California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

MEDICATION ERROR REDUCTION AND WORKFORCE CHAIR REPORT

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

During the meeting members will review a summary of the Committee's work at its September 14, 202 meeting, as well as updates for discussion and action as necessary.

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

Relevant Law
California Code of Regulations Section 1711, establishes required for each pharmacy to establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part to improve the quality of pharmacy service and prevent errors.

This section also defines a medication error as any variation from a prescription or drug order not authorized by a prescriber but 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. As required by this section an investigation of each medication error shall commence as soon as reasonable possible, but no later than two business days from the date the medication error is discovered.

Background
Originally effective in January 2002, these provisions have remained largely unchanged, with the exception of changes in 2004 and recent amendments in 2021 as part of the implementation of Automated Drug Delivery Systems (ADDS), including provisions to clarify the quality assurance (QA) program related to the uses of ADDS.

Generally, a QA program is intended to advance error prevention by analyzing individually and collectively, investigative, and other pertinent data to address the cause and contributing factors. Required elements include:

1. Date, location, and participants in the QA review.
2. Pertinent data and other information relating to the medication error reviewed and documentation of any patient contact.
3. Findings and determinations generated by the QA review.
4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

As report in the media, in survey results, and in public comments received, workforce strains are a contributing factor to medication errors; however, the Committee has received public comment that staff are prohibited from including staffing and other workforce issues in QA reporting.

Summary of Committee Discussion and Action

As part of the Committee's evaluation of medication errors and workforce issues, it considered if the Board's current QA program requirements are appropriate or if changes to regulation are necessary to advance error prevention. As part of its discussion, members considered several policy questions. Below is a summary of the questions and comments:

1. Should the date the error occurred be required?
   Members indicated that the date or date range should be included if the information can be identified.

2. Should the staff involved in the error be documented?
   Members determined that staff names should be included if the information is collected for non-punitive purposes noting it may be helpful in performing the root cause analysis and identifying if additional training is necessary. Members noted the importance of taking a just culture approach in collecting this information.

3. Should the type of error be required? (e.g., wrong patient, wrong directions, relevant drug information, etc.)
   Members agreed that it is appropriate to require the type of error is included in the report.

4. Should the volume of workload completed on the date the error occurred be required?
   Members concluded that workload volume is necessary to capture especially for evaluation of errors made in community pharmacies. Members noted that to complete a meaningful review, staffing needs to be considered as part of the review process along with the use of technology. Members also noted that prescriptions filled by a central fill pharmacy should be noted separately.

5. Are there standardized items that should be captured, e.g., prescription volume (new and refill), immunizations provided, MTM, etc.?
   Members concluded that workload volume must be reflected and must also include clinical services.

6. Should the number of staff and classifications on the date of the error be required?
   Members determined that the number of staff and classifications are appropriate for inclusion in the report.

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 it is important to memorialize the actions taken in response to the error to address contributing factors. Members noted that if the same conclusion continues to be documented with the same outcomes while the errors continue to occur, additional action needs to be taken and noted on the QA form.

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 consider this question and suggested it may be appropriate for the Board to develop a possible template that could be used, but that the Board should not require use of a specific form. As part of its discussion members asked how pharmacies identify at-risk behavior and corrective actions taken to address at-risk behavior.

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 this concept but noted possible challenges establishing an appropriate measurement that would be meaningful.

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 determined it is appropriate to extend the records retention for QA reports, suggesting between three to five years as an appropriate retention schedule.

Members also considered the ISMP root cause analysis template.

It is anticipated that members will continue assessment of this issue and consider possible regulation language that could facilitate changes to the QA process.

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

Background

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

This issue of medication errors is not new. A study published in 2003, National Observation Study of Prescription Dispensing Accuracy, concluded that dispensing errors are a problem on a national level with a rate of about 4 errors per day in a pharmacy filling 250 prescriptions daily.

Additionally, between February 1, 2007, to July 31, 2012, medication errors reported to the New Hampshire Board of Pharmacy were reviewed. Results of this study were provided in Evaluation of Medication Errors in Community Pharmacy Settings, published in the Journal of Pharmacy Technology in 2016. Results included:

- 40 percent of errors involved dispensing of incorrect medication
- 31 percent involved incorrect doses
- 12 percent involved incorrect directions
- 78 percent involved new prescriptions
- 51 percent occurred during the pharmacist final check
- 26 percent occurred during the data entry phase of the initial processing
- 68 percent of the errors occurred when only 1 pharmacist was on duty

Conclusions noted that a contributing factor for errors included high prescription volumes and lack of adequate pharmacist coverage. Limitations on the results of the study included that reporting of errors is not mandatory as well as bias related to the duration of time between when the error occurred and the QRER form was completed.

The practice of pharmacy has changed since these publications; however, published information (referencing 2018 data) suggests that about 1.5

percent of all prescriptions in the community setting have a dispensing error. The Board's survey results appear to demonstrate that a correlation between workload and medication errors continues. According to information published by the Kaiser Family Foundation, 333,906,521 retail prescription drugs were filled at pharmacies in California in 2019, which would total over five million dispensing errors in California that year.

Summary of Committee Discussion and Consideration

During the meeting members discussed medication error reporting including policy questions:

1. Should the Board establish a requirement to report medication errors? Some members noted support for such a requirement as it will provide a better understanding of the scope of the issue. Members noted the need for some anonymity if the board pursues a mandatory reporting requirement.

   Public comment indicated that mandatory reporting should include the name of the chain pharmacy. Additional comment agreed that reporting needs to be anonymous.

2. If yes, what would be the appropriate entity to receive such reports? Members also considered who would be the appropriate entity to receive such reports, with some members speaking in favor of the Board while others suggesting a third-party organization. Members noted that if a third party was to be used it would be important to understand what the potential costs would be.

   Public comments varied with some indicating that reports should go to a third party while others indicated the reports should be provided to the Board.

3. If yes, should the requirement be limited in duration for purposes of conducting a study similar to the approach taken in New Hampshire? Member expressed some hesitation about making the requirement limited in duration.

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

Members suggested development of a standardized form that could be used as a guideline specifying the elements for reporting while providing flexibility.

During its next meeting it is anticipated that members will continue its discussion of the issue.

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

California is not the only state evaluating the issue of workplace conditions with jurisdictions taking various approaches to address the challenge. As the Committee learned as part of its last meeting some approaches include potential research in workload engineering, adding provisions for anti-retaliatory (whistleblower) protections, and standardizing the CQI process. Some jurisdictions have reporting requirements for unsafe working conditions, some have provisions to ensure sufficient personnel are scheduled to work at all times, some have notification requirements to patient to advise them that the pharmacy is experiencing significant delays or cannot dispense prescriptions in a timely manner.

Jurisdictions are considering changes to provisions of the law to address workplace conditions. As an example, pending legislation in Kansas would have established a legislative joint committee to study pharmacy workplace conditions and the impact of such conditions on patient safety. The measure appears to have died in committee.

Pending legislation in New York would prohibit publicly traded pharmacies with twenty or more stores from establishing or enforcing quotas for duties performed by pharmacist and pharmacy technicians.

Below are more detailed examples from some state provisions.

<u>Illinois</u>
Under provisions in Illinois, the department may refuse to issue or renew, or may revoke a license, or take other action (including issuing a fine) with regard to any licensee for any one or combination of the following causes:

1. Failing to provide a work environment for all pharmacy personnel that protects the health, safety, and welfare of a patient which includes, but is not limited to, failing to:
    a. Employ sufficient personnel to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with

competency and safety or creates and environment that jeopardizes patient care.
   b. Provide appropriate opportunities for uninterrupted rest periods and meal breaks.
   c. Provide adequate time for a pharmacist to complete professional duties and responsibilities, to complete professional duties and responsibilities including, but not limited to:
      i. Drug utilization review
      ii. Immunization
      iii. Counseling
      iv. Verification of the accuracy of a prescription
      v. All other duties and responsibilities of a pharmacist as specified.
2. Introducing or enforcing external factors, such as productivity or production quotas or other programs against pharmacists, student pharmacists or pharmacy technicians, to the extent that they interfere with the ability of those individuals to provide appropriate professional services to the public.

