COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Agenda for Telephone Conference Call for Consideration of Possible Settlement

August 18, 2022

11 AM

****** For public participation please send an email request to Pharmbd@dhp.virginia.gov or call the Board office at 804-367-4456 to obtain information necessary to access this call ******

Case No. 210816

Quorum of the Board

Members: ***Dale St. Clair, RPh, PharmD**

Wendy Nash, PharmD
Patricia Richards-Spruill, RPh
Cherie Garvin, RPh
Ling Yuan, PharmD
Bill Lee, PharmD
Larry Kocot, JD

Adjourn

Workgroup Regarding Unprofessional Practice – Pharmacy Working Conditions

Members:

1. Cheryl Nelson, PharmD, Chairman, Board of Pharmacy
2. Dale St. Clair, PharmD, Vice-Chairman, Board of Pharmacy
3. Glenn Bolyard, RPh, Member, Board of Pharmacy
4. Kris Ratliff, DPh, Member, Board of Pharmacy
5. Patricia Richards-Spruill, RPh, Member, Board of Pharmacy
6. Bryan Lowe, Virginia Association of Chain Drug Stores
7. John Beckner, RPh, National Community Pharmacists Association
8. Cindy Warriner, Virginia Pharmacists Association

The following compounds are classified as synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. **1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

Based on its chemical structure, the following compound is expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

2. **4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. **alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. **ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA),** its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

5. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA),** its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(motion by Bolyard, seconded by Richards-Spruill)

ADOPTION OF RECOMMENDATIONS ON PERIODIC REVIEW

Ms. Yeatts reminded the Board that a notice of periodic review was published in December 2020/January 2021 and that no public comments were received. She commented that the Regulation Committee has recommended certain topics to be included in the periodic regulatory review. After Board consideration of these topics today, a notice will be published soliciting public comment regarding the identified topics and any other topics for inclusion in the periodic review. The Board will consider these comments at the March 2022 meeting prior to adopting a Notice of Intent. She stated the Board is not obligated to amending regulations on these topics at this time, but is simply identifying topics for which it may consider amending or drafting regulations to address. She recommended the Board address 18VAC110-20-25 regarding unprofessional conduct separately given the public comment received. Ms. Juran suggested the Board consider including recommendations from the legislative work groups to 1) make it clear that pharmacists and pharmacy technicians may administer CLIA-waived tests which is consistent with the Board's longstanding position and confirmed with board counsel, 2) that pharmacy technicians may independently take medication histories including drug name, dose, and frequency, and 3) to allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when

authorized by the pharmacist-in-charge.

MOTION: **The Board voted unanimously to continue Chapters 20, 21, and 30 with amendments and to include the topics recommended by the Regulation Committee as found on pages 80-82 of the agenda packet, along with the following topics to 1) make it clear that pharmacists and pharmacy technicians may administer CLIA-waived tests, 2) that pharmacy technicians may independently take medication histories including drug name, dose, and frequency, and 3) allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge. (motion by St. Clair, seconded by Henderson)**

MOTION: **The Board voted unanimously to continue Chapters 40 and 50 without amendment. (motion by Ratliff, seconded by Richards-Spruill)**

The Board had extensive discussion regarding 18VAC110-20-25, unprofessional conduct. Ms. Yeatts commented that 1) the Board could accept the Regulation Committee's recommendation to not include the suggested language for 18VAC110-20-25 in the periodic review because authority for disciplinary action already exists in 54.1-3316 (13) of the Code of Virginia, 2) include the suggested language to the Regulation Committee in the periodic review which will take approximately two years to complete the regulatory action, 3) take the subject up separately and create a work group to specify regulatory language, or 4) an association could have a bill introduced in the General Assembly with specific language. There was discussion regarding whether an emergency regulation could be passed. It was stated that the Office of Attorney General would need to confirm that the board acted properly and that evidence of an emergency exists. Evidence would likely need to go beyond anecdotal comment. Dr. Melton commented that it wouldn't hurt to form a work group and include it in the periodic regulatory review. Mr. Henderson recommended a work group to improve the vague language. Mr. Bolyard commented that the suggested language as written gives corporations loopholes, but that this language could be used as a checklist to evaluate activities. He recommended improving the language if the board elects for regulatory action. Dr. St.Clair provided background regarding the Regulation Committee's recommendation and indicated the following regarding the red-lined suggested language in the handout for 18VAC110-20-25: "engaging in a manner that discourages individuals from providing information regarding public safety concerns.." has already been included in the periodic review; "assuming duties and responsibilities within the practice of pharmacy without adequate training...." Appears to be addressed in 18VAC110-21-40; and, "incenting or inducing the transfer of a prescription absent professional rationale" is already at the Governor's office in a stalled regulatory action.

MOTION:

The Board voted unanimously to include the following suggested topics in the periodic regulatory review and convene a work group to further address the subject:

failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient including:

- sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care;
- appropriate opportunities for uninterrupted rest periods and meal breaks;
- adequate time for a pharmacist to complete professional duties and responsibilities including:
  - drug utilization review;
  - immunization;
  - counseling;
  - verification of the accuracy of a prescription
- introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public;

(motion by Ratliff, seconded by Richards-Spruill)

ADOPTION OF FINAL REGULATIONS FOR MEDICATION CAROUSELS

Ms. Yeatts stated that the Regulation Committee is recommending significant changes to the proposed regulations for use of medication carousels and RFID technology based on significant public comment received from VSHP. She recommended that the Board publish its adopted language for an additional public comment period with final adoption at the March 2022 full board meeting. Dr. Nelson asked several questions regarding the recommended changes and expressed concern for allowing visual verification by pharmacy technicians. A typographical error was noted on page 100.

MOTION:

The Board voted 8:1 to approve a 60-day public comment period on the recommended changes to the proposed regulations for medication carousels and RFID technology as presented in the agenda packet and recommended by the Regulation Committee. (motion by Bolyard, seconded by Melton; opposed by Nelson)

ADOPTION OF LIMITED LICENSES FOR NON-PROFIT CLINICS

There were no public comments submitted during the public comment period that ended on 10/15/21 regarding the adoption of limited-use licenses for practitioners of the healing arts to sell controlled substances in non-profit clinics.

MOTION:

The Board voted unanimously to adopt final regulations for limited-use licenses for practitioners of the healing arts to sell controlled substances in non-profit clinics as presented without changes from the proposed and emergency regulations. (motion by St. Clair, seconded by Bolyard)

APhA

WELL-BEING index

Well-being Index for Pharmacy Personnel

State Report for State Boards of Pharmacy

NABP District Two States

DECEMBER 2021

For Every Pharmacist. For All of Pharmacy.

pharmacist.com

Welcome to the
Well-being Index for Pharmacy Personnel Monthly State Report

What will you find in the monthly report?

Well-being Index Monthly Tracking

The monthly report includes a tracking of the Well-being Index Distress Percent. The Distress Percent is the percentage of assessors whose scores indicate they are at risk of high distress.

The monthly report tracking follows those states with the largest change in Distress Percent that month, a snapshot of the Distress Percent over time for the states in the district, and induvial state distress percent with COVID cases and immunization for the current and previous month.

