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

MEDICATION ERROR REDUCTION AND WORKFORCE COMMITTEE MEETING MINUTES

DATE: September 14, 2022

LOCATION: Pursuant to the provisions of Government Code section 11153, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Nicole Thibeau, Licensee Member, Chair
Seung Oh, Licensee Member, Vice Chair
Jessi Crowley, Licensee Member
Kula Koenig, Public Member
Jignesh Patel, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Thibeau called the meeting to order at 10:02 a.m. Chairperson Thibeau reminded everyone present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. Where protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Thibeau took roll call. Members present included: Seung Oh, Licensee Member; Jessi Crowley, Licensee Member; Kula Koenig, Public Member; Jig Patel, Licensee Member; and Nicole Thibeau, Licensee Member. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda.

A representative of UFCW Western States Council requested the Committee add to a future agenda the required training for pharmacists who administer the Monkeypox (MPX) intradermal vaccine include hands on training and recommended that it be away from workflow duty. The representative requested the training to be consistent across all employers and all healthcare settings.

Members were asked if they wanted to add any items for future agendas. No items for future agendas were discussed.

III. Approval of June 22, 2022, Committee Meeting Minutes

Members of the public were provided the opportunity to provide comment.

Motion: Approve the June 22, 2022, meeting minutes as presented in the meeting materials.

M/S: Oh/Patel

Members of the public were provided the opportunity to provide comment; however, no comments were provided.

Support: 5 Opposed: 0 Abstain: 0 Not Present: 0

Member	Vote
Crowley	Support
Koenig	Support
Oh	Support
Patel	Support
Thibeau	Support

IV. Discussion and Consideration of Possible Future Changes to Title 16, California Code of Regulations Section 1711 Related to Quality Assurance Programs

Chairperson Thibeau advised California Code of Regulations (CCR) section 1711 establishes the requirements for a pharmacy to establish or participate in an established quality assurance (QA) program. Dr. Thibeau noted this program is to document and assess medication errors to determine the cause and an appropriate response to improve the quality of pharmacy service and prevent errors.

Chairperson Thibeau stated the requirements for a QA program have been in place for 20 years and have remained largely unchanged and quite broad. Dr.

Thibeau noted as the Committee continues to evaluate medication errors and workplace issues, the Committee may consider if action was appropriate to address these issues and if a review of the QA program requirements appears appropriate.

Chairperson Thibeau noted as reported both in the media, reports, and in public comments received, workforce strains are a contributing factor to medication errors; however, the Committee has received comments that some staff are prohibited from including staffing and other workforce issues as part of the QA report.

Chairperson Thibeau advised the meeting materials included some policy questions to help guide the discussion.

1. ***Should the date the error occurred be required to be reported?***

   Members reached consensus that the date should be determined to the best of the person's ability as sometimes the date may not be able to be determined.

2. ***Should the staff involved in the error be required to documented?***

   Members agreed it was important to know who was involved for the purpose of determining the root cause of the error and identifying if additional training was needed. Members expressed concern that the names of the people involved would be used for disciplinary or punitive reasons. Members emphasized the use of Just Culture throughout the process.

3. ***Should the QA report include the type of error, for example, patient received the wrong medication, the wrong directions were provided, etc.?***

   Members agreed the type of error should be included and was important to understand the full picture and severity of error as well as allowed for patterns to be identified and may point to a systemic problem.

4. ***Should the volume of workload completed on the date the error occurred be required?***

   Members agreed this should be required with consideration for other factors such as practice setting (e.g., central fill, community, inpatient, long-term care, etc.); if the pharmacist was working alone; robotics used; number of pharmacists/pharmacy technicians working; and point in shift that the error occurred.

5. ***Are there standardized items that should be captured, e.g. prescription volume (new and refill), immunizations provided, MTM, etc.?***

   Members reached consensus that contributing clinical and non-clinical services provided as well as workload should also be included. Members noted a lot of feedback around immunizations and sufficient space needs to be allocated to account for all items.