Oklahoma

Oklahoma establishes adequate staffing rules for pharmacists and pharmacies. Specifically, the law provides.

1. Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner, each shall take action to correct the problem.
2. In order to ensure adequate staffing levels a staffing form shall be available in each pharmacy. A copy of the form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection. The form shall include at least the following:
   a. Date and time inadequate staffing occurred.
   b. Number of prescriptions filled during the time frame.
   c. Summary of events.
   d. Any comments or suggestions.

   The forms are not sent to the Board.
3. A pharmacist shall complete the staffing report form when:
   a. A pharmacist is concerned about staff due to specified criteria including inadequate number of support person or excessive workload.
4. If the pharmacy manager feels that the situation warrants earlier Board review, the pharmacy manager shall inform the Board.

5. Each pharmacy shall review staffing reports and address any issues listed as well as document any corrective action taken or justification for inaction to assure continual self-improvement.
6. Each pharmacy shall retain completed staffing reports until reviewed and released by the Board. Such reports requiring further review may be held by the Board and may become part of an investigation file.
7. A registrant, including a pharmacy, a pharmacy manager, or a pharmacist, shall not be subject to discipline by the employing pharmacy for completing a staffing report in could faith.

Source: *Okla. Admin. Code § 535:15-3-16*

Oklahoma established an inadequate staffing report that can be submitted to the Board by pharmacy personnel.

In July 2020, Oklahoma fined CVS Health $75,000 and placed a CVS pharmacy on probation for two years. As part of the order terms required a memorandum to all Oklahoma CVS pharmacies describing their rights and responsibilities, including the circumstances in which a pharmacist is required by the Board rule to document the existence of conditions that could cause prescriptions to be filled in an unsafe manner due to inadequate staffing. Further the memo was to make clear that no pharmacist will ever be retaliated against for compliance with the rule. CVS was also required to conduct an internal quality assurance analysis as specified in the order.

Vermont

Under provisions of law in Vermont, the Board may impose disciplinary sanctions against drug outlets in a retail chain; unprofessional conduct has occurred at one or more drug outlet's unprofessional conduct is attributable to corporate policies, practices, systems, or procedures, and sanctions are appropriate to protect the public. Vermont recently filed action against Walgreens alleging several violations include including:

- Violation One: 26 V.S.A. § 2053(a)(1) Introducing or enforcing policies and procedures related to the provision of pharmacy services in a manner that results in deviation from safe practice.
- Violation Two: 26 V.S.A. § 2053(a)(2) Unreasonably preventing or restricting a patient's timely access to patient records or essential pharmacy services.
- Violation Three: 26 V.S.A. § 2053(a)(3) Failing to identify and resolve conditions that interfere with a pharmacist's ability to practice with competency and safety or create an environment that jeopardizes patient care, including by failing to provide mandated rest periods.
- Violation Four: 26 V.S.A. § 2053(a)(4) Repeatedly, habitually, or knowingly failing to provide resources appropriate for a pharmacist of

reasonable diligence to safely complete professional duties and responsibilities, including: (A) drug utilization review; (B) immunization; (C) counseling; (D) Verification of the accuracy of a prescription; (E) all other duties and responsibilities of a pharmacist under State and federal laws and regulations.

- Violation Seven: 3 V.S.A. § 129a(b)(1) Failure to practice competently by reason of any cause on a single occasion or on multiple occasions may constitute unprofessional conduct, whether actual injury to a client, patient, or customer has occurred. Failure to practice competently includes: (1) performance of unsafe or unacceptable patient or client care.

Virginia

Virginia Law provides that, except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any workday and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Based on an investigation in Virginia, an order was issued against a single CVS store. In this instance the pharmacy license was reprimanded, a fine of $346,250 was assessed fine for the chain, the pharmacy was placed on an indefinite probation for a period of not less than two years subject to terms and conditions. Under conditions of the order the pharmacy has an appeal right to the order.

Source: 18VAC110-20-110. Pharmacy permits generally.

A copy of the order is provided in **Attachment 1**.

Summary Committee Consideration and Discussion

During the meeting members discussed the authorities established in other jurisdictions. Generally, members spoke in support of authorities noting that the provisions in Oklahoma appeared specifically helpful. Members also spoke in support of provisions that would limit the number of working hours noting that other professions have such requirements; however, noted that practice settings vary which could make such a required difficult across various practice settings. Members discussed the concept of establishing a minimum staffing floor and considered who within a pharmacy should have the authority to determine adequate staffing levels with some members suggesting such determination should reside with the PIC.

Public comment suggested that the Board should specify the number of staff versus delegating authority to a PIC, noting that the PIC may not be positioned to secure additional staffing based on decisions of the district manager for a pharmacy.

Chairperson Thibeau will work with staff to develop a proposal for future consideration.

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

In 2012, ISMP included an article, Just Culture and Its Critical Link to Patient Safety. As part of the article, ISMP noted that "Just Culture" is more than a trendy metaphor for what was previously called a "non-punitive or "blame-free" culture. "It is a robust set of values, beliefs and actions that provide solid guidance on how an organization can best manage safety."

As part of this article, ISMP discussed components associated with values, justice and safety, and reduction of at-risk behaviors.

Organizational Values include:
1. What are the organization's primary and secondary values?
2. Do managers' behaviors demonstrate that safety is a primary (high) value?
3. Is safety a value or a priority?

Justice and Safety
1. How does the organization respond to human error, at-risk behavior, and reckless behavior?
2. Are individual accountabilities documented in job descriptions, performance evaluations, and/or policies, and communicated to staff?
3. Does the potential or actual severity of an outcome play a role in how staff are treated when evaluating risks and errors?

Management of At-Risk Behaviors
1. Is the culture tolerate of at-risk behaviors?
2. Does the organization tend to punish safe behavior and/or reward at-risk behavior?
3. Is there visible evidence of coaching around at-risk behaviors?

ISMP followed with a second article, focusing on components associated with the establishment of an effective safety information system and learning environment.

Safety Information System and Learning
1. Is there an effective patient safety information system that collects and analyses information about hazards, at-risk behaviors, close calls, and errors both within the organization and externally?

2. Are staff committed to safety and willing to report hazards, risks, close calls, and errors, thus arming the organization with an accessible body of safety information?
3. Does the patient safety information system provide staff with knowledge of the current risks, errors, and prevention strategies necessary to improve safety?
4. Does the organization seek long-term system remedies to safety problems?
5. Does the organization possess the willingness and competency to dray responsible conclusions from the organization's safety information system so they can make substantial changes when necessary?

Summary of Committee Consideration and Discussion
During the meeting Chairperson Thibeau discussed her experience with Just Culture and how it is implemented within the organization. Dr. Thibeau noted that such a model, for example, has allowed for identification of system error as the cause of the issue. Dr. Thibeau also noted the importance of shared accountability. Dr. Thibeau discussed that the transition to Just Culture takes time and resources and noted a reduction in medication errors and improved patient outcomes. Other members indicated that their organization does not use a Just Culture model, but noted the benefits of such a model.

Public comment expressed concern with the frequency with which citations are issued for medication errors. It was suggested that the Board reevaluate its citation and fine program.

It is anticipated that the committee will receive a presentation on Just Culture at a future meeting.

