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



MEDICATION ERROR REDUCTION AND WORKFORCE CHAIR REPORT

March 8, 2023

Nicole Thibeau, Licensee Member, Chairperson
Seung Oh, Licensee Member, Vice-Chairperson
Jessica Crowley, Licensee Member
Kula Koenig, Public Member
Jignesh Patel, Licensee Member

I. Call to Order and Establishment of Quorum

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

*(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

III. Discussion, Consideration and Approval of Draft Minutes from the November 16, 2022, Medication Error Reduction and Workforce Committee

Attachment 1 includes a copy of the draft minutes.

IV. Presentation, Alliance for Quality Improvement and Patient Safety, on Patient Safety Organizations

Background

Federal law established the patient Safety and Quality Improvement Act (Patient Safety Act) of 2005 and authorized the Secretary of the U.S. Department of Health and Human Services to implement and enforce the Patient Safety Act.

The Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency in implementing the Patient Safety Act and Patient Safety Rules related to patient safety organizations and the network of patient safety databases (NPSD).

For Committee Consideration and Discussion

During the meeting members will receive a presentation from Peggy Binzer, Executive Director with the Alliance for Quality Improvements and Patient Safety.

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

As part of the January 27, 2022, members reviewed the January 2022 Pharmacist Well-being Index (Index) State Report. More recently as part of the June 2022 meeting, members received a presentation on Well-Being Index.

For Committee Consideration and Discussion

During the meeting members will have the opportunity the most recent report of the Well-Being Index. California's current distress rank is 40.

Attachment 2 includes a copy of the report.

VI. Future Committee Meeting Dates

- June 7, 2023

VII. Adjournment

Attachment 1



MEDICATION ERROR REDUCTION AND WORKFORCE COMMITTEE
Draft MEETING MINUTES

- DATE:** November 16, 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
 Jignesh Patel, Licensee Member
- COMMITTEE MEMBERS NOT PRESENT:** Kula Koenig, Public 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 8:36 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; and Nicole Thibeau, Licensee Member. A quorum was established.

Member Patel arrived at 8:47 a.m.

Due to technical difficulties experienced, Ms. Smiley recommended conducting a second roll call. Chairperson Thibeau took roll call. Members

present included: Seung Oh, Licensee Member; Jessi Crowley, Licensee 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 pharmacist/attorney member of the public requested seeing a discussion of automation and bar code use to be added to the agenda and noted there will be a hard deadline of 11/27/2023 for the Drug Supply Chain Security Act (DSCSA) that could cause more distraction in the pharmacy as each pharmacy will need to come into compliance.

A pharmacist representative of Walgreens requested the Board consider discussing the expiring remote processing waiver scheduled to expire at the end of February 2023 at the December 2022 Board Meeting rather than the January 2023 Licensing Committee Meeting. The representative noted Walgreens will be due to lose about 40 pharmacists that currently support pharmacies in California and it was a time sensitive issue for patient safety and team members.

A member of the public commented a friend from Paris ran out of medication and had difficulty obtaining medication.

A pharmacist requested the Committee add to a future agenda item the issue of students' and residents' experiences including people of color but specifically Hispanic women whose experiences are overlooked and marginalized. The pharmacist noted guidelines in health systems for diversity, equity and inclusion do not include addressing the concerns of the individuals. The commenter added in the case of this individual who is a Hispanic woman when looking at the intersection of race, gender, class, sexual orientation, or gender identity, situations are created where individuals' experiences are minimized. The pharmacist noted the individual works in an ASHP accredited residency program and has been given work related to addressing medication use evaluation or longitudinal experiences versus being able to maximize experiences in a clinical setting. The pharmacist noted it is a national issue but there should be something that can be done at the state level and suggested possibly being addressed with the bill about cultural competency.

Members were asked if they wanted to add any items for future agendas.

Member Crowley requested adding the automation issue and students in residencies to a future agenda.

Member Patel requested adding the remote processing to a future agenda.

III. Approval of September 14, 2022, Committee Meeting Minutes

Members were provided the opportunity to provide comment.

Motion: Approve the September 14, 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: 4 Opposed: 0 Abstain: 0 Not Present: 1

Member	Vote
Crowley	Support
Koenig	Not Present
Oh	Support
Patel	Support
Thibeau	Support

IV. Presentation, Discussion and Consideration of Just Culture

Chairperson Thibeau recalled previously sharing experiences with the transition to a Just Culture within her organization. Dr. Thibeau noted Just Culture was not a non-punitive or blame-free culture, but rather it was one that focuses on evaluation of the system to prevent future errors.

Chairperson Thibeau welcomed Matthew Grissinger and Christina Michalek with the Institute for Safe Medication Practices (ISMP) to provide a presentation on Just Culture.

Mr. Grissinger review the objectives for the presentation. Mr. Grissinger explained Just Culture system design; behavior choices; learning environment; and shared accountability for individuals, organizations, and others.

Mr. Grissinger reviewed latent and active failures. Mr. Grissinger noted medication errors were rarely caused by a single element or the fault of a singular practitioner.

Mr. Grissinger clarified catastrophic events were most likely the result of the combined effects of latent failures in the system and active failures by individuals. Latent failures (blunt end errors) were adverse consequences which lie hidden in a system and become evident when combined with other factors to cause or contribute an error. Mr. Grissinger noted they are often accidents waiting to happen and often originate where organizational policies, procedures, and resource allocation decisions are made.

Ms. Michalek reviewed systems impacting errors including environment, policies, institutional culture, team, individual competency, and technology/equipment impacting adverse events. Ms. Michalek reviewed active failures (sharp end). Ms. Michalek noted actions made by practitioners that contribute to error noting effects are felt almost immediately by slips or lapses and by behavioral choice.

Ms. Michalek reviewed the three fundamental beliefs in a Just Culture: to err is human; to drift is human; and risk is everywhere. Ms. Michalek reviewed human behaviors in a Just Culture. Ms. Michalek defined: human error is inadvertent action and inadvertently doing other than what was intended or what should have been done; at-risk behavior as behavioral choice that increases risk where risk is not recognized or is mistakenly believed to be justified or insignificant; and reckless behavior as behavioral choices to consciously disregard a substantial and unjustifiable risk. Ms. Michalek added the two behaviors most prevalent are human error and at-risk behavior.

Mr. Grissinger reviewed the behavior and responses for types of behaviors. For the human error behavior, the person didn't choose the behavior or see the risk. The response would be to console and review the system. Mr. Grissinger reviewed factors that degrade human performance including light, noise, climate, humidity, mental distractions, and physical distractions.

Ms. Michalek discussed elements of at-risk behaviors noting risk was not recognized or recognized and believe to be justified. Fading perception of risk increases as people become more comfortable with the task and desire to accomplish more. Ms. Michalek discussed at-risk behavior of drifting as a behavioral choice being ubiquitous and inevitable; no one is immune; lose situational awareness; and understanding why people aren't following policies. Ms. Michalek reviewed how at-risk behaviors were behavior choices driven by the perception of consequences including rewards for taking shortcuts; slowly become routine; and becomes the norm.

Mr. Grissinger advised examples of at-risk behaviors as processing illegible orders; technical workarounds; preparing more than one patient's medications at once; not using two patient identifiers; not counseling patients; and incomplete handoff during shift change.

Mr. Grissinger reviewed at-risk behavior noting the person chose the behavior and may or may not have seen the risk. Mr. Grissinger noted the response is to coach and review the system by teaching, supervising, training, and instructing.

Mr. Grissinger advised managing at-risk behaviors include coaching to change the perception of risk; changing systems that are causing behaviors; addressing rewards to change the consequence; and modify barriers that prevent compliance and add barriers to prevent noncompliance.