6. ***Should the number of staff and classification on the date of the error occurred by required?***

   Members agreed it was important to understand why distraction occurs and the root cause.

7. ***Should requirements be updated to require documentation of the actions taken (as well as recommended changes) and the date those actions occurred?***

   Members agreed requirements should be updated to require documentation of actions taken and review patterns in the QA. Ms. Sodergren provided QAs are not always available during inspection due to the retention schedule.

8. ***Should the Board standardize the QA form? Note: Staff note that the information varies greatly between pharmacies and at times appears too vague preventing sufficient review of the issue to identify recommended changes in a process.***

   Members agreed a standardize template would be helpful so long as the form is not required. This would allow companies to modify the form as needed. Members were interested in how at-risk behaviors were identified by pharmacies and what corrective action was taken for those behaviors. Members hoped this would help in catching the near misses and trying to prevent the errors from happening in the future.

9. ***Should a threshold be established after which a specified number of medication errors occur (i.e., 12 in a one-month period) that the pharmacy is required to take additional action? (i.e., complete the ISMP self-assessment tool, engage with a consultant that specializes in medication error reduction, etc.)***

   Members discussed factoring in the type of error and number of errors. Members discussed the complexities of this and that a number may not be the best gauge. Members agreed on the concept have had difficulty identifying how error severity would be accounted.

10. ***The current records retention schedule is one year. Should this be extended to allow for assessment of process improvements implemented or should aggregate year end data be required before removal of the QA records?***

    Members agreed the retention should be extended and suggested at minimum three years and possibly up to five years. Aggregate data would be important but members were unclear how to do it.

Members of the public were provided the opportunity to comment. The Committee heard comments from representatives from UFCW Western States Council, Kaiser, CPhA and CRA/NACDS.

Overall, the Committee heard comments in support of including staff involved; workload/volume including quantitative and qualitative; employer actions taken; standardizing minimum standards for a template/sample QA form with input from patient safety organizations; flexibility in requirements and time allowed to research the error; including ancillary documents involved; increased identifying trends to ensure same type of error isn't happening; increased implementation time; and increasing record retention to five years. The Committee heard comments about the Board not requiring staff involved being documented and not having required elements that may deter people from reporting errors.

Chairperson Thibeau surveyed the Committee after hearing public comment. Members indicated interest in hearing about the role a patient safety organization could play.

Chairperson Thibeau added as it appeared the Committee believed changes may be appropriate, the Committee would continue the discussion at the next meeting. Dr. Thibeau noted with the feedback provided, staff can begin developing a proposal for future consideration by members.

The Committee took a break from 11:12 a.m. to 11:17 a.m. Roll call was taken after break. Members present included Seung Oh, Licensee Member; Jessi Crowley, Licensee Member; Kula Koenig, Public Member; Jig Patel, Licensee Member; and Nicole Thibeau, Licensee Member. A quorum was established.

V. Discussion and Consideration of Medication Errors and Possible Future Development of Medication Error Reporting Requirements, Including Use of Required Standardized Report

Chairperson Thibeau advised the reporting of medications errors was voluntary and there were various sources that accept such reporting. Dr. Thibeau noted the issue of medication errors was not new. A study referenced in the meeting materials from

2003 concluded that dispensing errors were a problem at a national level with about 4 errors per day in a pharmacy filling 250 prescriptions daily.

Chairperson Thibeau provided the New Hampshire State Board of Pharmacy reviewed medication errors received between February 2007 and July 2012 and published its results that included 40 percent of the errors involved dispensing the incorrect medication and 68 percent of the errors occurred when only one pharmacist was on duty. Dr. Thibeau added limitations on the results included that the reporting of errors was not mandatory.

Chairperson Thibeau noted the practice of pharmacy has changed over the years. Dr. Thibeau noted changes include pharmacies that may have integrated technology in the dispensing process and expanded authorization for pharmacists.