National Pharmacy Workplace Survey – Preliminary Results on a Sample of Questions

This month, the questions focus on the preliminary district level results on the pharmacists/employer engagement and communication. An overall preliminary results report is expected at the beginning of 2022.

How can you use this information?

You can track the Well-being Index distress percent in your state and region. Is it trending down or up over time, are there blips that correspond with events in your state? With increasing pharmacy workplace issues being covered by consumer news outlets, you can use this information to engage in a conversation with your board members and reach out to state pharmacy association executives to work together on steps that can be taken to decrease pharmacy personnel stress and occupational burnout.

What is the Well-being Index for Pharmacy Personnel?

Research-validated online tool invented by Mayo Clinic

*100% anonymous
*Free/Do not have to be an APhA member
*Assess as often as the individual wants and track progress over time
*Access through website or through mobile app
*APhA launched at the WBI for Pharmacy Personnel in July 2019

How

*9-question assessment
*Takes just 5 minutes to complete
*APhA has added 3 optional questions on engagement with profession, workplace support of patient care services, and what APhA could do to help.

Measures dimensions of distress and well-being

*Likelihood of Burnout
*Severe Fatigue
*Suicidal Ideation
*Quality of Life
*Meaning in Work
*Work-Life Integration
*Risk of Medical Error
*Risk of Leaving Job
*Overall Well-Being

https://app.mywellbeingindex.org/signup

Invitation Code: APhA007

What is the WBI for Pharmacy Personnel's Distress Percent?

Distress Percent represents the percentage of individuals with a WBI score greater than or equal to 5 – the score, determined through a validation question process, indicates a risk of high distress.

Distress Percent is the percentage of those who completed the WBI who are at *risk of high distress*. It can not be generalized to the entire pharmacy personnel population.

Why is this Important?

Pharmacists identified as being at a *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
- ***2-fold higher risk of medication error***

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

National State-Based Pharmacy Workplace Survey

District-Level Data

~ Survey Overview

~ Employer/Employee Communications and Engagement

General Information

- Survey developed by APhA/NASPA Pharmacy Workplace Work Group
- Fielded March 22, 2021, through September 28, 2021
- Promoted through national associations and state pharmacy associations platforms/channels
- Preliminary Results - 4,200 Total Responses
- Preliminary Results are for those who responded and ***can not*** be generalized to all in the profession.

Total Responses by NABP District

District One	n=114	District Five	n=226
District Two	n=831	District Six	n=639
District Three	n=710	District Seven	n=251
District Four	n=691	District Eight	n=738

Responses Top Three Practice Settings By District

	One	Two	Three	Four	Five	Six	Seven	Eight	Total
Chain*	n=90 81.1%**	n=480 58.9%	n=520 73.7%	n=525 76.4%	n=103 46.6%	n=429 67.3%	n=138 56.1%	n=367 50.6%	n=2652 63.9%
Independent	n=2 1.8%	n=101 12.4%	n=63 8.9%	n=25 3.6%	n=37 16.7%	n=88 13.8%	n=13 5.3%	n=76 10.5%	n=405 9.8%
Hospital	n=7 6.3%	n=65 8.0%	n=49 7.0%	n=61 8.9%	n=30 13.6%	n=46 7.2%	n=26 10.6%	n=110 15.2%	n=394 9.5%

* Chain, grocery, mass merch
**Number of responses/
Percentage of all responses

APhA/NASPA National State-Based Workplace Survey

Reported by NABP/AACP District

Communication channel(s) exist for me to voice ideas and suggestions for process improvement.

			Strongly/Somewhat Agree	Neither Agree nor Disagree	Strongly/Somewhat Disagree	Total
NABP DISTRICT	1	Count	33	2	**72**	107
		% within NABP DISTRICT	30.8%	1.9%	**67.3%**	100%
	2	Count	285	75	**381**	741
		% within NABP DISTRICT	38.5%	10.1%	**51.5%**	100%
	3	Count	220	66	**376**	662
		% within NABP DISTRICT	33.2%	10.0%	**56.8%**	100%
	4	Count	236	65	**373**	674
		% within NABP DISTRICT	35.0%	9.6%	**55.4%**	100%
	5	Count	91	24	**84**	199
		% within NABP DISTRICT	45.8%	12.1%	**42.2%**	100%
	6	Count	229	59	**332**	620
		% within NABP DISTRICT	37.0%	9.5%	**53.5%**	100%
	7	Count	108	18	**103**	229
		% within NABP DISTRICT	47.1%	7.9%	**45.0%**	100%
	8	Count	282	59	**308**	649
		% within NABP DISTRICT	43.4%	9.1%	**47.5%**	100%
Total		Count	1484	368	**2029**	3881
		% of Total	38.2%	9.5%	**52.3%**	100%

APhA/NASPA National State-Based Workplace Survey

Reported by NABP/AACP District

Management is available for and open to discussing issues impacting patient care.

			Strongly/Somewhat Agree	Neither Agree nor Disagree	Strongly/Somewhat Disagree	Total
NABP DISTRICT	1	Count	19	14	**73**	106
		% within NABP DISTRICT	18.6%	13.2%	**68.9%**	100%
	2	Count	266	75	**389**	730
		% within NABP DISTRICT	36.4%	10.3%	**53.2%**	100%
	3	Count	204	48	**408**	660
		% within NABP DISTRICT	30.9%	7.3%	**61.8%**	100%
	4	Count	198	64	**410**	672
		% within NABP DISTRICT	29.5%	9.5%	**61.0%**	100%
	5	Count	83	16	**95**	194
		% within NABP DISTRICT	42.8%	8.2%	**49.0%**	100%
	6	Count	223	60	**336**	619
		% within NABP DISTRICT	36.0%	9.7%	**54.3%**	100%
	7	Count	98	22	**107**	227
		% within NABP DISTRICT	43.2%	9.7%	**47.1%**	100%
	8	Count	269	49	**323**	641
		% within NABP DISTRICT	42.0%	7.6%	**50.4%**	100%
Total		Count	1350	348	**2141**	3849
		% of Total Count	35.3%	9.0%	**55.6%**	100%

APhA/NASPA National State-Based Workplace Survey

Reported by NABP/AACP District

My employer actively seeks my opinion.						
			Strongly/Somewhat Agree	Neither Agree nor Disagree	Strongly/Somewhat Disagree	Total
NABP DISTRICT	1	Count	19	7	**80**	106
		% within NABP DISTRICT	17.9%	6.6%	**75.5%**	100%
	2	Count	216	62	**461**	739
		% within NABP DISTRICT	29.2%	8.4%	**62.4%**	100%
	3	Count	151	58	**451**	660
		% within NABP DISTRICT	22.8%	8.8%	**68.4%**	100%
	4	Count	151	71	**452**	674
		% within NABP DISTRICT	22.5%	10.5%	**67.0%**	100%
	5	Count	67	17	**115**	199
		% within NABP DISTRICT	33.7%	8.5%	**57.8%**	100%
	6	Count	179	44	**394**	617
		% within NABP DISTRICT	29.0%	7.1%	**63.8%**	100%
	7	Count	77	22	**131**	230
		% within NABP DISTRICT	33.5%	9.6%	**57.0%**	100%
	8	Count	221	58	**369**	648
		% within NABP DISTRICT	34.1%	9.0%	**56.9%**	100%
Total		Count	1081	339	**2453**	3873
		% of Total	27.9%	8.8%	**63.3%**	100%

APhA/NASPA National State-Based Workplace Survey

Reported by NABP/AACP District

My employer respects and values my input.