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

Background
The Pharmacist Well-being Index is a research-validated online tool invented by Mayo Clinic and is designed for pharmacy personnel to measure dimensions of distress and well-being. Pharmacists at risk of high distress are at a:

- 3-fold higher risk of low quality of life
- 8-fold higher risk of burnout
- 2.5-fold higher risk of high fatigue
- 2.5-fold higher risk of intent to leave their current job
- **2-fold higher risk of medication error**

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.

The Board recently included information on the Index in its newsletter. Staff was recently advised of a significant increase in the number of California licensees using the Index. The most recent report indicates a slight increase in the distress percent for California respondents.

Summary of Committee Discussion and Action
Members discuss the results of the report and requested that the Committee continue to receive updated reports. Members noted that the pandemic has taken a toll on everyone. Members requested that staff send out reminders about the Well-being Index.

Public comments expressed appreciation for the inclusion of this report and requested information about what action the Board intends to take indicating that the issue in retail pharmacies is dire.

Attachment 2 includes a copy of the September 2022 state report. The August 2022 Pharmacy Workplace and Well-being Report is also available.

Attachment 1

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: CVS PHARMACY #8302
Permit Number: 0201-004432
Case Number: 203229

ORDER

JURISDICTION AND PROCEDURAL HISTORY

Pursuant to Virginia Code §§ 2.2-4020, 2.2-4024(F), and 54.1-2400(11), a panel of the Virginia Board of Pharmacy ("Board") held a formal administrative hearing on February 7, 2022, in Henrico County, Virginia, to inquire into evidence that CVS Pharmacy #8302 may have violated certain laws and regulations governing its permit to conduct a pharmacy in the Commonwealth of Virginia.

Olivia Basseri, Pharmacist in Charge, appeared as the representative of CVS Pharmacy #8302 at this proceeding. CVS Pharmacy #8302 was also legally represented by the following attorneys from the Washington, D.C., law firm of Baker & Hostetler, LLP: Elizabeth Scully, Esq., Lee Rosebush, Esq., and Marc Wagner, Esq..

NOTICE

By letter dated November 22, 2021, the Board sent a Notice of a Formal Administrative Hearing ("Notice") to CVS Pharmacy #8302 notifying it that a formal administrative hearing would be held on January 11, 2021. The Notice was sent by certified and first class mail to the legal address of record on file with the Board, and a copy of the Notice was also mailed to George Parsells, III, Esquire, counsel for CVS Pharmacy #8302. By letter dated November 31, 2021, the Board notified CVS Pharmacy #8302 that the formal administrative hearing was continued from January 11, 2022, as requested by CVS Pharmacy #8302 through its counsel, and the Board scheduled the hearing for February 7, 2022. Copies of the letter were also mailed to George Parsells, III, Esquire, counsel for CVS Pharmacy #8302, and Brian Johnson, counsel for CVS Pharmacy #8302.

Upon consideration of the evidence, the Board adopts the following Findings of Fact and Conclusions of Law and issues the Order contained herein.

FINDINGS OF FACT

1. On October 7, 2011, the Board issued Permit Number 0201-004432 to CVS Pharmacy #8302 to conduct a pharmacy in the Commonwealth of Virginia. Said permit is scheduled to expire on April 30, 2022. At all times relevant to the allegations herein, said permit was in full force and effect.

2. Multiple pharmacists and pharmacy technicians reported to an Inspector from the Virginia Department of Health Professions ("DHP Inspector") that Respondent is routinely understaffed compared to the workload, despite multiple requests for additional staff to be scheduled. Moreover, in or about January and February 2020, prescription volume increased; yet despite this knowledge Respondent cut pharmacy technician staffing hours. Due to the lack of adequate staffing, multiple pharmacists reported that the facility would be so busy that pharmacy staff would barely be able to take a bathroom break during a 12-hour shift. Other pharmacy staff also reported getting home from a shift and realizing that due to the inadequate staffing, pharmacy staff never had time to use the bathroom during their entire shift.

3. Multiple pharmacy staff attributed medication dispensing errors to Respondent's facility being understaffed. Specifically:

a. Multiple pharmacy technicians reported about one occasion, where a pharmacist dispensed an extra 100 Percocet (oxycodone, C-II) tablets when filling a prescription.

b. A prescription for atorvastatin, a medication used to regulate cholesterol, was dispensed with incorrect instructions to "insert 1 vaginally."

c. On or about April 2020, a pharmacist dispensed Norco (hydrocodone/acetaminophen, C-II) to a patient instead of Percocet, the medication prescribed to this patient.

d. A pharmacist reported that "staffing levels contributed to errors" and that "she herself made a few errors in quantity given to a patient because the pharmacy was so slammed." She further reported other errors where prescriptions were entered under the incorrect patient name.

e. A DHP Inspector reviewed approximately 100 hardcopy prescriptions for the period of November 25, 2019 through January 4, 2020 and 100 hardcopy prescriptions for the period of February 8, 2020 through March 9, 2020, for a total of approximately 200 prescriptions, and discovered a total of 74 medication dispensing errors, for an error rate of approximately 37%. The error types can be described as follows:

i. The prescriptions with the following numbers had errors, which included prescriptions with the incorrect prescriber location, the wrong prescriber, or incomplete directions: 834925, 834923,834905, 834868, 834856, 834855, 834854, 834830, 834804, 834792, 834791, 834790, 834623, 834616, 834587, 834586, 834585, 834575, 834563, 834486, 834328, 834327, 834316, 834282, 834258, 834019, 818606, 834929, 834927, 807304, 807477, 807753, 808132, 816543, 816557, 816582, 816583, 816619, 816784, 816785, 816786, 816792, 816879, 816908, 816907, 816909, and 816916.

ii. The prescriptions with the following numbers had errors that put the patients at risk for harm, which included incomplete directions, incorrect prescriber location, the incorrect refill, or the wrong quantity: 818922, 834869, 834858, 834857, 818915, 834649, 834621, 834438, 834426, 834367, 834319, 818270, 834928, 807986, and 816528.

f. Multiple pharmacy staff reported that the ten phone lines into the pharmacy were "always ringing off the hook" and one reported that patients have reported not being able to get through to the pharmacy over the phone or long wait times.

g. Multiple pharmacy staff attributed "unsafe" and "stressful" work conditions to the lack of adequate staffing and a corporate focus on numerous burdensome metrics that Respondent expected them to meet, such as prescription turnaround time, quotas for calls to patients asking patients if they want refills, offering to contact doctors to switch to more affordable prescriptions, and promoting various programs at the pharmacy. Multiple pharmacy staff reported that these "metrics affect the ability to dispense prescriptions safely." Multiple pharmacy staff reported feeling stressed or overworked, including one pharmacist who was diagnosed with anxiety and took a medical leave of absence, one pharmacy technician who took a leave of absence because of stress, and another pharmacy technician who was placed on anti-anxiety medication because of the stress of working at Respondent's facility.

4. Multiple pharmacists reported being unable to take a 30-minute break when working longer than six continuous hours on a shift. Pharmacists reported that though they were "allowed" by company policy to take a break, they were unable to leave the prescription department because there was little or no pharmacist overlap scheduled and a pharmacist had to be present in the prescription department to verify prescriptions and counsel patients, as needed. One pharmacist reported routinely eating her lunch behind the safe because the facility was too busy to take a designated lunch break.

5. Multiple pharmacists reported routinely staying late on shifts to keep the prescription queue from getting too far behind, working for as many as one to three additional hours per shift.

6. The pharmacist-in-charge and the pharmacist on duty repeatedly requested additional staffing hours to prevent the pharmacy from falling behind on prescription filling and dispensing and concerns for patient safety; however, the district leader, a pharmacist who does not work at Respondent's

facility, repeatedly denied these requests. If the pharmacy staff scheduled hours beyond what was approved by the district leader, the district leader would contact the pharmacist-in-charge and require her to cut hours to stay within the budgeted staffing hours.