Mr. Grissinger reviewed reckless behavior as conscious disregard of a substantial and unjustifiable risk where harm doesn't have to result, just the risk of harm. Management of reckless behavior included possible disciplinary action and considering the intent of the behavioral choice.

Ms. Michalek reviewed a case study of hospital patients exposed to HIV and hepatitis.

Mr. Grissinger discussed how people think about and respond to errors both active and latent failures reflect in the healthcare culture. Mr. Grissinger noted the effects on pharmacy staff include unfair to workforce; underreporting; not learning or improving; and can't fix what is not known. Mr. Grissinger review the punitive culture as a degree of discipline and strength by severity of outcome; procedural violations and unacceptable; telling staff to "be more careful"; and focus on re-education of individuals. Mr. Grissinger reviewed the Just Culture Algorithm.

Members were provided the opportunity to ask questions.

Member Crowley inquired about the difference between punitive culture reeducation and coaching in a Just Culture. Mr. Grissinger advised coaching is discussing with the person who made the poor behavioral choice and why the decision was made. Mr. Grissinger noted it was a two-sided conversation to understand why the error occurred. Ms. Michalek noted reeducation can be seen as punitive to the person as all the people in the organization may have been doing the same behavior.

Members Oh and Patel thanked the ISMP representatives for their presentation.

Chairperson Thibeau noted drift was one of the biggest problems and inquired if preemptive reeducation would assist in preventing drift. Ms. Michalek agreed and noted it was the role of a leader to try to identify drift before error and coach when it occurs. Mr. Grissinger encouraged to inquire why errors are happening and asking about concerns, work-around, etc.

ISMP President Rita Jew thanked the Board for the invitation and recommended reaching out to the Idaho Board of Pharmacy who recently adopted just culture model when considering penalties to licensees as well as referred to an NABP Report of the Task Force on Safety-Sensitive Measures to Review Medication Errors.

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

A pharmacist suggested recommending as a requirement or recommendation for pharmacist-in-charge to have Just Culture certification.

A consumer commented his medication was provided to someone else and the pharmacy blamed the consumer for the error saying a family member must have picked it up. The commenter stated pharmacy staff should own the error and the attitude of the pharmacy staff should change.

A member of the public commented about Idaho's use of Just Culture and recommended the California State Board of Pharmacy adopt Just Culture.

A member of the public was advised that starting in 2023 the Board would require medication error reporting and requesting clarification on the details of the process.

Members were provided an opportunity to comment.

Member Crowley requested to have someone from the Idaho Board of Pharmacy to discuss their experience with Just Culture. Chairperson Thibeau agreed with the recommendation.

Chairperson Thibeau thanked Mr. Grissinger and Ms. Michalek for the educational presentation.

The Committee took a break from 10:00 a.m. to 10:15 a.m. Chairperson Thibeau took roll call. Members present included: Seung Oh, Licensee Member; Jessi Crowley, Licensee 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 California Code of Regulations (CCR) section 1711 establishes the requirements for a pharmacy to establish or participate in an established quality assurance program. Dr. Thibeau noted the program is to document and assess medication errors to determine the cause and an

appropriate repose to improve the quality of pharmacy service and prevent errors. Dr. Thibeau added the requirements for a quality assurance program have been in place for 20 years and have remained largely unchanged and are quite broad. Dr. Thibeau noted as the Committee continues to evaluate medication errors and workplace issues and consider if action is appropriate to address these issues, review of the QA program requirements appeared appropriate. Dr. Thibeau added as has been 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 recalled at the last meeting, the Committee considered several policy questions related to the Board's quality assurance program requirements. Dr. Thibeau referenced a summary of the questions and discussion for each question. Chairperson Thibeau recounted the Committee determined changes in the Board's current quality assurance program appeared appropriate and requested staff to prepare regulation language for consideration for review.

Chairperson Thibeau reviewed the language and believed it appropriately captured the Committee's prior discussion. Dr. Thibeau recommended review the policy questions to assist with finalizing the language.

Members were provided the opportunity to provide comment.

Policy Question #1

Does the Committee believe the new proposed requirements established in 1711(e)(2)(A)-(E) are necessary for reporting incidents involving the use of an ADDS or should such incidents be exempt from including these additional elements of QA reports?

Chairperson Thibeau didn't believe the information was needed to be included in a QA report stemming from the use of an ADDS. Members Oh and Patel agreed.

Policy Question #2

As drafted the QA reports records retention period is extended to three years. During prior discussion members considered if, prior to destruction, aggregate data should be maintained to allow for trending and assessing for outcomes.

Member Oh agreed aggregating the data in theory but wondered how practical it would be. Dr. Oh agreed with a change to a three-year retention.

Member Crowley agreed to raising the minimum retention and three years was a good place to start.

Member Patel noted mining data and finding trends was difficult with paper records but using a patient safety organization (PSO) allows for electronic data and would be easier to data mine. Mr. Patel agreed with a 1–3 year retention period.

Chairperson Thibeau believed that some basic aggregate information may be appropriate to maintain (including the type of error, etc.) to allow for assessment of improvements based on the actions taken. Dr. Thibeau believed the Committee could either incorporate this into the regulation language or recommend but not mandate such a practice.

Member Crowley spoke in support of seeing area for at-risk behavior to be documented and believed aggregate data should be mandated. Dr. Crowley was comfortable moving forward with the language.

Motion: Recommend to the Board approval of the proposed regulatory text for Section 1711 as presented, direct staff to submit the text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any nonsubstantive changes to the package, and set the matter for hearing if requested. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all necessary steps to complete the rulemaking and adopt the proposed regulations at section 1711 as noticed.

Proposal to Amend 16 CCR § 1711 as follows:

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

- (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
- (A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
 - (B) Communicate to the prescriber the fact that a medication error has occurred.
- (3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
- (4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- (e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
- (1) The date, location, and participants in the quality assurance review;
 - (2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c); including:
 - (A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.
 - (B) The names of staff involved in the error.
 - (C) The use of automation, if any, in the dispensing process.
 - (D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.

(E) The volume of workload completed by the pharmacy staff on the date of the error including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.

(3) The findings and determinations generated by the quality assurance review; and,

(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part quality assurance report.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125 and 4427.7, Business and Professions Code.

M/S: Oh/Crowley

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

A representative from the UFCW Western States Council commented the proposal should include strong retaliation and recommended in addition to documenting errors and needing to provide training. The representative expressed support for the proposal.

A pharmacist commented the language was not ready and the definition of the error in (b) needed to be changed. The definition should be clear that when the medication is sold to the patient is defined as an error. The pharmacist noted the consultation should be documented but does not require the name of the pharmacist providing the consultation be documented. The pharmacist noted the error should be document in the patient profile with the time and date.

A pharmacist representative from Kaiser commented based on medication safety experts noting the increases of information required in each QA record will be administratively burdensome. The representative noted pharmacist-in-charges (PICs) will be spending more time investigating and documenting errors resulting in less time with patients. The representative didn't understand why workload statistics were required in every QA record and thought it was unlikely to promote or enhance a decrease in errors but rather result in oversimplification .

A representative from Albertson's companies echoed colleagues and urged committee to not move forward and encouraged the Board not to move forward with the language. The pharmacist noted by reporting incidents to PSOs, there are some prohibitions on what can be provided to PSOs. Prohibitions in place to protect providers and the facilities using the services of the organizations noting federal law does preempt when in conflict with state law. The commenter urged to have a PSO present to the Committee.

A representative of Walgreens echoed the concerns Kaiser and Albertsons and agreed the language was not ready to move forward. The representative encouraged the Board to look at New Jersey model and have a PSO come and speak to the Committee.

Members were provided an opportunity to comment after the public comment. Member Crowley expressed concern and requested if retaliation language could be added. Counsel Smiley commented anti-retaliation is covered with California Labor Law. Member Crowley required if adding a reference to the anti-retaliation would be helpful. Ms. Smiley noted it was not necessary and companies are required to follow all aspects of California law.