Chairperson Thibeau noted more recent information published suggests that about 1.5 percent of all prescriptions in the community setting have a dispensing error. Dr. Thibeau added while that percentage sounds low, given the number of prescriptions dispensed in California, that estimated number of dispensing errors was staggering.

Chairperson Thibeau advised the Committee would discuss the policy questions provided in the meeting materials.

1. ***Should the Board establish a requirement to report medication errors?***

   Some members thought the Board should establish a requirement to report medication errors so that there was data available rather than antidotal information and noted favor toward anonymity for the need for protections for the pharmacies and individuals. Some members thought it would be burdensome.

2. ***If yes, what entity should receive the reports to receive such reports?***

   Some members thought the Board should collect the reports while others thought there could be a better result if a third-party entity (e.g., patient safety organization, ISMP, etc.) collected the information so that the Board could extract the data. A member encouraged the Board to reach out to New Hampshire to review their process.

3. ***If yes, should the requirement be limited in duration for purposes of conducting a study similar to the approach taken in New Hampshire?***

   Members recognized the time and resources that would be required to initiate such a project and were concerned about spending time and resources for a

limited amount of time. Members acknowledged something needed to be done but did not reach a consensus on how to do it.

4. Should the Board establish a standardized medication error reporting form?

Members recommended developing a standardized form to work in conjunction with the QA form. Members agreed the form should be simple.

Members of the public were provided the opportunity to provide comment.

The Committee heard comments from CRA/NACDS, UFCW Western States Council, CPhA and Kaiser.

Public comment was received in support of having data be collected by a patient safety organization provided the Board was required to analyze the data. Public comment was received in support of using existing organizational forms provided elements for CCR 1711 were included noting it would take time to update software system for new requirements. A comment was also made recommending the name of chain pharmacies should be noted to identify repeat issues as well as best practices. Public comment indicated there could be a concern to have to report errors to the regulatory body who could discipline for the errors being reported.

Chairperson Thibeau noted there appeared to be consensus that as a Committee additional requirements may be appropriate regarding the reporting of medication errors. With the Committee's agreement, Chairperson Thibeau will work with staff to develop a possible proposal that could serve as a possible framework for future consideration.

VI. Discussion and Review of Enforcement Actions Taken and Enforcement Authority Exercised by Other Jurisdictions Related to Workplace Conditions

Chairperson Thibeau advised the next item for consideration was enforcement authority exercised by other jurisdictions related to workplace conditions. Dr. Thibeau reminded the Committee at the previous meeting, the Committee heard in Nova Scotia, legal provisions require that pharmacy managers ensure the staffing plan is commensurate with the needs of the patients of the pharmacy and that when staffing issues are related to errors, the Board can require the pharmacy owners and managers to show proof of how they insured that regulatory requirement was met.

Chairperson Thibeau noted there were several jurisdictions within the US that were evaluating this issue. Dr. Thibeau added some actions taken by other jurisdictions included establishing requirements to report unsafe working conditions, having provisions to ensure sufficient personnel are scheduled to work and having

requirements that a pharmacy must notify patients if the pharmacy is experiencing significant delays or cannot dispense prescriptions in a timely manner. Dr. Thibeau added in California, there were provisions establishing when a pharmacist is at lunch, requiring a community chain pharmacy to ensure designated staff are available to assist a pharmacist when requested as well as a new requirement establishing a prohibition on workload quotas.

Chairperson Thibeau referred to the meeting materials that included specific legal requirements for some other states and noted several states include a requirement for the pharmacy to ensure sufficient staffing.

Members were provided the opportunity to comment.

Members spoke in favor of all four states' models highlighting inadequate staffing report forms, limitations on working, and mandatory rest periods. Members suggested taking the highlights from each model and consolidating into one California model. Members spoke in favor of staffing floors as well as pharmacists and pharmacists-in-charge (PIC) being able to make decisions on staffing.

