AQIPS ALLIANCE FOR QUALITY IMPROVEMENT AND PATIENT SAFETY

Patient Safety Organizations and Healthcare Providers Advancing Patient Safety

TRANSMITTED VIA ELECTRONIC MAIL

California Board of Pharmacy

Re: Implementation of 4113.1 of AB 1286

Dear California Board of Pharmacy Members:

The Alliance for Quality Improvement and Patient Safety (AQIPS) appreciates the opportunity to submit comments on the Enforcement and Compounding Committee (Enforcement Committee) Report (the Report) and the implementation of Section 4113.1 of AB 1286 Pharmacy to the California Board of Pharmacy (the Board).[i] AQIPS continues to encourage the Board to select a listed Patient Safety Organization as the "entity approved by the board" to receive reports of medication errors from community pharmacies under Section 4113.1.

AQIPS' comments here focus primarily on the Scope of Work and Contract Requirements for Inclusion in the Invitation for Bid for Interested Parties Seeking to Serve as the Approved Entity under Business and Professions Code section 4113.1. First, as more fully discussed below, the inclusion of a "Pharmacy Unique Identifier" in the Report as a recommended data element is not appropriate. Second, many of the Enforcement Committee's recommendations in the Report go well beyond what AB 1286 contemplates and are, in fact, statutory modifications or interpretations. Such recommendations cannot be adopted and enforced by the Board unless the Board undertakes a regulatory process, including a Request for Information and notice and comment rulemaking. Finally, AQIPS highlights that if the Committee delegates a member of the Board to serve on the panel responsible for approving the winning vendor, it has satisfied its authority to approve the entity under section 4113.1.

I. The "Pharmacy Unique Identifier" should be removed as a data element.

a. The Pharmacy Unique Identifier serves no analytical purpose and is not a reporting element in the AHRQ Community Pharmacy Common Format.

The "Pharmacy Unique Identifier (Unique Identifier to be established by the contracted vendor)" is **not** a reporting element of the AHRQ Community Pharmacy Common format. (see https://www.psoppc.org/psoppc_web/publicpages/commonFormatsCPV1.0). This is incorrectly stated in the Report. The Enforcement Committee staff note in the Report that "the community pharmacy common format

established by AHRQ provides the foundation for many of the recommendations offered here." Therefore, the "Pharmacy Unique Identifier" should not be characterized as a common format data element and should be replaced with the "Type of Pharmacy" data element to enable analysis of data collected across pharmacies of similar size and type. Data provided to the board will be nonsensical if the board is unable to identify the type of pharmacy as opposed to the identity of the pharmacy.

Because the approved entity will not have the data or authority to evaluate each pharmacy's proprietary dispensing systems, it will not be capable of providing specific recommendations to a single identified pharmacy. Rather, the expected purpose and benefit of the approved entity under AB 1286 is to collect data that can be aggregated and analyzed across all community pharmacies to make broad recommendations to improve patient safety and quality. For example, an alert concerning a sound alike/look alike drug. The Board recognizes this limited efficacy of the approved entity and the data collected as it only is requiring that best practice feedback be developed once per year. The Report recommends that "the Committee prefers the entity to develop and disseminate information gained from the reporting to improve patient safety such as recommendations or best practices *annually*" (see report page 5, emphasis added). Because the approved entity is not empowered provide direct feedback to a Community Pharmacy, a "Pharmacy Unique Identifier" is irrelevant.

b. The Pharmacy Unique Identifier is inconsistent with encouraging a safety culture and may discourage reporting out of fear of reprisal.

A critical component of any state medication error reporting system is to create an environment that encourages organizations to identify errors, evaluate causes and design systems to prevent future errors from occurring. In order to accomplish this goal, the law must promote a learning environment that moves beyond shame and punishment that suppresses information about medication errors to a "culture of safety" that focuses on information sharing and improved medication safety. Requiring each pharmacy to be identified using a "Pharmacy Unique Identifier," even to the approved entity, will result in suppressed reporting out of fear of reprisal (see Senate report 108-196, 2003).

II. Many of the Enforcement Committee's recommendations go beyond the statutory authority in AB 1286 and instead must be implemented through a regulatory process, including a Request for Information (RFI) and notice and comment rulemaking

Section 4113.1 of AB 1286 Pharmacy is not specific enough to be self - implementing. AQIPS points out that the Enforcement Committee's recommendations in the Report go well beyond the plain language of the statute. For example, to avoid unintended consequences - and for the reasons specified above - the specific data elements that community pharmacies must report under AB 1286 are not listed in the statutory text itself and therefore need to be elucidated through a public process. Further,

other recommendations made in the Committee Report require the collection of information, followed by a public notice and comment process including:

- **The method(s) of reporting to the approved entity must be identified prior to the contracting process through a Request for Information and implemented through notice and comment rulemaking.** How data is reported to the entity approved by the Board is delegated to the entity in the Enforcement Committee's report. However, the entity has no authority to mandate how a pharmacy or its agent reports the medication errors and therefore must accept reports in any manner that they are given. As the reporting of medication errors to the Board is mandatory, pharmacies and their agents need notice of how the reporting will be permitted and need the opportunity to recommend different methods that are more efficient or cost effective. Pharmacies should not be surprised after the contract award of how the entity plans to collect the medication errors and may have cause to object to the methods. The contracted entity has no authority under section 4113.1 to require any method of reporting by a pharmacy or a Patient Safety Organization or other reporting agent. The method of reporting will affect the costs to a pharmacy, Patient Safety Organization or other reporting agent that need to be considered under the proposal. The Committee Members agreed that the cost to reporting pharmacies needs to be considered as a factor in determining the awarding of the bid. However. the board has no process to collect the actual costs to the pharmacies under any reporting method, simply the costs charged by the entity to analyze the reports (see Report page 6.)