7. Between on or about February 8 and March 10, 2020, the pharmacist-in-charge did appear on occasion but never staffed a complete single shift during the four-week period at the Respondent's facility.

8. On or about September 9, 2020, a DHP Inspector conducted an inspection of Respondent's facility and found the following deficiencies:

a. Following the resignation of the former pharmacist-in-charge on or about February 8, 2020, the Board did not receive an application and the associated fee for the incoming pharmacist-in-charge until on or about February 26, 2020, sixteen days later.

b. The emergency key to the prescription department was kept in a stapled bag in the safe located in the manager's office and was not maintained in an envelope with the pharmacist's signature across the seal.

c. The biennial inventory was taken on time, but Respondent failed to document if the biennial inventory was taken before or after receipt or distribution of drugs in a 24-hour pharmacy.

9. In interviews with the investigator and in testimony, pharmacists and pharmacy technicians testified that pharmacists worked extra hours to keep up with the volume of prescriptions for which they were unpaid.

10. A CVS witness testified that they were instituting a revised lunchbreak policy for its employees in the future.

11. A pharmacy technician testified that two CVS representatives visited her during the investigation of CVS #8302. She testified that the CVS representatives were "putting words in my mouth despite how much I was trying to explain myself."

12. A second pharmacy technician testified that she felt threatened and scared because CVS sent an email stating that employees had to sign the email, which stated the employee was not going to give a statement to the Board of Pharmacy, and the employee was not going to speak to the Board of Pharmacy. At that time, the pharmacy technician had already spoken to the Board of Pharmacy.

13. A former pharmacist-in-charge of CVS #8302 testified that she told the CVS district manager that "someone was going to die with these working conditions."

14. A pharmacist who worked at CVS #8302 testified that "you go so fast, you just get it done and you are going to hurt somebody. It is just a given. And as a pharmacist, that's your worst fear. Corporate will survive if they kill somebody but is a pharmacist going to?"

15. An expert witness for CVS #8302 testified that medication errors are never "okay".

CONCLUSIONS OF LAW

1. Finding of Fact Number 2, 3(a), 3(g) and 3(e)(ii) constitute violations of Virginia Code § 54.1-3316(1) and (13).

2. Finding of Fact Number 3(b), 3(c), 3(d), and 3(e)(i) constitute violations of Virginia Code § 54.1-3316(1).

3. Finding of Fact Number 3(f) constitutes a violation of Virginia Code § 54.1-3316(13).

4. Finding of Fact Number 4 and 5 constitute violations of Virginia Code § 54.1-3316(7) and 18 VAC 110-20-110(B) of the Regulations Governing the Practice of Pharmacy ("Regulations").

5. Finding of Fact Number 6 constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-110(C) of the Regulations.

6. Finding of Fact Number 7 constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-110(G) of the Regulations.

7. Finding of Fact Number 8(a) constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-110(H) of the Regulations.

8. Finding of Fact Number 8(b) constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-190(B)(1) of the Regulations.

9. Finding of Fact Number 8(c) constitutes a violation of Virginia Code § 54.1-3316(2) and 18 VAC 110-20-25(10) and 18 VAC 110-20-240(A)(4) of the Regulations.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. CVS Pharmacy #8302 is REPRIMANDED.

2. CVS Pharmacy #8302 is assessed a MONETARY PENALTY of $346,250.00. This penalty shall be paid to the Board by certified check or money order made payable to the Treasurer of Virginia within 60 days from the date of entry of this Order. Failure to pay the full monetary penalty by the due date may cause the matter to be sent for collection and constitutes grounds for an administrative proceeding and further discipline.

3. CVS Pharmacy #8302 is placed on INDEFINITE PROBATION for a period of not less than two years subject to the following terms and conditions:

a. The period of probation shall begin on the date that this Order is entered and shall remain in effect until the Board has notified CVS Pharmacy #8302 in writing that it is released from probation.

b. CVS Pharmacy #8302 shall be subject to quarterly unannounced inspections by an inspector of the Department of Health Professions. The inspections shall be conducted during normal business hours and shall include a review of prescription records and an audit of pharmacy errors. CVS Pharmacy #8302 shall be responsible for the payment of an inspection fee to be paid to the Board within 30 days of each inspection. Any fee not paid in a timely manner will be sent for collection. In the event that any inspection reveals a possible violation of the laws or regulations pertaining to the practice of pharmacy in Virginia or the Virginia Drug Control Act (Virginia Code §§ 54.1-3400 *et seq.*), the Board may notice CVS Pharmacy #8302 to appear for an administrative proceeding.

c. CVS Pharmacy #8302 shall submit quarterly "Self Reports" which include a reporting of hours worked each week by pharmacists and pharmacy technicians and the number of prescriptions dispensed weekly. Self Reports shall be submitted on a quarterly basis to the Board, with the first report due no later than 60 days from the date of entry of the Order and subsequent reports due the last day of the March, June, September, and December until CVS Pharmacy #8302 is notified, in writing, that the reporting requirement is ended.

4. CVS Pharmacy #8302 shall bear any costs associated with the terms and conditions of this Order.

5. CVS Pharmacy #8302 shall comply with all laws and regulations governing the practice of pharmacy in the Commonwealth of Virginia. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of pharmacy shall constitute grounds for further disciplinary action.

6. This Order shall remain in effect until the Board has notified CVS Pharmacy #8302 in writing that it is released from all terms and conditions.

7. The Executive Director of the Board is authorized to issue a letter acknowledging satisfactory completion of the foregoing conditions or to refer the matter to a Special Conference Committee for review of CVS Pharmacy #8302's compliance with the foregoing conditions.

Pursuant to Virginia Code § 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

ENTERED AND MAILED ON:
3/17/2022

NOTICE OF RIGHT TO APPEAL

As provided by Rule 2A:2 of the Supreme Court of Virginia, CVS Pharmacy #8302 has 30 days from the date it is served with this Order in which to appeal this decision by filing a Notice of Appeal with Caroline Juran, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233. The service date shall be defined as the date CVS Pharmacy #8302 actually received this decision or the date it was mailed to CVS Pharmacy #8302, whichever occurred first. In the event this decision is served upon it by mail, three days are added to that period.

Attachment 2

APhA

WELL-BEING index

Well-being Index For Pharmacy Personnel

State Report For State Boards of Pharmacy

NABP District Eight States

SEPTEMBER 2022

pharmacist.com

For Every Pharmacist. For All of Pharmacy.

DISTRESS PERCENT BY PRACTICE ROLE

All Assessments versus First Time Assessments

January 2020/September 2020/September 2021/September 2022

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

Distress Percent – Overall and By Role

Since inception (July 2019) through month listed

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

	As of January 2020	As of September 2020	As of September 2021	As of September 2022
All Assessors *All Assessments**	35.25% n=5363	33.41% n=6775	32.12% n=7604	32.04% n=9010
All Assessors *1st Time Assessments Only*	37.31%	36.75%	36.09%	36.51%
Pharmacists Only *All Assessments**	36.74% n=4141	34.54% n=5007	33.46% n=5512	33.19% n=6674
Pharmacists Only *1st Time Assessments Only*	38.32%	37.81%	37.41%	37.65%
Student Pharmacists Only *All Assessments**	31.39% n=923	28.48% n=1194	26.35% n=1425	26.36% n=1646
Student Pharmacists Only *1st Time Assessments Only*	35.32%	32.19%	30.67%	30.78%
Pharmacy Technicians Only *All Assessments**	45.59% n=114	46.08% n=366	45.32% n=384	48.12% n=462
Pharmacy Technicians Only *1st Time Assessments Only*	49.12%	48.36%	48.18%	51.95%