Member Patel commented if the motion should be held until after a PSO can present to the Committee. Ms. Sodergren noted this was for a QA program done by the pharmacy and the information was not going to a PSO. Counsel Tomaselli agreed with Ms. Sodergren.

Support: 4 Opposed: 0 Abstain: 0 Not Present: 1

Member	Vote
Crowley	Support
Koenig	Not Present
Oh	Support
Patel	Support
Thibeau	Support

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

Chairperson Thibeau recalled previous discussion about the reporting of medications errors which was generally voluntary with many sources accepting such reporting. Dr. Thibeau noted the issue of medication errors was not new. Dr. Thibeau recalled during the last meeting, the Committee discussed some of the studies in the area including a study referenced in the meeting materials from 2003 that concluded dispensing errors were a problem at a national level with about four errors per day in a pharmacy filling 250 prescriptions daily.

Chairperson Thibeau added during the September meeting, the Committee considered several policy questions related to medication error reporting. Dr. Thibeau advised a summary of the questions and discussion was detailed in the meeting materials. Dr. Thibeau noted three different approaches to medication error reporting were referenced in the meeting materials including examples of a mandatory reporting requirement to a state agency, a mandatory reporting requirement to a third party, and a voluntary reporting requirement. Dr. Thibeau advised included in the meeting materials was a framework for a possible statutory proposal to establish a mandatory reporting requirement and recommended reviewing the policy questions noting as drafted, this requirement would be limited to community pharmacies. Dr. Thibeau added the language makes clear that the reports are not discoverable and the report itself would not be the source of investigation by the Board.

Members were provided the opportunity to provide comment to the policy questions.

Policy Question #1

Identification of the appropriate entity to receive reports, perform analysis to assist the Board in policy making and release reports on trends, educational information, etc.

Chairperson Thibeau noted staff indicated that the model used in Canada was most like the stated goals of the Committee. Dr. Thibeau agreed and believed a third party should receive the reports. Dr. Thibeau believed ISMP had a strong history of performing medication error related evaluations and providing education on the issue. Members were comfortable with ISMP as a single location. A comment was made suggesting the possible use of a PSO.

Policy Question #2

As drafted, the mandatory reporting would begin with community pharmacy. Does the Committee believe this is appropriate?

Members agreed it was a good place to start.

Policy Question #3

As drafted, the reporting timeframe established is seven days. Does the Committee believe this is an appropriate timeframe?

Members discussed having seven- and 14-day timeframes. Members agreed a reporting timeframe of 14 days was appropriate.

Members discussed the possibility of using a PSO but had concerns if the PSO was owned by a chain pharmacy. Members agreed a centralized single entity to aggregate the information was appropriate and agreed upon ISMP.

Motion: Recommend to the Board pursuit of a statutory proposal to establish a mandatory medication error reporting requirement consistent with the language presented and amended by the Committee consistent with its policy discussion.

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 (ISMP). 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.

M/S: Oh/Crowley

Members of the public were provided the opportunity to comment.

A representative of CRA/NACDS commented in favor of using a third-party and would like to have a PSO present to the Committee.

A pharmacist commented ISMP gave up PSO status in 2020. The pharmacist agreed with the proposed statute and thought it was important to collect information within an organization.

A pharmacist representative from Kaiser commented in support of having errors reported to PSO and not the Board of Pharmacy. The pharmacist spoke in support of partnering with a PSO and agreed with the increase to 14 days.

A pharmacist requested clarification about near misses being clarified as a medication error. The pharmacist agreed with reporting to a PSO, not Board, and de-identification of information. The pharmacist recommended a carve-out for those pharmacies under an acute care license.

A member of the public requested clarification if this requirement would exclude hospital outpatient pharmacy associated with a hospital.

A representative from UFCW Western States Council spoke in support of increasing record retention from one to three years noting it was important that data was regularly shared with the Board and reported quarterly in aggregate form. The representative believed there was a drafting error in the proposal as the statute referenced the PRA process but noted documents are not *disclosed* to discovery or subpoena under the PRA process as the documents are *requested* under the PRA process. The representative added by submitting discovery and subpoena in the statute, it may preclude the Board from obtaining the documents for a disciplinary case through discovery or subpoena.

Matthew Grissinger of ISMP clarified ISMP merged with ECRI and ISMP is now part of ECRI.

A representative from Albertsons clarified there are some PSOs that are components of large organizations as well as third-party PSOs that can aggregate data from multiple entities. The representative encouraged hearing from a PSO so that the PSO can clarify where legal interplays occur between what is considered discoverable and what is considered privileged and confidential information which includes the work product of the PSO (e.g., analysis, trends, recommendations for change, etc.). Albertsons has contracted with a PSO and working on implementing the expensive and time-consuming process. The representative noted a fiscal impact and could possibly be a cost prohibited impact for the requirement. The representative urged the Committee to hear from a PSO and suggested checking with New Hampshire requirement that allows for reporting to PSO.

Members were provided an opportunity to comment after the public comment.

Member Patel inquired if a PSO should present about the process. Member Crowley inquired if the pharmacy in Nova Scotia was required to pay the annual \$70 fee to ISMP. Chairperson Thibeau and Ms. Sodergren clarified the pharmacy was required to pay the fee. Dr. Thibeau suggested starting the process while collecting additional information and have a PSO present later. The Committee agreed.

Support: 4 Opposed: 0 Abstain: 0 Not Present: 1

Member	Vote
Crowley	Support
Koenig	Not Present
Oh	Support
Patel	Support
Thibeau	Support

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

Chairperson Thibeau advised the Committee previously discussed the legal provisions of other jurisdictions within Canada and the US including requirements to report unsafe working conditions. Dr. Thibeau noted some have provisions seek to ensure sufficient personnel are scheduled to work, others have notification requirements requiring a pharmacy to notify patients if the pharmacy is experiencing significant delays or cannot dispense prescriptions in a timely manner.

Chairperson Thibeau provided in California, there were provisions establishing provisions for 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 specific legal requirements for some other states previously considered by the Committee in the meeting materials. Dr. Thibeau noted during the September 2022 meeting, the Committee reviewed several of these provisions and requested that staff develop a statutory proposal for consideration. Dr. Thibeau noted the meeting materials highlighted the various types of changes that are being offered for the Committee's consideration.

Chairperson Thibeau reviewed the language proposed and believed the proposed changes were appropriate. Dr. Thibeau highlighted BPC 4113.5 which seeks to establish a minimum staffing floor. Dr. Thibeau stated if the Committee believed establishing a staffing floor was appropriate, it appeared appropriate to also amend out the provisions related to no pharmacist left behind as it would no longer be relevant.

Members were provided the opportunity to provide comment.

Member Oh applauded working with staff on drafting the text and agreed the draft hits the mark. Dr. Oh stated it balanced current law and the landscape of pharmacy to address concerns raised. Dr. Oh stated it was a compromised approach to step farther to address patients are taken care of and public receive safe pharmacists' services.

Member Crowley supported the staffing floor. Dr. Crowley stated clarification was needed to possibly delete prior language to clarify a pharmacist must be staffed with a pharmacy technician or clerk at all times. Dr. Crowley appreciated the retaliation language and would be open to adding a penalty provision. Dr. Crowley noted often a pharmacy can't meet staffing requirement or require approval from non-pharmacy staff. Dr. Crowley inquired if a non-licensed individual would be held accountable through the pharmacy license. Dr. Crowley noted subsection (y) may be redundant.

Member Patel noted it was a good step in the right direction. Mr. Patel expressed concern about the pharmacist having the ability to close the pharmacy noting patient access was important and closing a pharmacy seemed extreme. Mr. Patel spoke in support of breaks and lunches being taken.