			Strongly/Somewhat Agree	Neither Agree nor Disagree	Strongly/Somewhat Disagree	Total
NABP DISTRICT	1	Count	15	13	**78**	106
		% within NABP DISTRICT	14.1%	12.3%	**73.6%**	100%
	2	Count	215	81	**484**	740
		% within NABP DISTRICT	29.1%	10.9%	**60.0%**	100%
	3	Count	149	69	**442**	660
		% within NABP DISTRICT	22.6%	10.5%	**66.9%**	100%
	4	Count	135	86	**453**	674
		% within NABP DISTRICT	20.1%	12.8%	**67.2%**	100%
	5	Count	70	19	**110**	199
		% within NABP DISTRICT	35.2%	9.5%	**55.3%**	100%
	6	Count	164	67	**387**	618
		% within NABP DISTRICT	26.5%	10.8%	**62.6%**	100%
	7	Count	86	17	**126**	229
		% within NABP DISTRICT	37.6%	7.4%	**55.0%**	100%
	8	Count	235	74	**339**	648
		% within NABP DISTRICT	36.2%	11.4%	**52.3%**	100%
Total		Count	1069	426	**2379**	3874
		% of Total	27.6%	11.0%	**61.40%**	100

DISTRESS PERCENT CHANGES

National and District

November 2021 versus December 2021

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Changes in Distress Levels

As of December 2021

State	Change in Distress % November 2021 vs December 2021	Distress % December 2021	State Rank for Distress Level December2021
Largest Increase in Distress Percent			
Alaska	1.32%	25.00%	2
Nevada	0.84%	55.56%	27 (t)
West Virginia	0.76%	42.21%	50
Idaho	0.63%	32.71%	13
South Dakota	0.58%	25.88%	43
Largest Decrease in Distress Percent			
Puerto Rico	-2.62%	44.44%	40
District of Columbia	-0.84%	28.57%	9
Alabama	-0.77%	37.14%	1
Rhode Island	-0.76%	30.95%	41
Tennessee	-0.67%	31.75%	44
NATIONAL	0.16%	32.13%	----

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Changes in Distress Levels – District Two

As of December 2021

	Change in Distress % Dec 21 vs Nov 21	Distress % Dec 2021	Distress % State Rank Dec 2021	COVID-19 Vaccine Admin Dec 2021	Change in Distress % Nov 21 vs Oct 21	Distress % Nov 2021	Distress % State Rank Nov 2021	Distress % Oct 2021	Distress % State Rank Oct 2021	Distress % State Rank Sep 2021	Distress % State Rank Aug 2021	Distress % State Rank Jul 2021	Distress % State Rank Jun 2021	Distress % State Rank Apr 2021	Distress % State Rank Feb 2021	Distress % State Rank May 2020	Distress % State Rank Apr 2020
Delaware	**No Change**	**31.71%**	**35**	**1880895**	No Change	31.71%	35 (T)	31.71%	32 (T)	33	33	35	35	35	35	30	32
District of Columbia	**-0.84%**	**28.57%**	**43**	**1473965**	4.41%	29.41%	42	25.00%	46 (T)	48	48	45	45	48	47	51	51
Maryland	**0.33%**	**33.83%**	**24**	**12344110**	No Change	33.50%	26	33.50%	24	24	24	24	25	25	25	13	15
New Jersey	**0.27%**	**37.44%**	**16**	**17272705**	0.41%	37.17%	17	36.76%	17	17	17	18	19	17	16	19(t)	21
New York	**-0.19%**	**31.21%**	**36**	**36218565**	-0.26%	31.40%	37	31.66%	34	32	31	32	31	26	29	31	33
Pennsylvania	**-0.17%**	**35.71%**	**19**	**24070415**	0.36%	35.88%	19	35.52%	20	20	20	19	20	22	22	28	28
Virginia	**No Change**	**40.19%**	**12**	**15822135**	1.44%	40.19%	12	38.75%	13	13	13	14	13	18	18	22	18
West Virginia	**0.76%**	**42.21%**	**8**	**3396865**	0.51%	41.45%	9	40.94%	9	9	9	9	10	10	10	10	12

Note: Historic data from 2020/2021 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

November 2021 versus December 2021

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PHARMACISTS WELL-BEING INDEX