** Combination of first-time assessments and reassessments*

DISTRESS PERCENT CHANGES

National and District

August 2022 versus September 2022

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

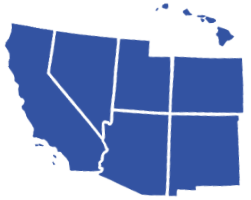
Changes in Distress Levels

As of September 2022

State	Change in Distress % August 2022 vs September 2022	Distress % September2022	State Rank for Distress Percent September2022
Largest Increase in Distress Percent			
North Dakota	+2.96%	34.78%	19
Utah	+0.53%	30.53%	39
Texas	+0.44%	34.38%	22
North Carolina	+0.43%	38.26%	15
California	+0.38%	29.37%	44
Largest Decrease in Distress Percent			
Wyoming	-0.72%	16.67%	52
New Hampshire	-0.66%	47.95%	2
South Dakota	-0.51%	25.00%	48
Virginia	-0.47%	44.72%	6
Pennsylvania	-0.45%	34.12%	23

Changes in Distress Levels – District Eight

As of September 2022



	Change in Distress % Aug2022 vs Sep 2022	Distress % Sep 2022	Distress % State Rank Sep 2022	Change in Distress % Jul 2022 vs Aug 2022	Distress % State Rank Aug 2022	Distress % State Rank Jul 2022	Distress % State Rank Jun 2022	Distress % State Rank May 2022	Distress % State Rank Apr 2022	Distress % State Rank Feb 2022	Distress % State Rank Jan 2022	Distress % State Rank Dec 2021	Distress % State Rank Apr 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Arizona	**0.05%**	**39.44%**	**12**	-0.05%	12	12	13	13	13	13	13	14	13	16	17
California	**0.38%**	**29.37%**	**44**	-0.04%	45	45	45	44	44	43	41	40	38	35	35
Colorado	**-0.22%**	**31.41%**	**34**	0.03%	34	34	35	30	28	27	27(T)	25	23	14	19
Hawaii	**-0.43%**	**38.46%**	**14**	-0.44%	13	13	12	12	10	8	8	7	6	2	2
Nevada	**-0.26%**	**59.74%**	**1**	0.54%	1	1	1	1	1	1	1	1	1	18	11
New Mexico	**No Change**	**29.58%**	**43**	No Change	43	43	43	42	3	33	36	42	44	39	39
Utah	**0.53%**	**30.53%**	**39**	0.31%	40 (T)	42	42	41	39	39	38	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
September 2022 versus August 2022

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

SEPTEMBER 2022

As of September 6, 2022, the Arizona distress percent was 39.44% (ranked 12/52) with 192 assessors.

AUGUST 2022

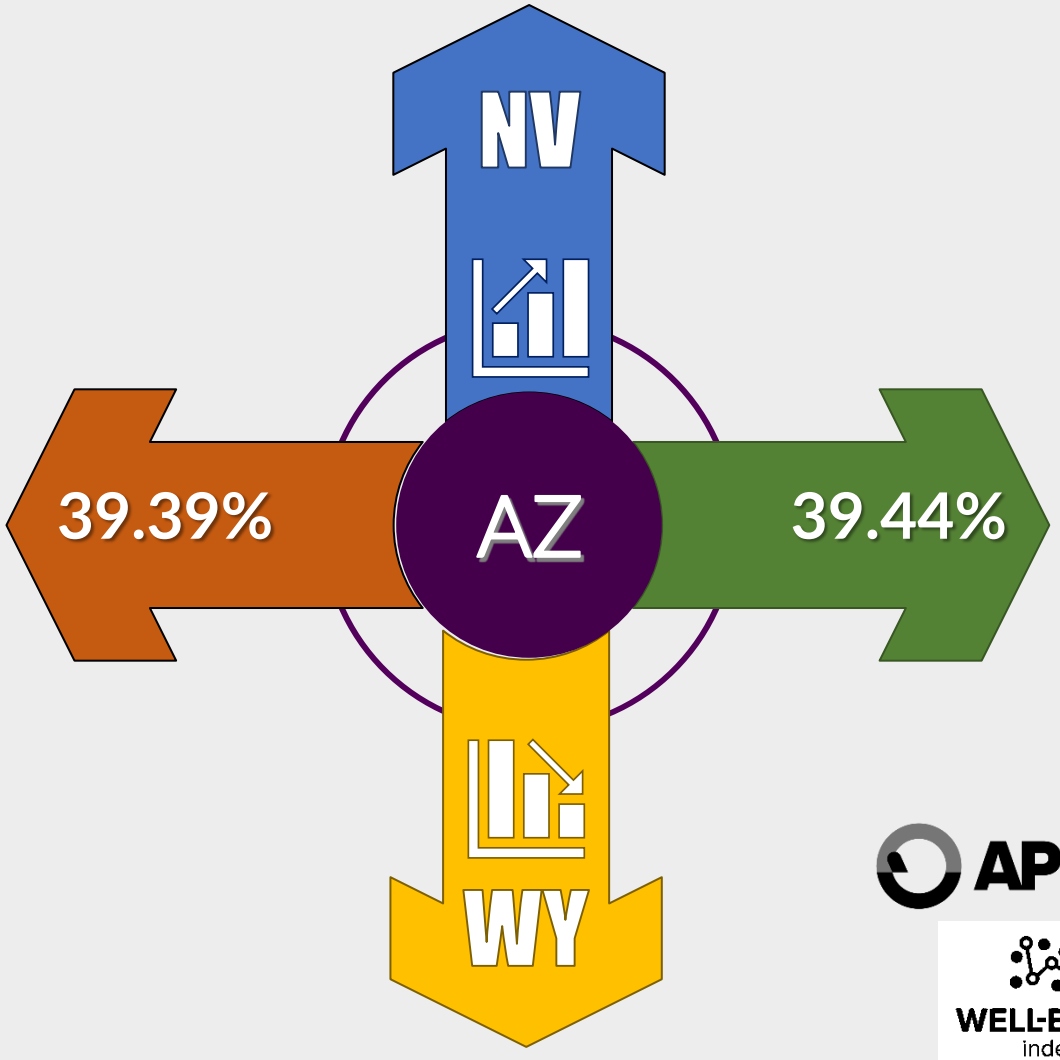
As of August 6, 2022, the Arizona distress percent was 39.39% (ranked 12/52) with 192 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



APhA

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

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*

SEPTEMBER 2022

As of September 6, 2022, the California distress percent was 29.37% (ranked 44/52) with 756 assessors.