Chairperson Thibeau clarified the language doesn't require a pharmacist to close a pharmacy but allows the pharmacist the ability to do so if needed.

Member Oh stated he didn't believe pharmacists would abuse the new authority based on his experience.

Member Crowley expressed the concerns of Member Patel and was concerned where patients can't get medications. Dr. Crowley supported the PIC having autonomy for staffing where staffing often requires pharmacy district leader approval. Dr. Crowley noted bonuses are often determined by staying underbudget and there were financial incentives to be understaffed. Dr. Crowley supported the language overall.

Motion: Recommend to the Board pursuit of a statutory proposal to add and amend Business and Professions Code sections BPC 4113.5, 4113, and 4301 consistent with the committee's discussion of the language as presented.

Proposed Amendment to BPC 4113.5.

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) The pharmacist on duty may close a pharmacy if, in their opinion, the staffing at the pharmacy is inadequate to safely fill or dispense prescriptions or provide other patient care services in a safe manner without fear of retaliation.

(f) A pharmacy is always staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services. Where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing phone message.

(g) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Proposal to Amend BPC 4113.

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge shall have autonomy to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction or other conditions that may interfere with a pharmacist's ability to practice competently and safely.

(d) The pharmacist-in-charge shall have the authority to close a pharmacy if workplace hazards, such as unsanitary conditions, temperatures deviate from appropriate drug storage conditions, or other conditions based on their professional judgement may create an unsafe environment for personnel or pharmacy staff. In the event the pharmacist-in-charge is not available, the pharmacist on duty, after a reasonable attempt to reach the pharmacist-in-charge, may close the pharmacy to the reasons previously cited.

(e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the

pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

Proposal to Amend BPC 4301.

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

- (a) Procurement of a license by fraud or misrepresentation.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
- (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the

course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending

the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily

or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" has the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributor as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

(v) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgement, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.

(w) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgement, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner.

(x) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist intern or and pharmacy technician to comply with laws or regulations.

(y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless such guarantees are required by law or to meet contractual requirements.

M/S: Oh/Crowley

Members of the public were provided the opportunity to comment.

A representative of UFCW Western States Council spoke in support of the proposal as it addressed many issues from the Board's pharmacist survey. The representative made comments on multiple provisions: (f) to ensure pharmacists are not working alone and ensuring pharmacists are able to take breaks and urged the Board to ensure pharmacy staff are taking their legally required 15-minute breaks; (c) to give PICs the authority to make staffing decision and urged clarification on the autonomy the PIC is given; (v), (w), (x) and (y) to ensure the Board will be able to enforce against chain pharmacies who are purposefully interfering and prohibiting implementation of patient safety measures and urged the Board to add a requirement to have pharmacies share with pharmacists and pharmacy technicians when policies and procedures are developed to implement laws and then train staff on the policies and procedures; and recommended consolidating all pharmacists and patient safety concerns in all legislative proposals.

A retail pharmacist agreed with Dr. Oh that a pharmacist will not likely close a pharmacy unless needed. The pharmacist noted in his experience he was told to stay in a pharmacy during a medical emergency when he probably should have closed the pharmacy as he was having an asthma attack. The pharmacist requested clarification on BPC 4113 (d) on why the PIC needs to be contacted.

A pharmacist commented in support of the statutory proposal but stated the language must be clear and noted there is already a statute that makes it a crime for an owner to thwart a PIC from running the pharmacy appropriately.

Members were provided with an opportunity to comment.

Member Crowley agreed the pharmacist on duty should have the authority to close the pharmacy.

Member Oh believed the language allows for the pharmacist on duty to make the decision to close and as written the pharmacist on duty should attempt to contact the PIC. Dr. Oh was open to amending the motion.

Members Crowley and Oh amended their motion to strike out, "after a reasonable attempt to reach the pharmacist-in-charge," in proposed BPC 4113 (d).

**Amended
Motion:**

Recommend to the Board pursuit of a statutory proposal to add and amend Business and Professions Code sections BPC 4113.5, 4113, and 4301 consistent with the committee's discussion of the language as presented.

Proposed Amendment to BPC 4113.5.

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) The pharmacist on duty may close a pharmacy if, in their opinion, the staffing at the pharmacy is inadequate to safely fill or dispense prescriptions or provide other patient care services in a safe manner without fear of retaliation.

(f) A pharmacy is always staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services. Where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing phone message.

(g) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Proposal to Amend BPC 4113.

(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

(b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. The pharmacist-in-charge shall have autonomy to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction or other conditions that may interfere with a pharmacist's ability to practice competently and safely.

(d) The pharmacist-in-charge shall have the authority to close a pharmacy if workplace hazards, such as unsanitary conditions, temperatures deviate from appropriate drug storage conditions, or other conditions based on their professional judgement may create an unsafe environment for personnel or pharmacy staff. In the event the pharmacist-in-charge is not available, the pharmacist on duty may close the pharmacy to the reasons previously cited.

(e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the

pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

Proposal to Amend BPC 4301.

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

- (a) Procurement of a license by fraud or misrepresentation.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
- (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a

person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with

Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical

information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" has the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized distributor as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

(v) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgement, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care.

(w) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgement, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner.

(x) Actions or conduct that would subvert or tend to subvert the efforts of a pharmacist intern or and pharmacy technician to comply with laws or regulations.

(y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless such guarantees are required by law or to meet contractual requirements.

M/S: Oh/Crowley

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

A pharmacist supported the language recommended removing “, after a reasonable attempt to reach the pharmacist-in-charge,” from BPC section 4113 (d).

A representative of CRA commented in understanding the challenges that face the healthcare workforce. The representative stated the language was subjective and provided the example the pharmacist may close a pharmacy if the pharmacist feels staffing is insufficient and will have an enormous impact on patient safety. Requiring having a pharmacy technician or clerk on staff at all times would present logistical challenges. The representative appreciated the intent but had concern about unintended consequences that could limit access.

Support: 4 Opposed: 0 Abstain: 0 Not Present: 1

Member	Vote
Crowley	Support
Koenig	Not Present
Oh	Support
Patel	Support
Thibeau	Support

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

Chairperson Thibeau advised included in the meeting materials was a copy of the most recent state report noting 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 added the meeting materials also included information released by the National Academy of Medicine related to the National Plan of Health Workforce Well-being. Dr. Thibeau noted some of the actions being considered by the Committee as well as work under development by the Communication and Public Education Committee appear to align with some of these areas.

Members were provided the opportunity to comment; however, no comments were made.

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

Chairperson Thibeau reported the Committee will continue to monitor the Well-being reports and reminded 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 February 1, 2023.

X. Adjournment

The meeting adjourned at 12:02 p.m.

Attachment 2



Well-being Index For Pharmacy Personnel

State Report
For
NABP District Eight States

February 2023

For Every Pharmacist. For All of Pharmacy.

pharmacist.com

Assessments and Reassessments

July 19, 2019 through February 6, 2023



WELL-BEING
index

<https://app.mywellbeingindex.org/signup>

Invitation Code: APhA

WBI Assessments and Reassessments

Why is a state's Distress Percent different this month over last month even though the number of assessors has not changed?

It's due to those who are reassessing!