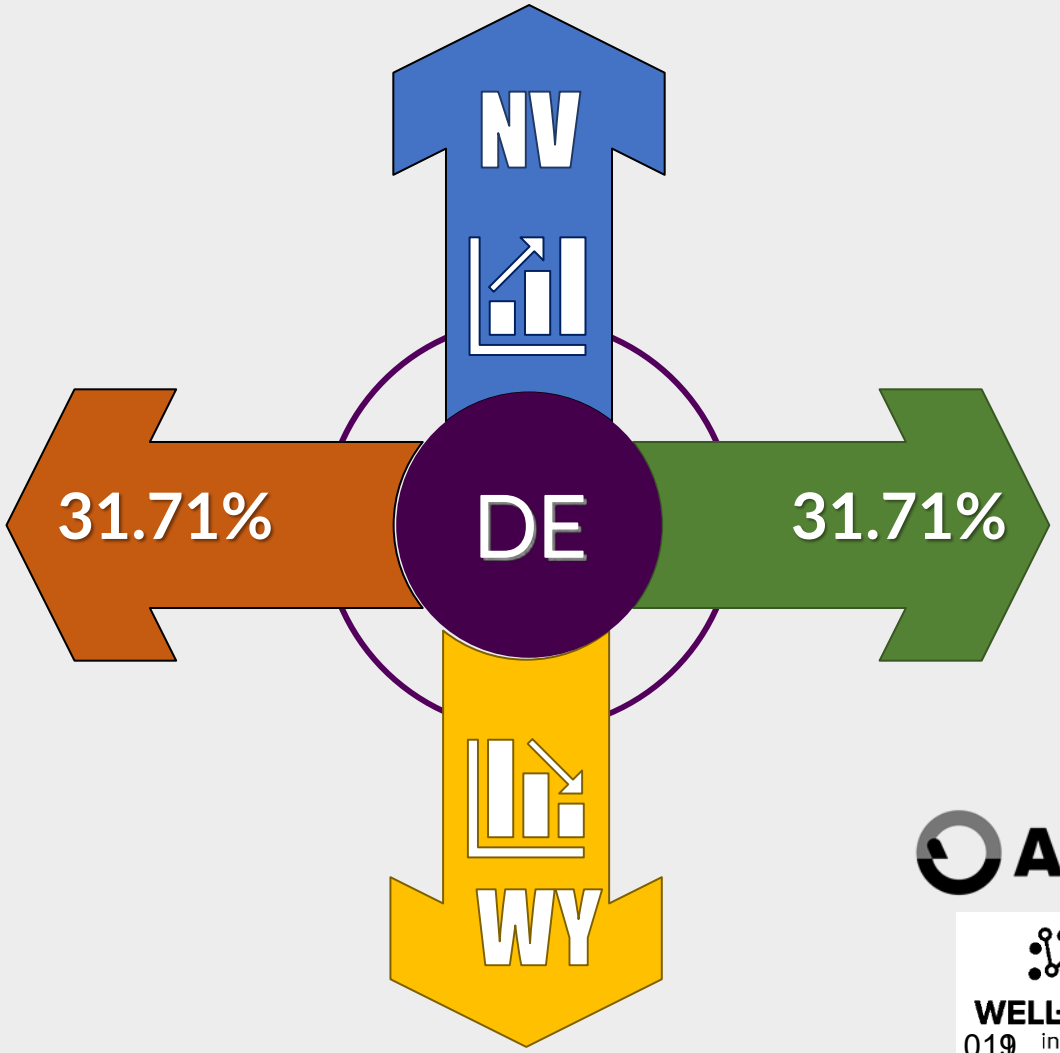
State Distress Percent*

December 2021

As of December 6, 2021, the Delaware distress percent was 31.71% (35th highest) with 22 assessors. On this same date, the CDC reported 1,880,895 COVID-19 vaccines administered and 156,454 cases in the state.

November 2021

As of November 6, 2021, the Delaware distress percent was 31.71% (tied for 35th highest) with 22 assessors. On this same date, the CDC reported 1,760,605 COVID-19 vaccines administered and 145,330 cases in the state.



State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)

Distress Percent is the percentage of individuals with a Pharmacist 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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PHARMACISTS WELL-BEING INDEX

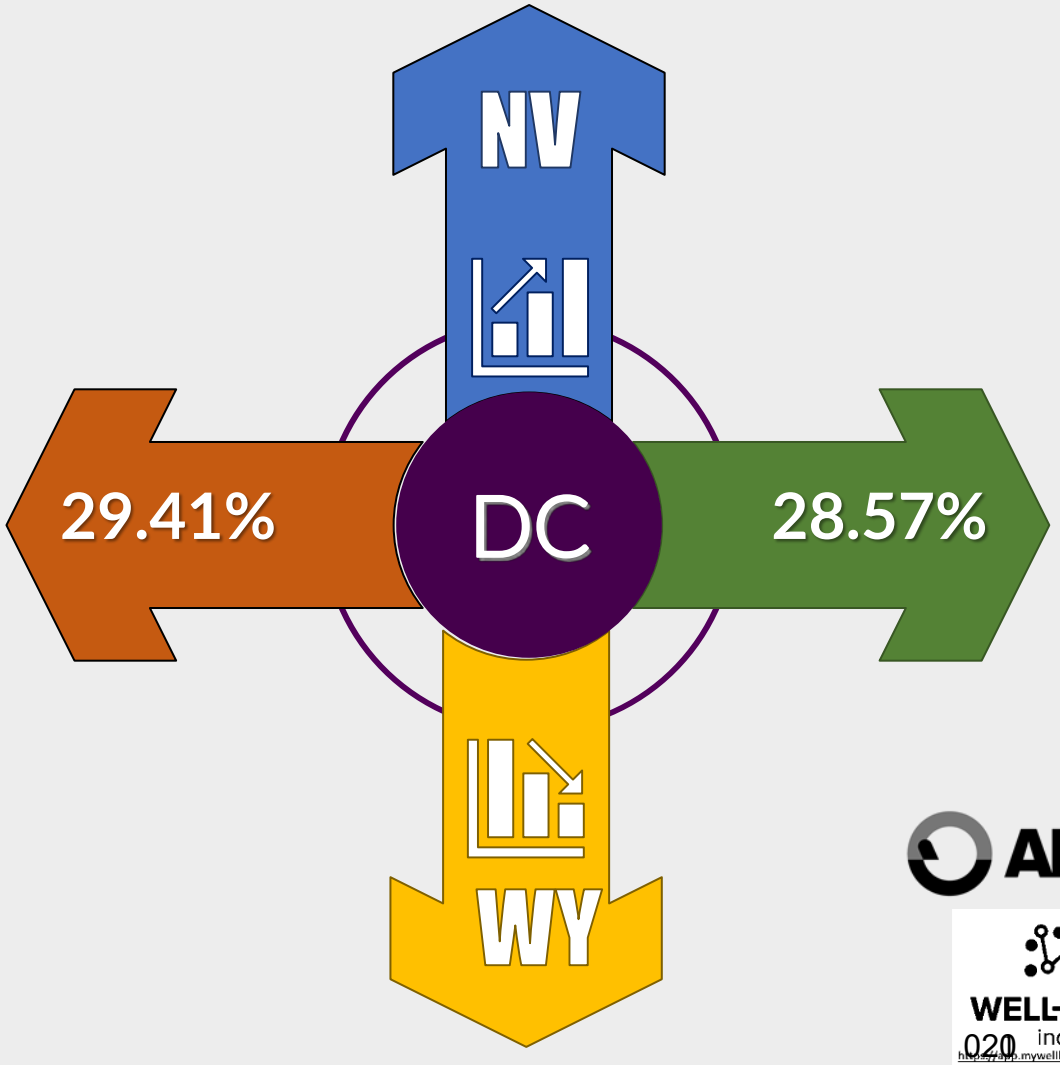
State Distress Percent*

December 2021

As of December 6, 2021, the Washington, DC distress percent was 28.57% (10th lowest) with 25 assessors. On this same date, the CDC reported 1,473,965 COVID-19 vaccines administered and 67,430 cases in the state.

November 2021

As of November 6, 2021, the Washington, DC distress percent was 29.41% (11th lowest) with 25 assessors. On this same date, the CDC reported 1,349,795 COVID-19 vaccines administered and 64,799 cases in the state.



State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)

Distress Percent is the percentage of individuals with a Pharmacist 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 2020

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PHARMACISTS WELL-BEING INDEX

State Distress Percent*

December 2021

As of December 6, 2021, the Maryland distress percent was 33.83% (24th highest) with 113 assessors. On this same date, the CDC reported 12,344,110 COVID-19 vaccines administered and 592,679 cases in the state.