AUGUST 2022

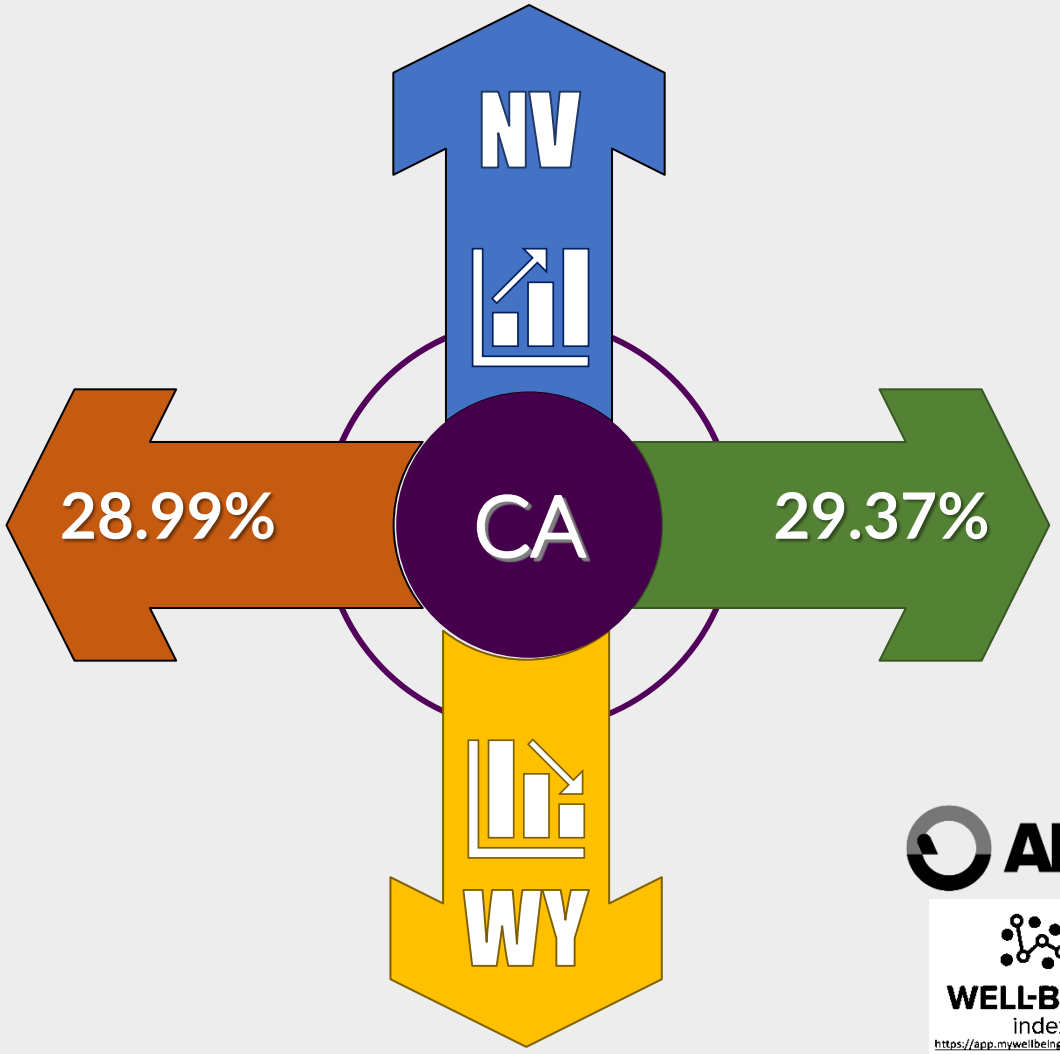
As of August 6, 2022, the California distress percent was 28.99% (ranked 45/52) with 611 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



APhA

WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

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*

SEPTEMBER 2022

As of September 6, 2022, the Colorado distress percent was 31.41% (ranked 34/52) with 205 assessors.

AUGUST 2022

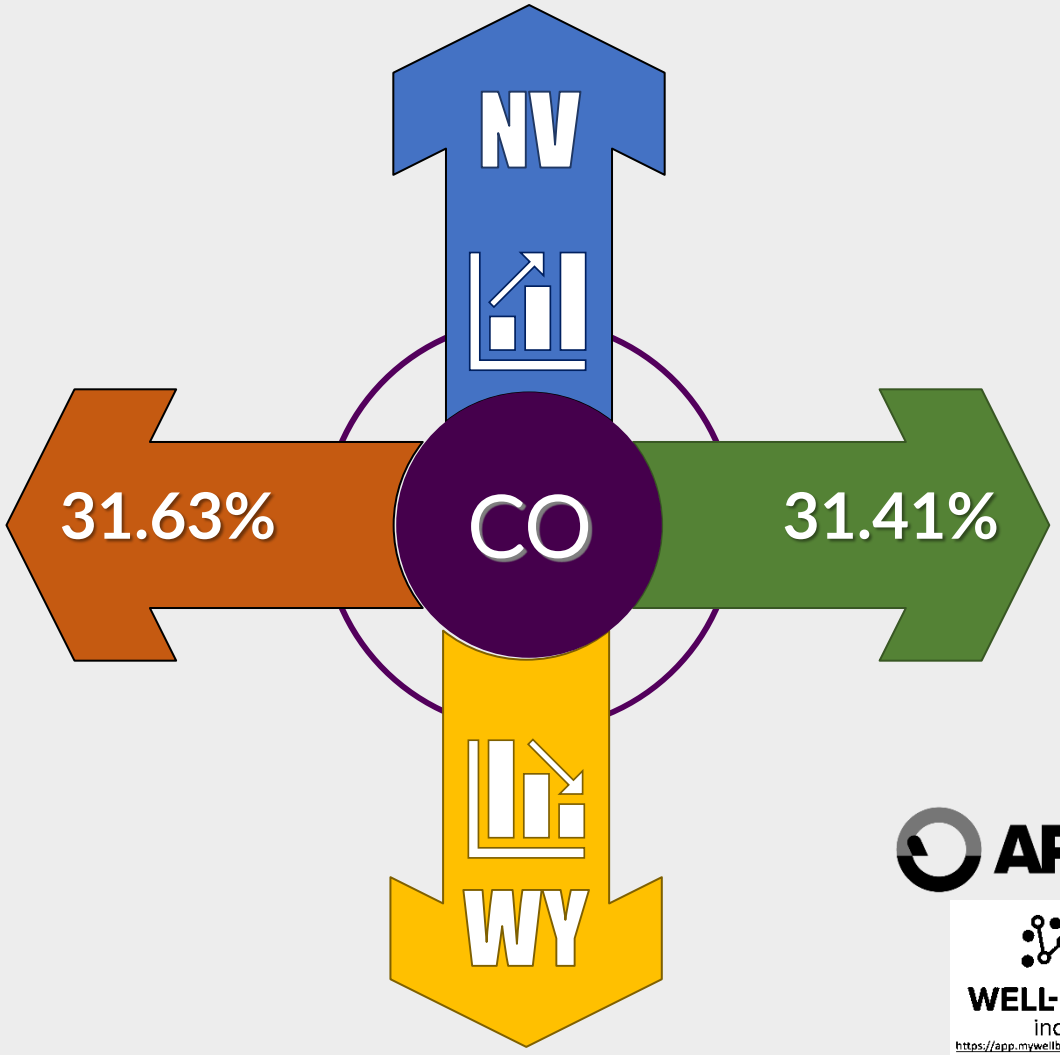
As of August 6, 2022, the Colorado distress percent was 31.63% (ranked 34/52) with 203 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



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WELL-BEING index
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Invitation Code: APhA

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*

SEPTEMBER 2022

As of September 6, 2022, the Hawaii distress percent was 38.46% (ranked 14/52) with 29 assessors.