As of February 6, 2023:

- ❖ **The percentage of first-time assessments and reassessments is equal.**
- ❖ **There are 2812 unique assessors who have completed the 9567 reassessments. Some assessors have reassessed more than one time.**
- ❖ **The Distress Percent for all assessors is 31.45% (1st time and reassessments combined)**
- ❖ **The Distress Percent for first-time assessors only is 36.29%. The Distress Percent for first time assessors has been higher than when combined with reassessments. Likely indicating that those that reassess are taking some measures to address their well-being and distress.**

Assessment and Reassessments in District Eight

As of February 6, 2023

	First Time Assessment	Reassessments	Unique Number of Reassessment Assessors	Total Assessments
Arizona	194	185	47	379
California	799	713	318	1512
Colorado	227	245	67	472
Hawaii	29	68	11	97
Nevada	34	47	7	81
New Mexico	52	22	9	74
Utah	74	66	23	140

DISTRESS PERCENT CHANGES

National and District

January 2023 versus February 2023

Changes in Distress Levels

As of February 2023

State	Change in Distress % January 2023 vs February 2023	State Rank for Distress Percent February 2023	Distress Percent February 2023
Largest Increase in Distress Percent			
North Dakota	2.67%	17	36.00%
New Hampshire	0.70%	2	47.37%
Louisiana	0.47%	3	47.32%
Massachusetts	0.40%	9	41.80%
Oregon	0.32%	19	34.62%
Smallest Increase in Distress Percent			
Florida	-0.55%	23	33.77%
Mississippi	-0.53%	30	32.80%
Wisconsin	-0.44%	47	24.84%
Idaho	-0.44%	11	40.22%
New Mexico	-0.39%	44	28.38%
NATIONAL	-0.13%	31.45%	----



Changes in Distress Levels – District Eight

As of February 2023

	Change in Distress % Jan 2023 vs Feb 2023	Distress % Feb 2023	Distress % State Rank Feb 2023	Change in Distress % Dec 2022 vs Jan 2023	Distress % State Rank Jan 2023	Distress % State Rank Dec 2022	Distress % State Rank Nov 2022	Distress % State Rank Oct 2022	Distress % State Rank Sep 2022	Distress % State Rank Jul 2022	Distress % State Rank Apr 2022	Distress % State Rank Dec 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Arizona	No Change	39.84%	12	No Change	12	12	12	12	12	12	13	14	13	16	17
California	-0.11%	29.50%	40	-0.12%	40	40	40	43	44	45	44	40	38	35	35
Colorado	-0.12%	31.78%	33	-0.62%	33	33	34	34	34	34	28	25	23	14	19
Hawaii	-0.39%	37.11%	15	-0.39%	14	14	15	15	14	13	10	7	6	2	2
Nevada	No Change	60.49%	1	No Change	1	1	1	1	1	1	1	1	1	18	11
New Mexico	-0.39%	28.38%	44	No Change	43	44	45	44	43	43	3	42	44	39	39
Utah	-0.21%	28.57%	42	-0.42%	42	41	41	40	39	42	39	37	32	27	31

T=Tied in rank with another state.

Note: Some historic data from 2020/2021/2022 has been removed to allow space for current month. Refer to previous months' reports or contact ashaughnessy@aphanet.org for data.

DISTRESS PERCENT MONTHLY REPORTS

State-Specific

January 2023 versus February 2023

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2023

As of February 6, 2023, the Arizona distress percent was 39.84% (ranked 12/52) with 197 assessors.

JANUARY 2023

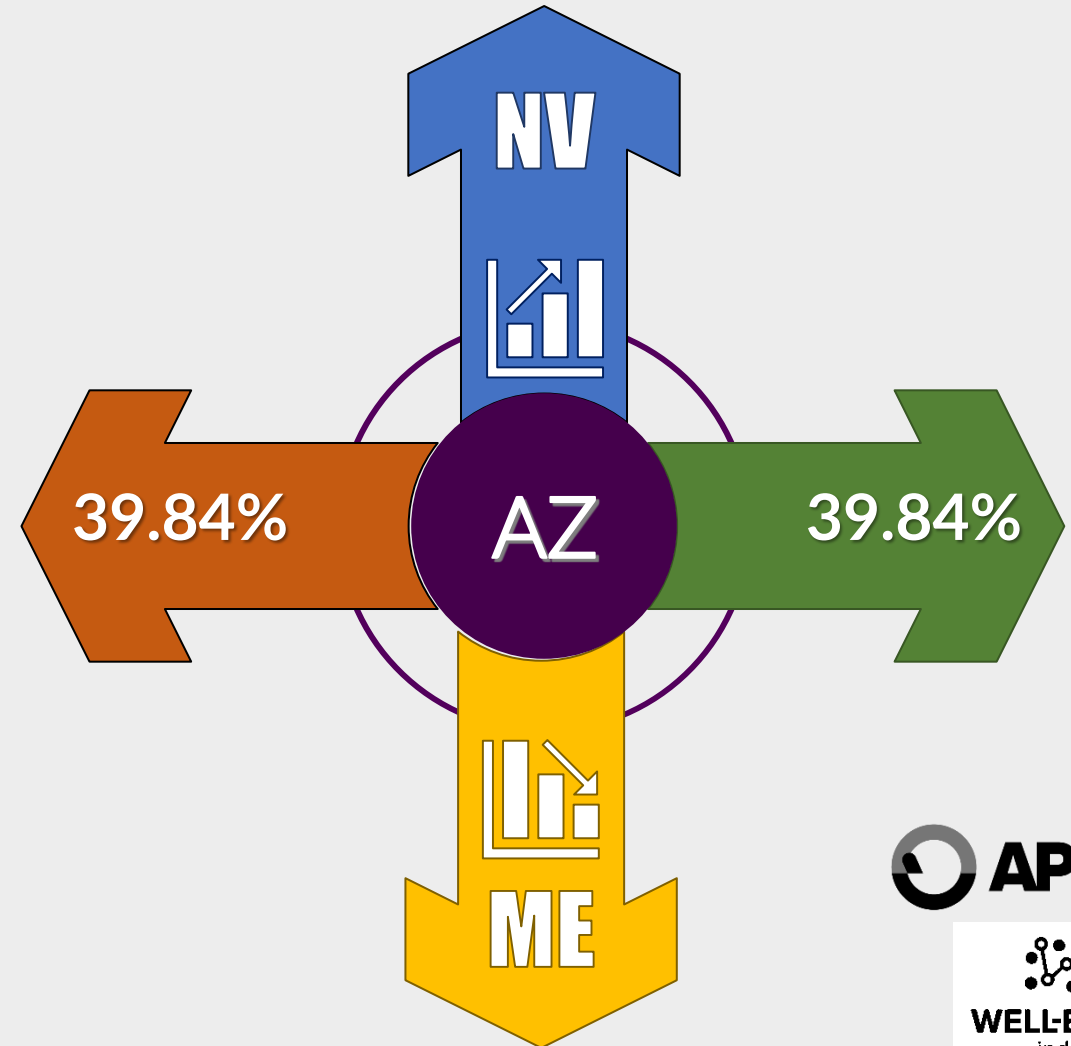
As of January 6, 2023, the Arizona distress percent was 39.84% (ranked 12/52) with 195 assessors.

STATE COMPARISON

As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2023

As of February 6, 2023, the California distress percent was 29.50% (ranked 40/52) with 803 assessors.