November 2021

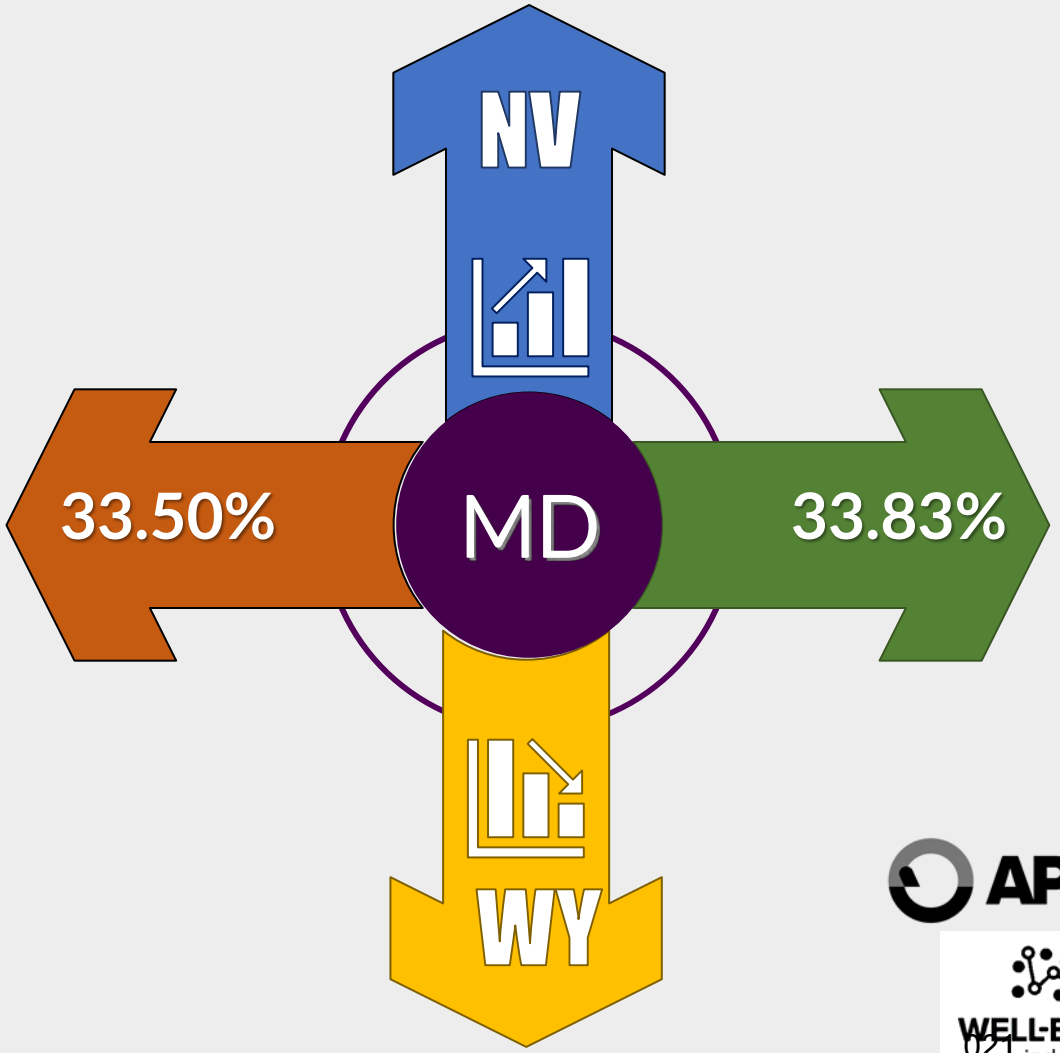
As of November 6, 2021, the Maryland distress percent was 33.50% (26th highest) with 113 assessors. On this same date, the CDC reported 112,626,690 COVID-19 vaccines administered and 565,355 cases in the state.

State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)



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

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PHARMACISTS WELL-BEING INDEX

State Distress Percent*

December 2021

As of December 6, 2021, the New Jersey distress percent was 37.44% (16th highest) with 102 assessors. On this same date, the CDC reported 17,272,705 COVID-19 vaccines administered and 1,272,728 cases in the state.

November 2021

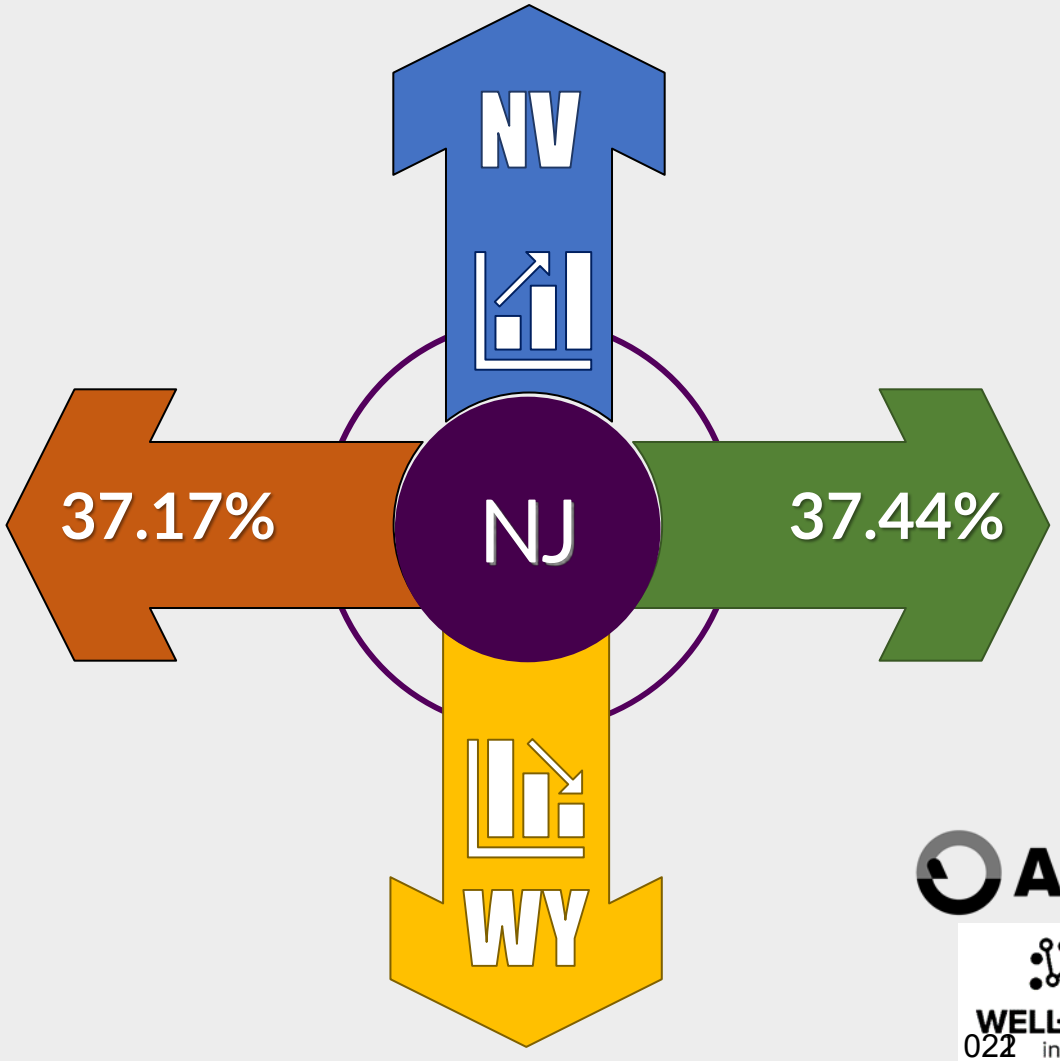
As of November 6, 2021, the New Jersey distress percent was 37.17% (17th highest) with 102 assessors. On this same date, the CDC reported 15,643,415 COVID-19 vaccines administered and 1,205,140 cases in the state.

State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)



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

APhA

WELL-BEING index

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PHARMACISTS WELL-BEING INDEX

State Distress Percent*

December 2021

As of December 6, 2021, the New York distress percent was 31.21% (36th highest) with 212 assessors. On this same date, the CDC reported 36,218,565 COVID-19 vaccines administered and 2,783,423 cases in the state.

