events) or potential for harm (incidents). "The PSA analyzes those reports to prevent recurrence either by identifying trends unapparent to a single facility or flagging a single event that has a high likelihood of recurrence and disseminates that information through multiple channels."

Under the provisions of the Pennsylvania law, the PSA developed the Pennsylvania Patient Safety Reporting System (PA-PSRS), a secure, web-based system that permits healthcare facilities to submit reports as well. The statewide mandatory reporting went into effective in June 2004 for hospitals, ambulatory surgical facilities and birthing centers. Over the years additional facilities have been required to report including nursing homes. Community pharmacies are not required to report.

The reporting system contains strong confidentiality and whistleblower protections, and no information about individual facilities or providers will be made public. Several entities were involved in the development and implementation of the system including the Institute for Safe Medication Practices (ISMP).

ISMP has noted that the automated data interface between the PA-PSRS and the facilities' existing internal error/risk management reporting systems was an important step to facilitate reporting. Staff was also advised that some smaller facilities used the PA-PSRS system as their primary reporting program as they did not have their own program internally.

One of the primary outcomes of the system are quarterly publications. Until the last few years, ISMP reviewed the data sets and published articles.

ISMP Canada's National Incident Data Repository for Community Pharmacies (NIDR) is a collection of reported medication incidents submitted anonymously by community pharmacies for the purpose of improving medication safety. The system was developed in 2008. In 2010, Nova Scotia was the first jurisdiction to implement a requirement for community pharmacies to anonymously report medication incidents for quality improvement and the submission of data to the NDIR. Since that time additional provinces have implemented similar requirements.

Reporting into this system has contributed to improvements in practice through shared learning, medication safety and quality improvements, as well as informing research and policy including:
Drugs associated with quality-related events reported by community pharmacies in Nova Scotia, Canada, [manuscript published in BMJ Open Quality in May 2020]

Funding for this system is through Health Canada through an agreement with ISMP Canada. In addition, a data processing fee is charged on an annual per-community-pharmacy basis. The data processing fee is $70 per pharmacy, paid annually.

In both examples listed above, reporting is mandatory. This stands in contrast to reporting to Patient Safety Organizations (PSO), which collect and analyze data voluntarily reported by healthcare providers. These provisions were established as part of the Patient Safety and Quality Improvement Act of 2005 which authorized the creation of PSOs to improve quality and safety by reducing the incidents of

events that adversely affect patients. The Agency for Healthcare Research and Quality (AHRQ) is responsible for regulation of PSOs. There are currently about 100 approved PSOs. Voluntary reporting by PSOs to the Network of Patient Safety Databases (NPSD) provides for the aggregation of non-identifiable data from across the country. NPSD has data available on medication errors occurring in the hospital setting only.

Under the provisions of the federal law, there are a number of entities excluded from serving as a PSO including a health insurance issuer, regulatory agencies, entities that carry our inspections or audits for a regulatory agency, and entities that administer a federal, state, local, or tribal patient safety reporting system to which healthcare providers are required to report by law or regulation. PSOs are required to collect and analyze patient safety work product in a standardized matter (referred to as a common format), where possible, to permit valid comparisons of similar cases among similar providers. Community pharmacies have a common format available.

A review of the PSO's operating in California filtered for "retail pharmacy" reveals eight potential PSOs including:

1. Alliance for Patient Medication Safety
    - Components of Parent Organizations: National Alliance of State Pharmacy Associations
2. Center for Patient Safety
3. CEIR and the Institute for Safe Medication Practices PSO
    - Components of Parent Organizations: Emergency Care Research Institute d/b/a ECRI
4. Safety Culture Patient Safety Organization
    - Components of Parent Organizations: Walmart
5. The Patient Safety Research Foundation, Inc.
    - Components of Parent Organizations: Walgreen Co.
6. The PSO Advisory, LLC (Rhode Island)
7. Virginia PSO
    - Components of Parent Organizations: Virginia Hospital and Healthcare Association
8. Vizient PSO
    - Components of Parent Organizations: Vizient Inc.

Provisions for the Nova Scotia law require the reporting of quality related events (QREs) to a database that contributes to the Canadian Medication Incident Reporting and Prevention System National Incident Data Repository for Community Pharmacies and enables this reporting to be anonymous. Anonymous reporting means that no identifying information about the patient, the reporter, or individual staff members involved is transmitted to the system. QREs include errors that reach

the patient as well as those that are intercepted prior to dispensing. The extent to which intercepted errors are reported is based upon the professional judgment of the pharmacy manager in consideration of the nature of the intercepted error, its implications for patient safety and the extent to which it is recurring.

Members considered some additional policy questions and determined that the Institute for Safe Medication Practices would be the appropriate entity to receive the reports. Members also noted that the provisions should be related to community pharmacies and that the appropriate timeframe for reporting errors should be 14-days. Members noted agreement that it is necessary for a single entity to receive all reports.

Public comment on the proposal varied from support opposition. Comments in support included a reporting requirement if it was to a third-party versus the Board, while others suggested that the third-party should be a PSO.

Public comment also requested clarification in the language that prescriptions dispensed by a hospital outpatient pharmacy associated with a hospital be excluded from the provisions.

Some public comments suggested that the committee hear a presentation from a PSO to understand the legal requirements regarding what is considered discoverable and what is considered work product of the PSO. Members were advised that one entity has contracted with a PSO and is in the process of implementing a reporting process noting it is expensive and time-consuming.

Following public comment members agreed to have a presentation in the future from a PSO but to continue to move the proposal forward.

For Member Consideration

During the meeting members will have the opportunity to consider the matter and review the proposed statutory language. As drafted the proposal would establish a mandatory requirement for community pharmacies to report medication errors to the Institute for Safe Medication Practices within 14 days. Further, the language is explicit that the reports are deemed confidential and that a report made pursuant to this section shall not be subject to discipline or other enforcement action by the Board based solely on the report.

**Committee Recommendation**: Pursue a statutory proposal to establish a mandatory medication error reporting requirement consistent with the language presented.

Following this memo is a copy of the draft language.

In response to public comments received, staff have reviewed the federal provisions and regulations related to patient safety organizations established in federal law

and have not identified any legal barriers to establishing a reporting requirement to an entity such as ISMP as proposed in the language. Staff have requested start up costs for the Canadian model and will provide that information if available, during the meeting.

**Proposed addition of Business and Professions Code Section 4113.1 Pharmacy Operations**

Any community pharmacy licensed pursuant to this article shall report all medication errors to the Institute for Safe Medication Practices. Reporting shall be submitted no later than 14 days following discovery of the error. Such reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to Chapter 3.5 (commencing with Section 6250) of Division of Title 1 of the Government Code. The pharmacy shall maintain records demonstrating compliance with this requirement for three years and shall make such records immediately available at the request of an inspector. A medication error report made pursuant to this section shall not be subject to discipline or other enforcement action by the Board based solely on the report; however, if the Board receives other information regarding the medication error, that information may serve as basis for discipline or other enforcement by the Board.