JANUARY 2023

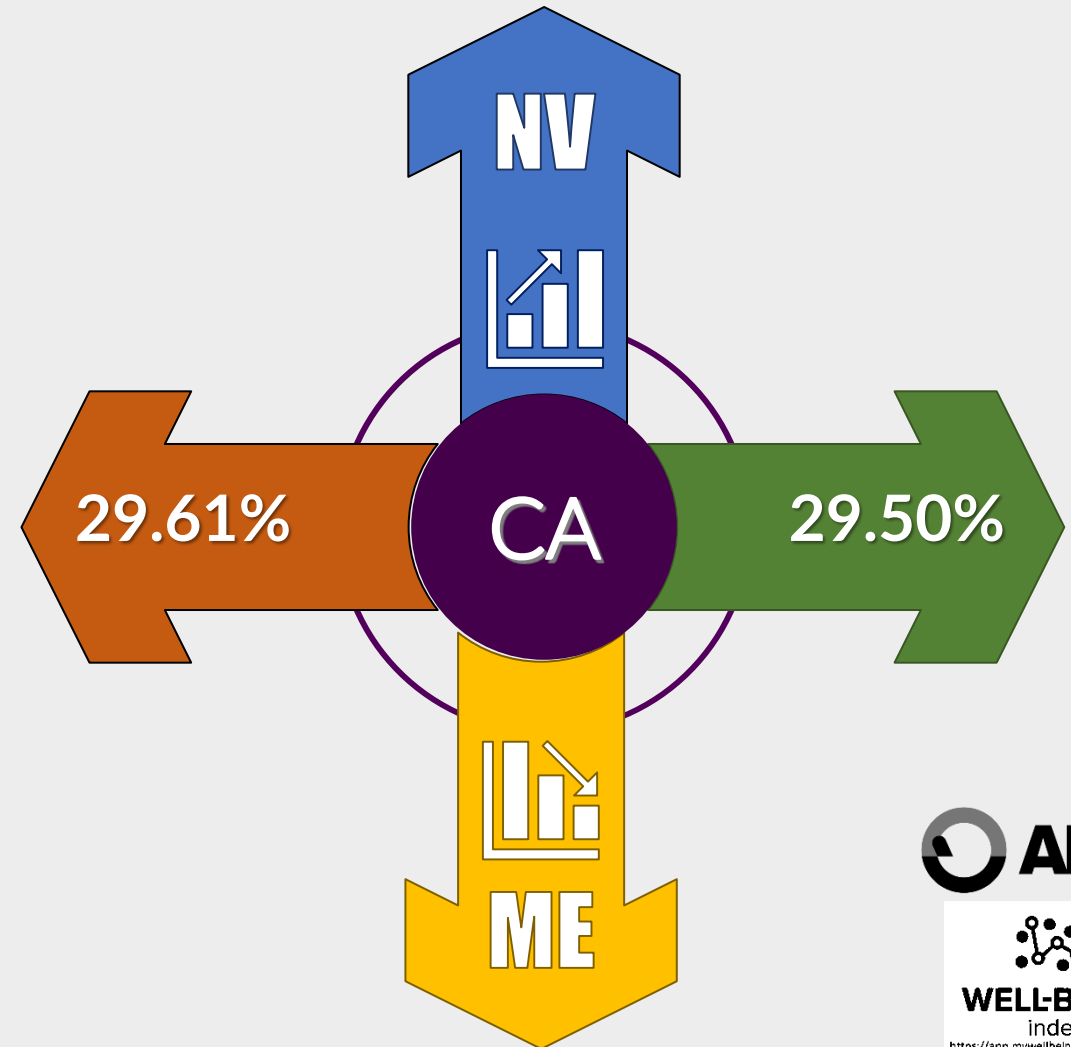
As of January 6, 2023, the California distress percent was 29.61% (ranked 40/52) with 798 assessors.

STATE COMPARISON

As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2023

As of February 6, 2023, the Colorado distress percent was 31.78% (ranked 33/52) with 230 assessors.

JANUARY 2023

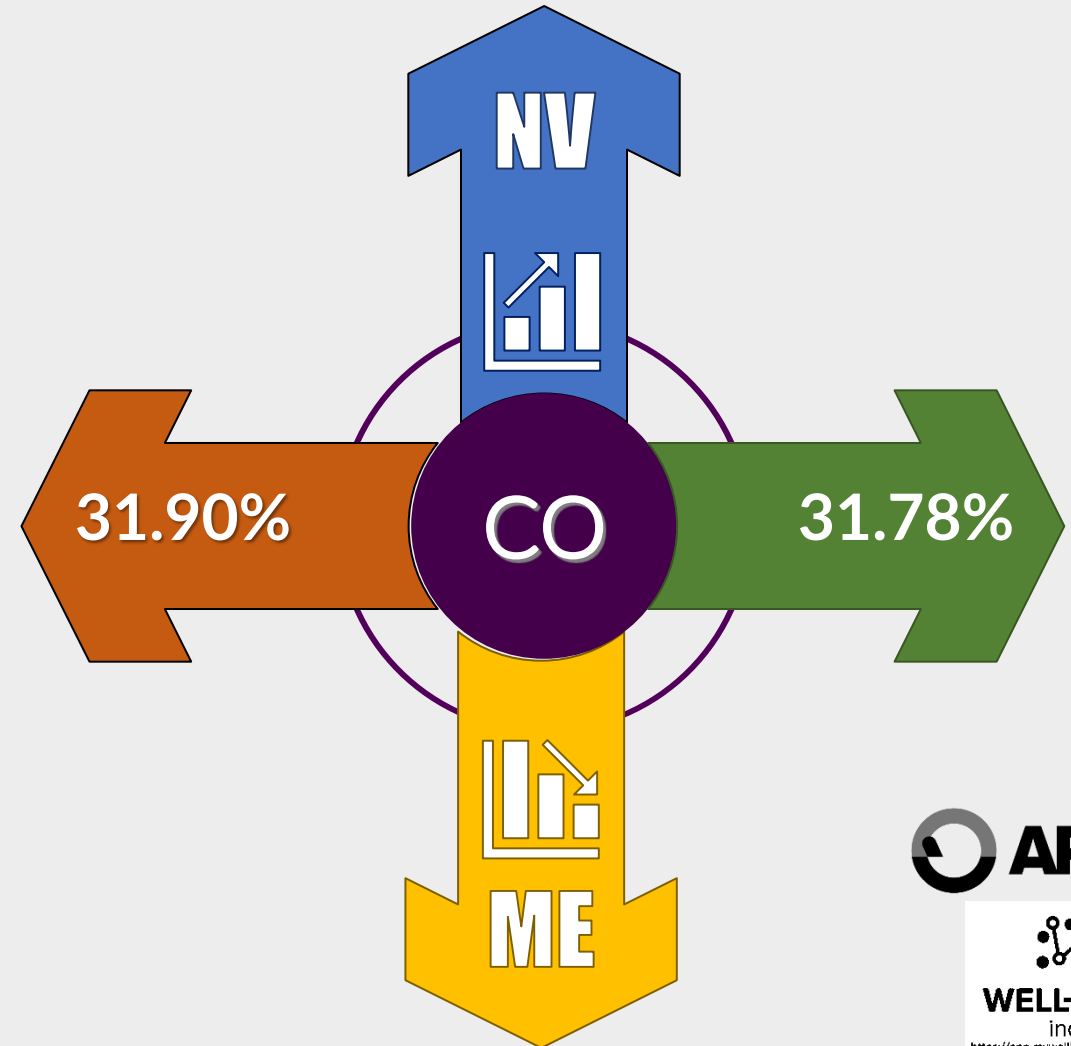
As of January 6, 2023, the Colorado distress percent was 31.90% (ranked 33/52) with 229 assessors.

STATE COMPARISON

As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

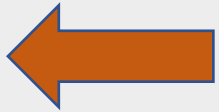
WELL-BEING INDEX FOR PHARMACY PERSONNEL STATE DISTRESS PERCENT*

FEBRUARY 2023



As of February 6, 2023, the Hawaii distress percent was 37.11% (ranked 15/52) with 30 assessors.

JANUARY 2023



As of January 6, 2023, the Hawaii distress percent was 37.50% (ranked 14/52) with 30 assessors.