November 2021

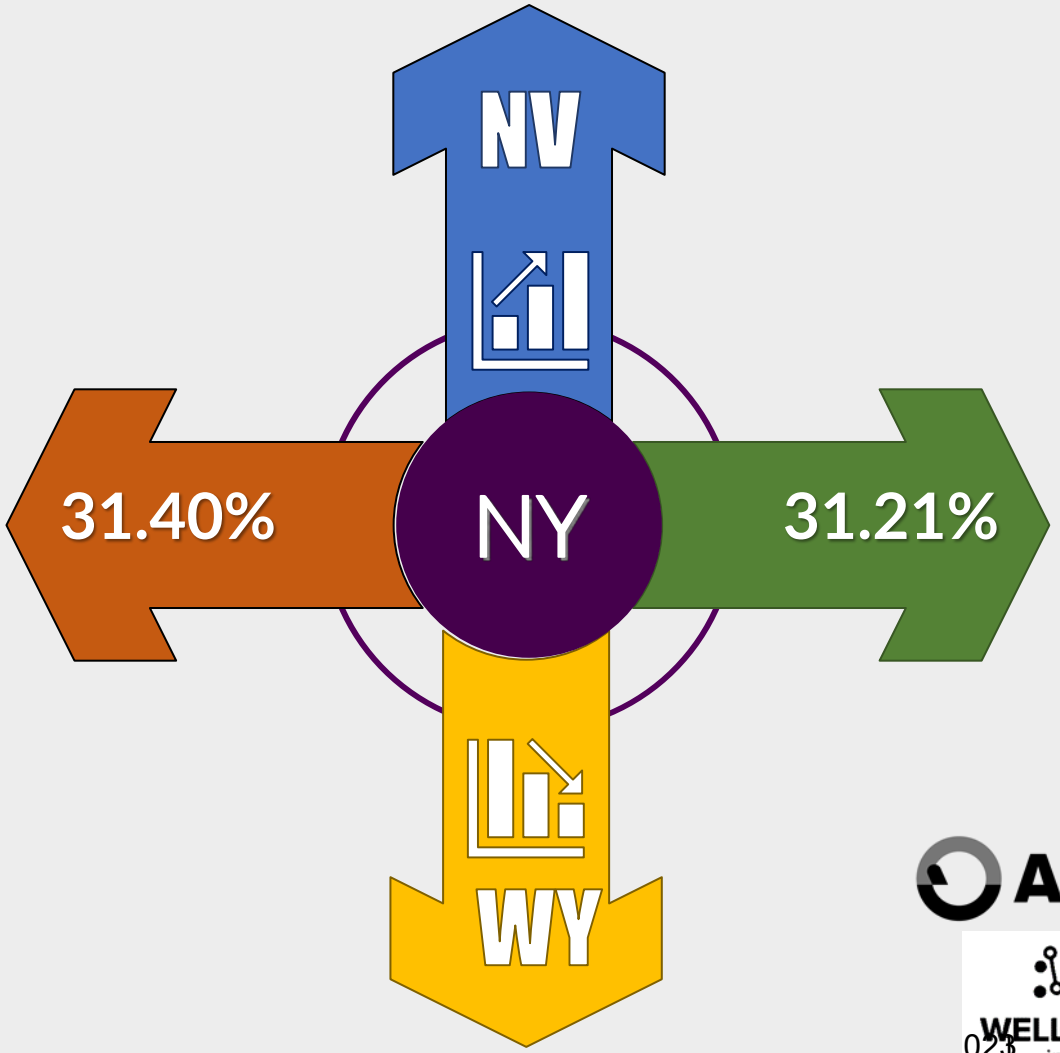
As of November 6, 2021, the New York distress percent was 31.40% (37th highest) with 212 assessors. On this same date, the CDC reported 33,056,425 COVID-19 vaccines administered and 2,581,607 cases in the state.

State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)



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

APhA

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PHARMACISTS WELL-BEING INDEX

State Distress Percent*

December 2021

As of December 6, 2021, the Pennsylvania distress percent was 35.71% (19th highest) with 411 assessors. On this same date, the CDC reported 24,070,415 COVID-19 vaccines administered and 1,779,155 cases in the state.

November 2021

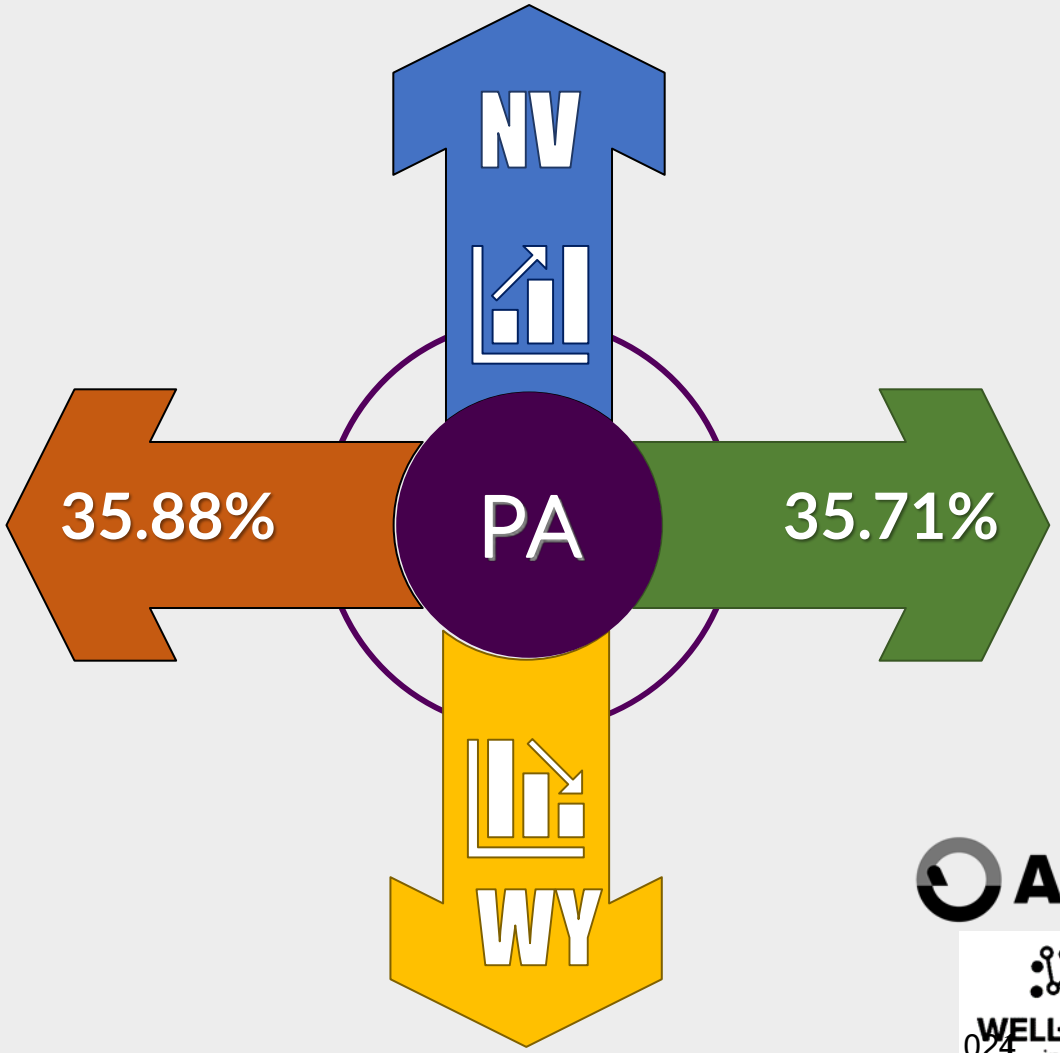
As of November 6, 2021, the Pennsylvania distress percent was 35.88% (19th highest) with 411 assessors. On this same date, the CDC reported 21,905,315 COVID-19 vaccines administered and 1,585,475 cases in the state.