AUGUST 2022

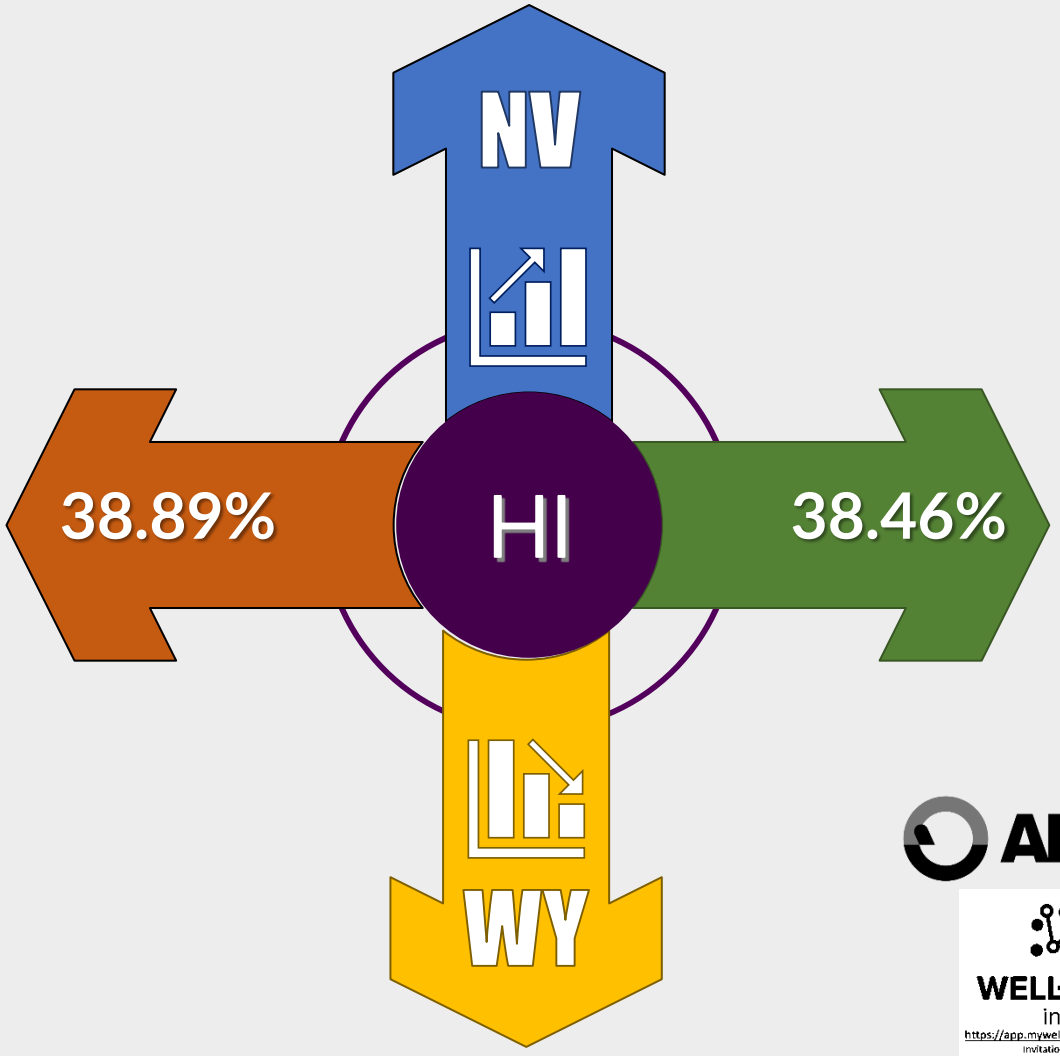
As of August 6, 2022, the Hawaii distress percent was 38.89% (ranked 13/52) with 29 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



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WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

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*

SEPTEMBER 2022

As of September 6, 2022, the Nevada distress percent was 59.74% (ranked the highest at 1/52) with 33 assessors.

AUGUST 2022

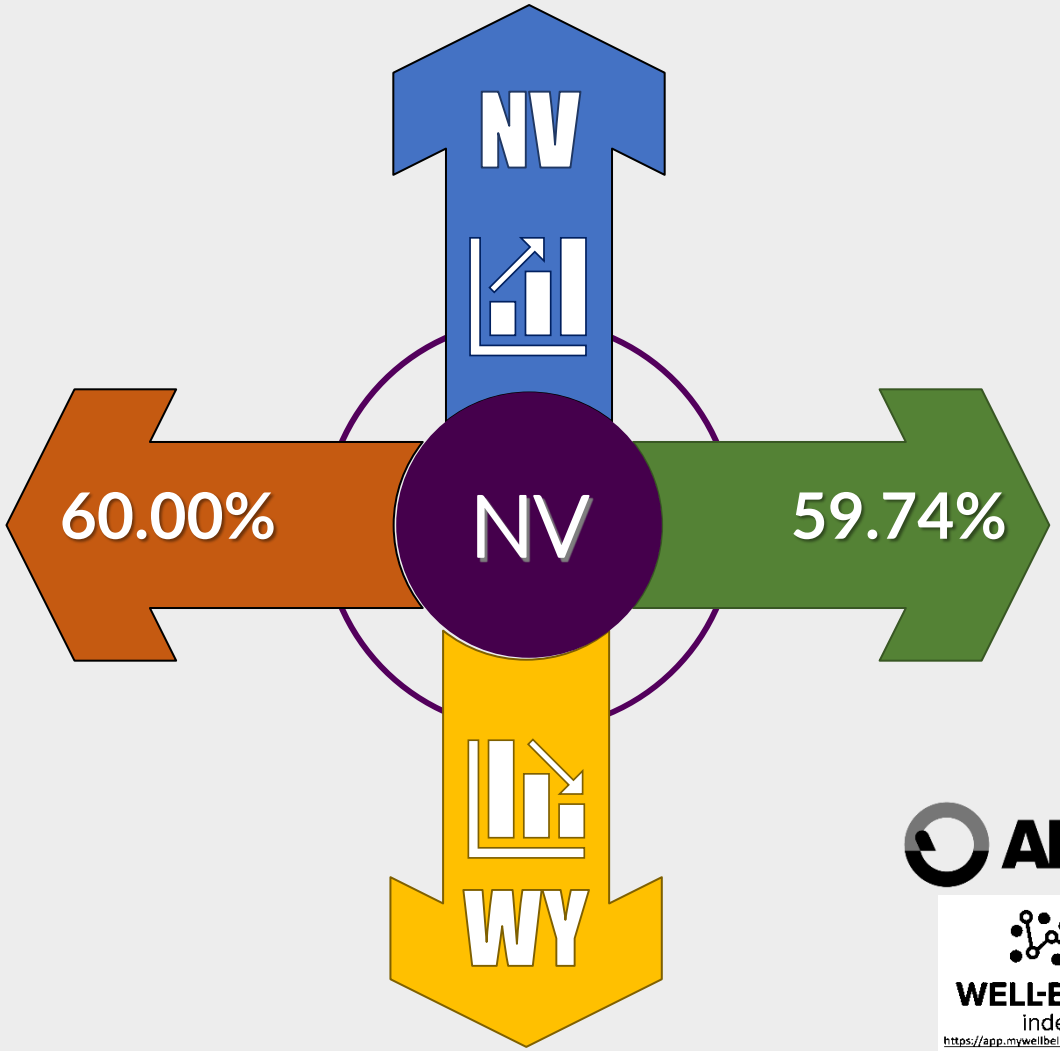
As of August 6, 2022, the Nevada distress percent was 60.00% (ranked the highest at 1/52) with 33 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



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WELL-BEING index
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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*

SEPTEMBER 2022

As of September 6. 2022, the New Mexico distress percent was 29.58% (ranked 43/52) with 50 assessors.