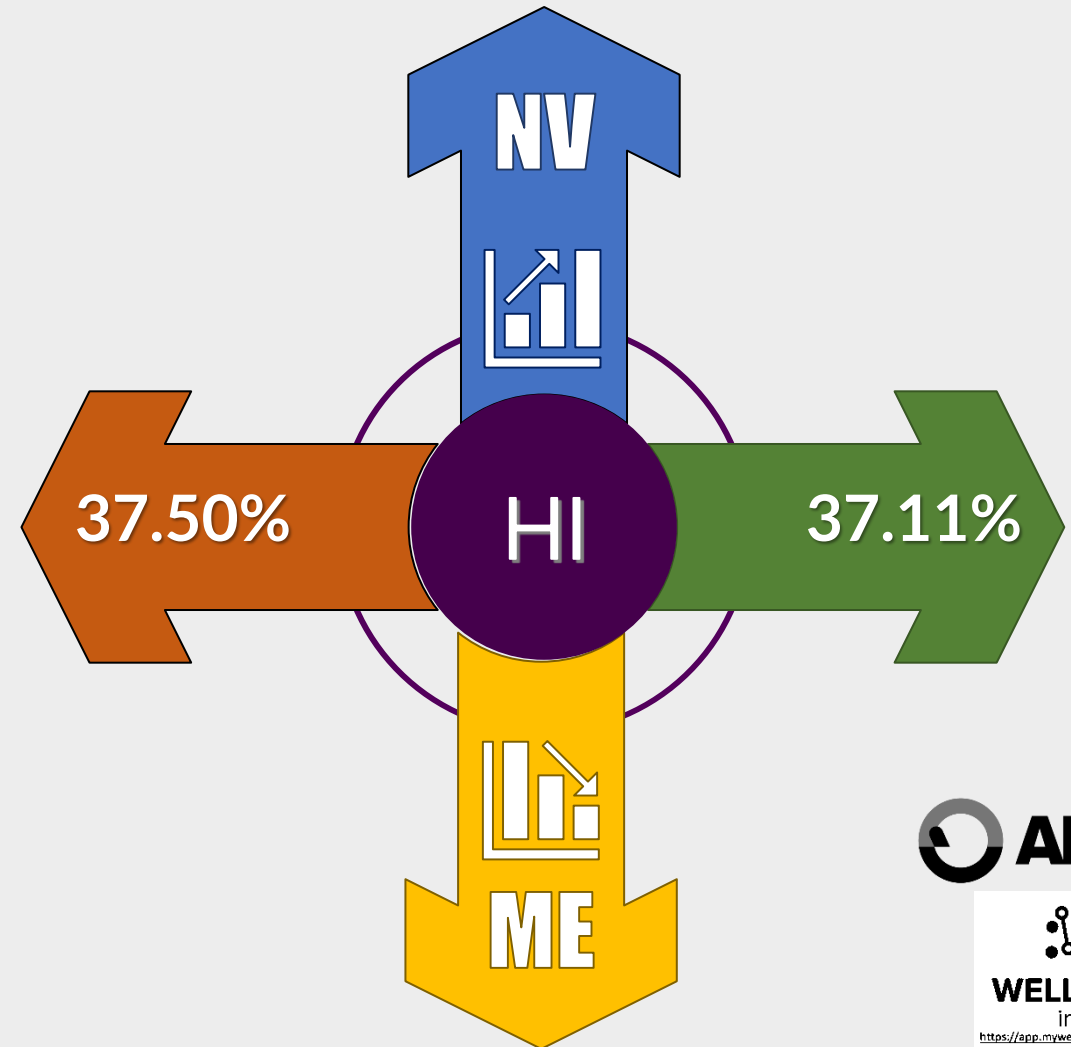
STATE COMPARISON



As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL STATE DISTRESS PERCENT*

FEBRUARY 2023

As of February 6, 2023, the Nevada distress percent was 60.49% (ranked the highest at 1/52) with 34 assessors.

JANUARY 2023

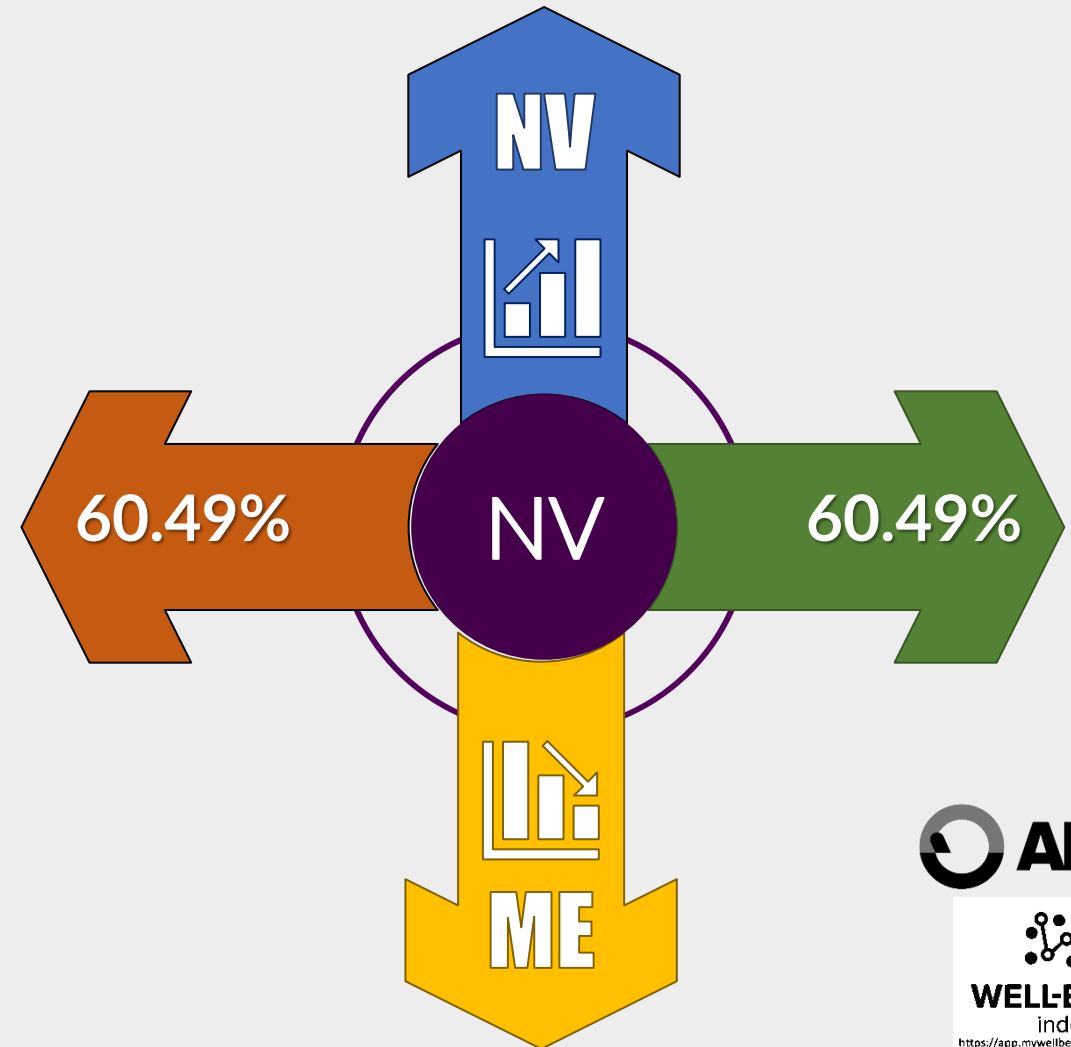
As of January 6, 2023, the Nevada distress percent was 60.49% (ranked the highest at 1/52) with 34 assessors.

STATE COMPARISON

As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2023

As of February 6, 2023, the New Mexico distress percent was 28.38% (ranked 44/52) with 52 assessors.