State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)



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

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PHARMACISTS WELL-BEING INDEX

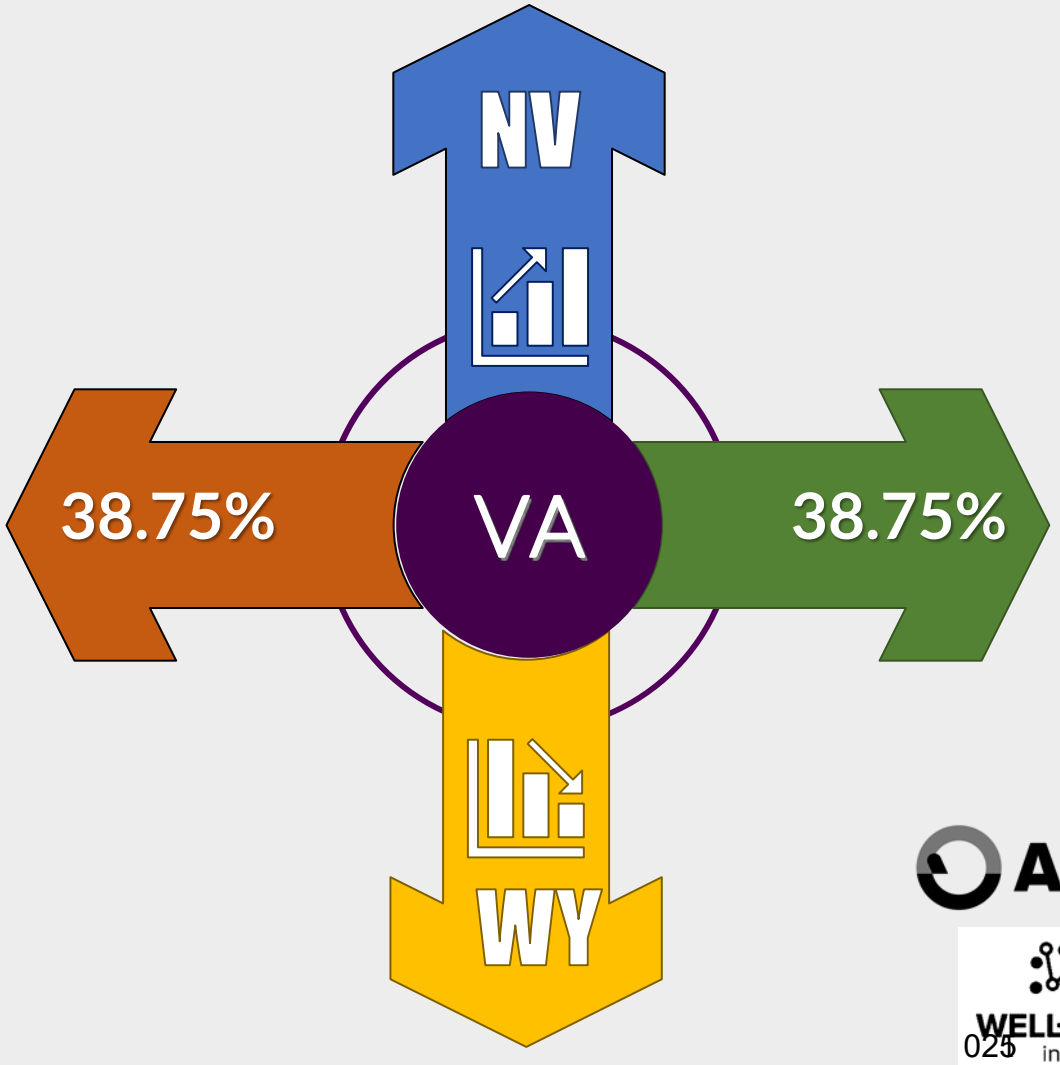
State Distress Percent*

December 2021

As of December 6, 2021, the Virginia distress percent was 38.75% (12th highest) with 230 assessors. On this same date, the CDC reported 15,822,135 COVID-19 vaccines administered and 979,219 cases in the state.

November 2021

As of November 6, 2021, the Virginia distress percent was 38.75% (13th highest) with 217 assessors. On this same date, the CDC reported 12,884,195 COVID-19 vaccines administered and 882,437 cases in the state.



State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)

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

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PHARMACISTS WELL-BEING INDEX

State Distress Percent*

December 2021

As of December 6, 2021, the West Virginia distress percent was 42.21% (8th highest) with 92 assessors. On this same date, the CDC reported 3,396,865 COVID-19 vaccines administered and 300,660 cases in the state.