Members of the public were provided the opportunity to comment.

The Committee heard comments from Pizza is Not Working, UFCW Western States Council, and CVS Health. Members heard comments in support of having descriptive language rather than a finite number; support of the PIC to have the staff needed; factor in all services provided when determining staffing; allow the Board to have authority to look at staffing in all capacity where prescriptions are filled; consider staffing as a mitigating factor in disciplinary cases; develop a staffing floor; and discussion on four state models and focus on patient safety.

The CVS Health representative noted the article about CVS Health was not correct.

Chairperson Thibeau concluded there appeared to be consensus that additional authority is appropriate. The Committee was agreeable for Dr. Thibeau to work with staff to develop a possible proposal that could serve as a possible framework for future consideration.

VII. Discussion and Consideration of Just Culture Approach to Managing Patient Medication Errors and Patient Safety

Chairperson Thibeau reported Just Culture as a means of managing patient medication errors and patient safety. The Institute for Safe Medication Practices (ISMP) had good information on Just Culture including how a pharmacy organization could adopt such an approach. Dr. Thibeau noted a Just Culture is not a "non-punitive or blame-free culture", rather it is one focusing on the entire

system to evaluate what occurred in an error and what future action can be taken to prevent such errors in the future.

Chairperson Thibeau had experience with Just Culture through Dr. Thibeau's current employer to both participate in and observe the direct impact of a pharmacy implementing such an approach. Dr. Thibeau explained the process of talking to people involved to determine what happened, what went wrong and determine where the issue was by using a fishbone diagram and asking five "why's" to determine root cause. This process allowed for the errors in systems to be identified.

Members were provided an opportunity to comment.

Some members had experience with Just Culture in their current organizations and believed it was critical to success. Other members didn't use Just Culture at their current organizations but like the concept of going back five steps before the error and assessing systemic errors. The Committee discussed to what extend it would appear in the enforcement mechanism. Ms. Sodergren advised this will be seen where the respondent is providing mitigation (e.g., system changes, training, etc.).

Members of the public were provided the opportunity to comment. A representative from Kaiser commented about a concern that cite and fines were issued for medication errors and is probably stifling the reporting of medication errors.

Chairperson Thibeau noted as there appeared be interest in learning more about Just Culture, Dr. Thibeau will ask staff to arrange for a presentation at a future meeting.

VIII. Discussion and Consideration of Pharmacist Well-Being Index State Report

Chairperson Thibeau referenced the copy of the most recent Pharmacist Well-Being Index. Dr. Thibeau noted there has been an increase in the number of California pharmacists using the index as well as a slight increase in the distress percentage for pharmacists licensed in California. Dr. Thibeau reported the updated pharmacy workplace and well-being reporting, which included data from January 10, 2022, to August 11, 2022, included 14 positive experiences and 159 negative experiences. Dr. Thibeau reported the negative submissions included categories focused on staffing/scheduling, workload/workload expectations, working conditions, pharmacy metrics. Dr. Thibeau noted numerous pharmacists reported verbal or emotional harassment, physical harm, including by patients, and discrimination. Dr. Thibeau added relating this information to the specific well-being index, individuals reported that the factors increased stress, increased burnout, weakened family and personal relationships, and lessened happiness.

Members were provided an opportunity to comment. Members agreed to watch this in the future.

Members of the public were provided an opportunity to comment. A licensed pharmacist in California inquired what the Board intended to do with the results of the survey.

Chairperson Thibeau stated the Committee will continue to monitor these reports and the Communication and Public Education Committee will be developing a campaign to educate the public about pharmacists and the important role they have in patient health.

IX. Future Committee Meeting Dates

Chairperson Thibeau advised the next Committee Meeting was scheduled for November 16, 2022.

X. Adjournment

The meeting adjourned at 12:36 p.m.