JANUARY 2023

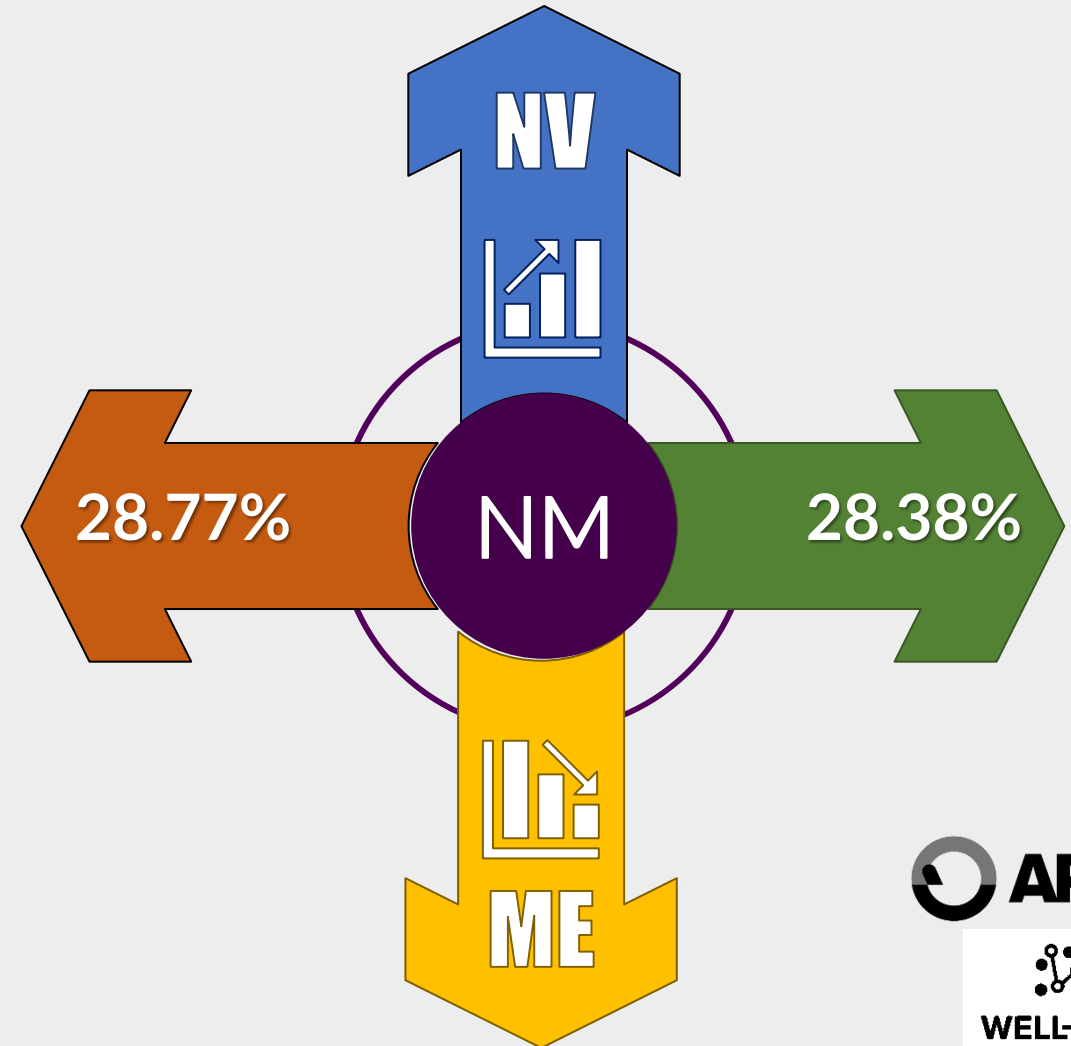
As of January 6, 2023, the New Mexico distress percent was 28.77% (ranked 43/52) with 52 assessors.

STATE COMPARISON

As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

FEBRUARY 2023

As of February 6, 2023, the Utah distress percent was 28.57% (ranked at 42/52) with 74 assessors.

JANUARY 2023

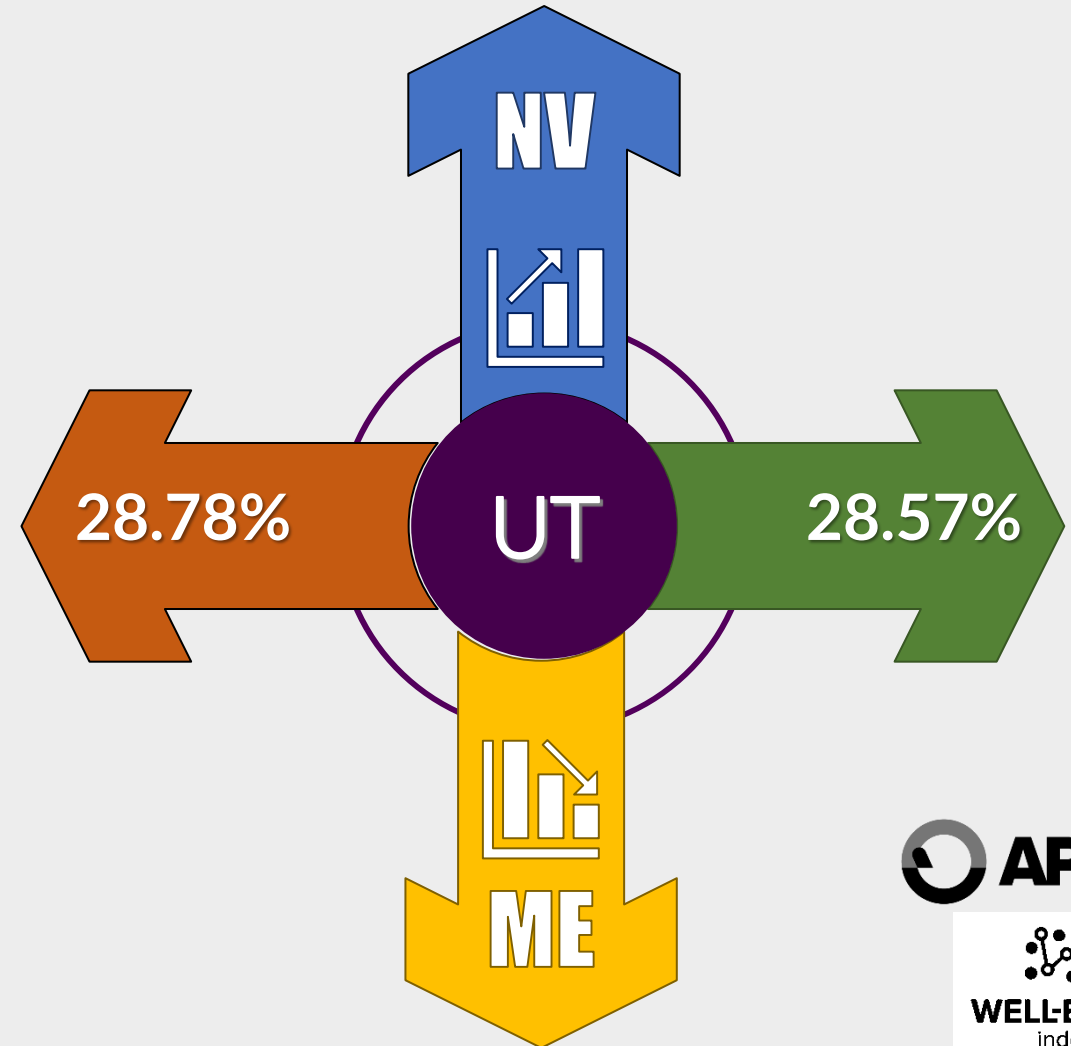
As of January 6, 2023, the Utah distress percent was 28.78% (ranked at 42/52) with 74 assessors.

STATE COMPARISON

As of February 6, 2023

Nevada is the highest at 60.49% (n=34)

Maine has the lowest 18.18% (n=27)



*Distress Percent is the percentage of individuals with a Well-Being Index (WBI) score ≥ 5 . It measures the percent of individuals that are at a high level of distress.

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