- **The Enforcement Committee is recommending to the Board to modify section 4113.1 by requiring that certain patient outcomes be reported to the board prior to the 14 day following the date of discovery of the error timeline.** The Board needs to collect information and implement a notice and comment rulemaking to modify section 4113.1 to require expedited reporting by community pharmacies of specific outcomes. Section 4113.1 specifically specifies the types of medication errors that are required to be reported; and under recognized principles of statutory interpretation, the State Legislature recognized that certain outcomes may occur with such medication errors. Yet, the law states a 14-day reporting period and not an expedited reporting process for any outcomes. This recommendation has the feel of compliance monitoring. Section 4113.1 specifically states that "A medication error report made pursuant to this section shall not be subject to investigation, discipline, or other enforcement action by the board based solely on a report received pursuant to this section." The Board could consider an expedited analysis of the reported medication error by the approved entity based on a specific outcome; however, we believe that comments should be collected concerning requiring responses based on "outcomes" rather than on the medication error. Importantly, Community Pharmacy Patient Safety Organizations work closely with pharmacies to analyze events, including conducting root cause analysis and developing solutions to issues to prevent their reoccurrence.

- **The qualifications of the approved entity need to be specified and public comment permitted.** Section 4113.1 requires that "any entity approved by the board shall have experience with the analysis of medication errors that occur in the outpatient setting."

- **The security and confidentiality requirements for the approved entity need to be established via regulation subject to public comment.** In order to ensure the confidentiality of the reports and the confidence in the approved entity by the California pharmacy community, the confidentiality and security requirements must be identified by regulation. Section 4113.1 provides that "[T]hese reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code), except that the board may publish deidentified case summary information compiled from the data in the reports so long as deidentification is done in accordance with the requirements set forth in Section 164.514(b)(2) of Title 45 of the Code of Federal Regulations, and includes omitting the name of the reporting pharmacy." The regulations must require that the entity cannot use the information in the reports for any other purpose other than to implement section 4113.1 as the Board's authority is limited to this purpose under the state law.

- **The types of feedback recommendations to be provided from the approved entity to the pharmacies.** Community Pharmacies and Patient Safety Organizations are in a good position to identify the types of feedback that are most useful to improve medication safety.

Stakeholder community pharmacies and Patient Safety Organizations and other reporting agents are confused about how section 4113.1 will be implemented. We encourage the California Board of Pharmacy to work with stakeholder community pharmacies and Patient Safety Organizations to successfully implement this law.

III. If the Committee delegates a member to serve on the panel responsible for approving the winning vendor it has satisfied the statutory provision to approve the entity. Under the law, the California Board of Pharmacy gets one opportunity to approve the vendor not an opportunity at every stage of the contracting process.

Under the law, if the board delegates its authority for a member of the Board to appear on the panel to approve the winner – it forgoes its opportunity to approve the entity prior to awarding the contact. According to the Report, the Enforcement Committee recommends that a Board member be delegated to serve on the panel to approve the winning vendor and suggests that the Board would retain its authority to approve the entity. The Record correctly states that Section 4113.1 provides that approval of an entity resides with the Board. However, under the law, the California Board of Pharmacy gets one opportunity to approve the vendor. Therefore, either the Board's representative can approve the entity as part of the contracting process or the board can approve the winning bidder following the state contracting process, and prior to awarding the contract. The

state law does not provide that the board approve the entity at every stage of the contracting process; and therefore, gain more than one opportunity to approve the entity. This is consistent with the aim of the California procurement statute, which is to limit the possibility of any influence, direct or indirect, that might bear on an official's decision: "to guard against favoritism, improvidence, extravagance, fraud and corruption, and to secure the best work or supplies at the lowest price practicable . . . for the benefit of property holders and taxpayers, and not for the benefit or enrichment of bidders." *Domar Elec., Inc. v. City of Los Angeles*, 9 Cal. 4th 161, 173 (1994).

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Should you have any questions or require additional information, please contact me at pbinzer@allianceforqualityimprovement.org or 703.581.9285.

Sincerely yours,

Margaret C Binzer

Margaret Binzer
Executive Director and General Counsel

[i] AQIPS is a not-for-profit, national professional association for Patient Safety Organizations and their health care providers, including pharmacies and pharmacists, and other providers in California and throughout the United States. As having significant experience in safety culture and medication safety, AQIPS is uniquely qualified to provide the CA BOP with insight on how to implement section 4113.1 of AB.