AUGUST 2022

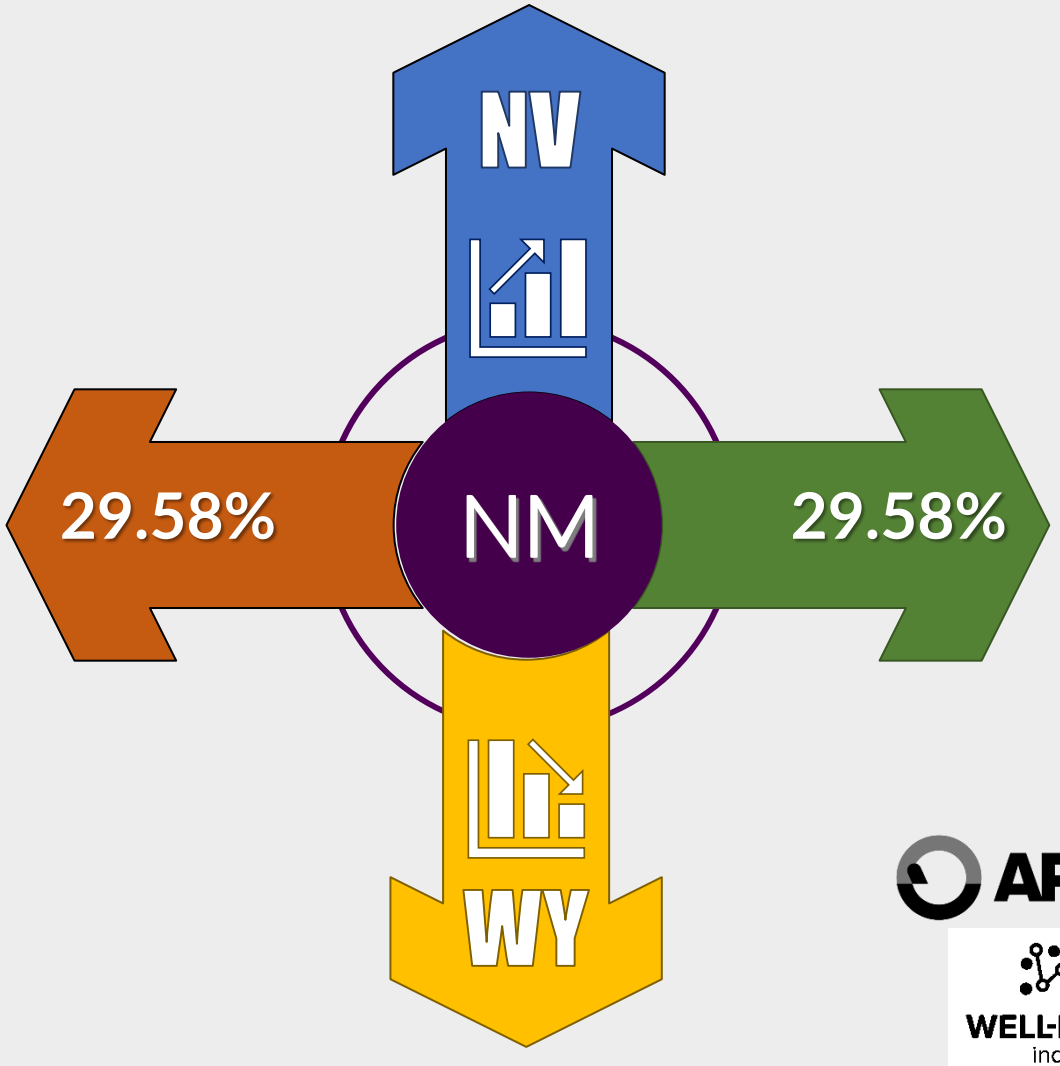
As of August 6. 2022, the New Mexico distress percent was 29.58% (ranked 43/52) with 50 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



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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WELL-BEING index
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WELL-BEING INDEX FOR PHARMACY PERSONNEL

STATE DISTRESS PERCENT*

SEPTEMBER 2022

As of September 6, 2022, the Utah distress percent was 30.53% (ranked tied at 39/52) with 71 assessors.

AUGUST 2022

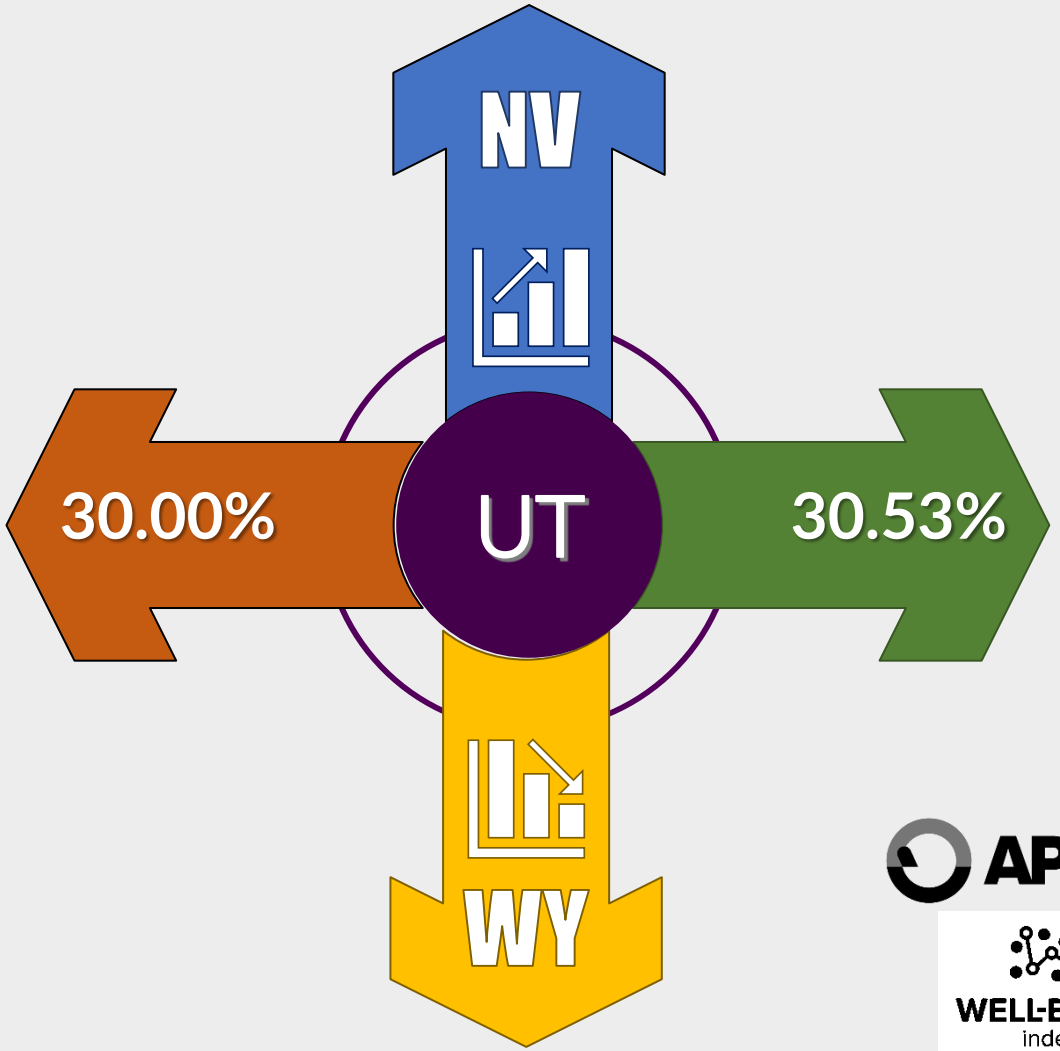
As of August 6, 2022, the Utah distress percent was 30.00% (ranked tied at 40/52) with 71 assessors.

STATE COMPARISON

As of September 6, 2022

Nevada is the highest at 59.74% (n=33)

Wyoming has the lowest 16.67% (n=17)



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WELL-BEING index
https://app.mywellbeingindex.org/signup
Invitation Code: APhA

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 Resources Promo Slides*

For Your Use in State Social Media and Periodicals

** Please do not change the content of these promotional slides*

WELL-BEING index

Burnout is real.

**Take advantage of APhA's online screening tool, invented by the Mayo Clinic,
to evaluate your fatigue, depression, burnout, anxiety, and stress and assess your well-being.
It takes less than 5 minutes to answer 9 short questions.
It's 100% anonymous, free, and you do not need to be an APhA member.
Resources are available once you submit your assessment.**

Well-being Index for Pharmacists, Student Pharmacists, & Pharmacy Technicians
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PWWR

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Pharmacy Workplace and Well-being Reporting.
www.pharmacist.com/pwwr

Your report is confidential, anonymous, and protected by the Alliance for Patient Medication Safety - a recognized national patient safety organization.

Share the PWWR link with your colleagues!