November 2021

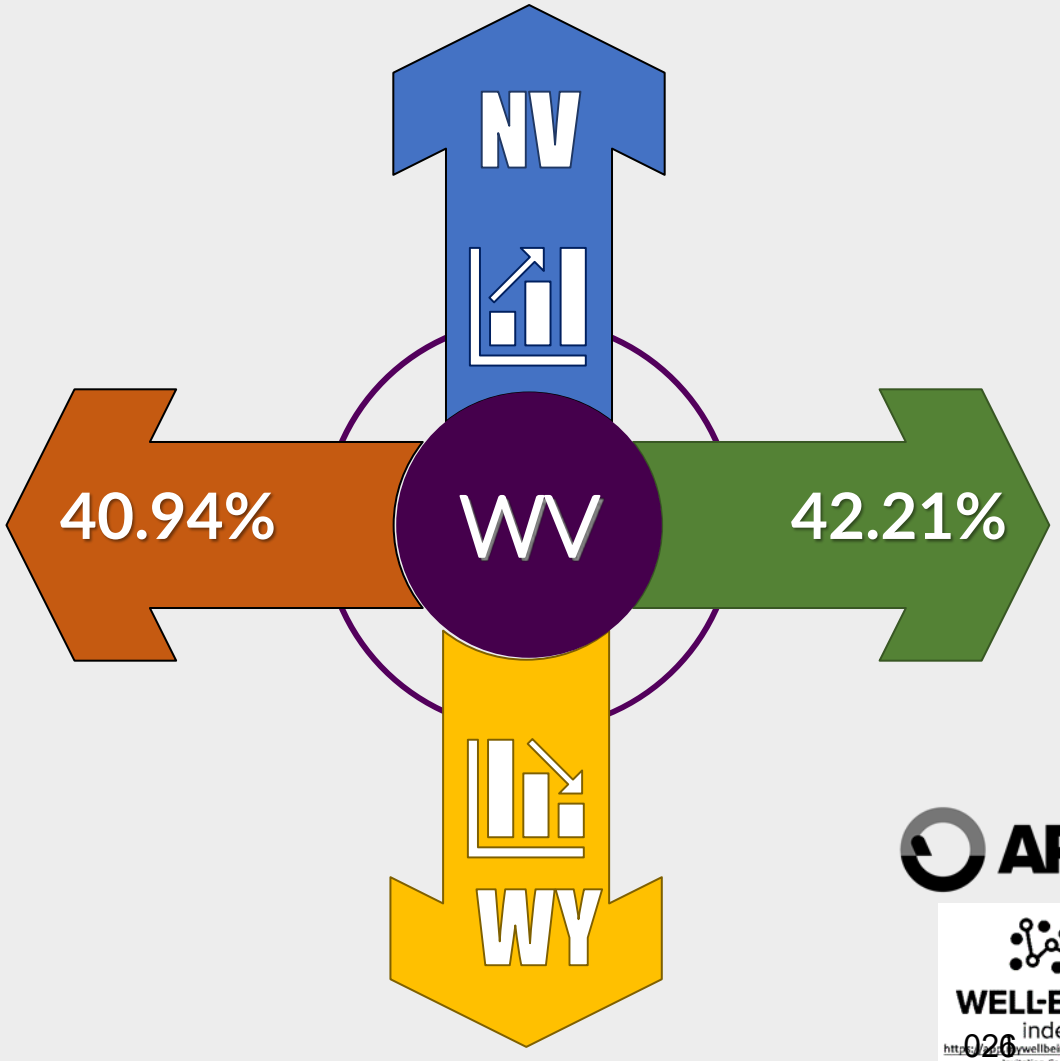
As of November 6, 2021, the West Virginia distress percent was 40.94% (9th highest) with 92 assessors. On this same date, the CDC reported 3,010,965 COVID-19 vaccines administered and 246,408 cases in the state.

State Comparison

As December 6, 2021

Nevada is the highest at 55.56% (n=23)

Wyoming has the lowest 18.18% (n=15)



Distress Percent is the percentage of individuals with a Pharmacist 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 Resources Promo Slides*

For Your Use in State Social Media and Periodicals

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

PHARMACY WORKPLACE & WELL-BEING REPORTING

Your experiences – positive and negative – tell a powerful story!

Your experience can be the spark that helps change and enhance the pharmacy workplace, pharmacy personnel well-being, and patient safety.

Submit your experience report to
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!

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.**

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RESOLUTION NO:	**117-4-21**
TITLE:	**Task Force on Workplace Safety and Well-Being**
ACTION:	**PASS**

WHEREAS, it has been noted that some pharmacists throughout the country are voicing concerns over pharmacy practice operations, metrics, and workplace safety issues that potentially put patients at risk; and

WHEREAS, some local, state, and national pharmacy associations are addressing system issues, such as pharmacy workplace conditions and expectations that may impact pharmacists' ability to provide patient care; and

WHEREAS, some state boards of pharmacy are investigating the potential negative effects and/or patient safety risks presented by specific staffing models, metrics, and pharmacy staff workload expectations;

THEREFORE BE IT RESOLVED that NABP convene a task force to examine the topic of pharmacy workplace safety and well-being and the effects on patient safety, which will include members with experience overseeing investigative activities related to these topics and other stakeholders to develop suggested guidelines and objective tools that may be used by member state boards of pharmacy.

29. Miscellaneous State Pharmacy Laws (cont.)

State	Does State Require Pharmacies to Conduct Self-inspections?	Does Board Require Pharmacies to Maintain Any Type of Continuous Quality Improvement Program to Monitor and Prevent Quality-Related Events?	Does Board Have Regulations Aimed at Relieving Pharmacist Workload?	Does Board Have Regulatory Oversight of Pharmacy Benefit Managers?
Alabama	No	Yes O4	Yes KK	No
Alaska	Yes H5	Not addressed	No	No
Arizona	No	Yes	No	No
Arkansas	No	No	No	No
California	Yes L5	Yes	Yes U6	No
Colorado	No	No	No	No
Connecticut	No	Yes	No	No
Delaware	Yes	No	No	No
District of Columbia	No E5	No	No	No
Florida	No	Yes	Yes KK	No
Georgia	No	No	No	Yes PP
Guam	No	Not addressed	Not addressed	No G4
Hawaii	Yes F5	No	No	No
Idaho	No L4	No	No	No Y4
Illinois	Yes	No Z4	Yes †	No A5
Indiana	Yes E6	Yes VV	No	Yes C6
Iowa	No	No	No	No
Kansas	No	Yes	No	No
Kentucky	No	Yes	No	No
Louisiana	No	No	No	Yes
Maine	Yes F5	No	No	No
Maryland	No	Yes	No	No
Massachusetts	No	Yes	No MM	No
Michigan	Yes P5	No	No	No
Minnesota	No	No	Yes X5	No
Mississippi	No	No	No	Yes
Missouri	No	Yes I5	No	No
Montana	No	Yes	Yes EE	No
Nebraska	Yes	No	No	No C5
Nevada	Yes M5	No	No	No
New Hampshire	N5	Yes †	Yes KK	No
New Jersey	No	No	Yes JJ	No
New Mexico	Yes	No	No	No
New York	No	No W	Yes II	No
North Carolina	No	Yes	Yes D4	No
North Dakota	Yes G5	Yes	No	Yes
Ohio	No	No	No	No
Oklahoma	No	Yes P	Yes	No
Oregon	Yes	Yes	Yes XXX	No D5
Pennsylvania	No	I	No	No
Puerto Rico	—	K	Yes	—
Rhode Island	No	Yes	Yes	No
South Carolina	No	No	No	No
South Dakota	No	No DD	No	No
Tennessee	No W	No	Yes	No
Texas	No	Recommended	No	No
Utah	No	No	No	No
Vermont	No	No	Yes X4	No
Virginia	No	Yes	Yes J5	No OO
Washington	Yes Y5	No †	No	No
West Virginia	No	Yes	Yes X, JJ, QQ	No
Wisconsin	No	No	No	No
Wyoming	No W	Yes N4	No	No

Colored text denotes change from 2020 edition.

† Other comments noted in 2020 edition no longer apply.

— Indicates information is not available.

29. Miscellaneous State Pharmacy Laws (cont.)

Legend

A — Prescriber ownership of pharmacies is prohibited if prescribers are likely to benefit due to the prescriptions they write.
B — Limited to industrial accident prescriptions.
C — See ILCS 85/3(d)(9).
D — Prescriber(s) may own no more than 10% total interest in a pharmacy.
E — Does not apply to HMO or self-funded Employee Retirement Income Security Act plans.
F — Department of Health & Human Services, Division of Public Health, Licensure Unit.
G — Prescriber ownership of pharmacy is not prohibited; however, benefits earned in connection to patient referral may violate rebating laws RCW 19.68.010.
H — Referral to pharmacies in which the prescriber has ownership interest is prohibited.
I — Required for automated medication systems.
J — In the Division of Facilities' Standards, Department of Health.
K — Not specifically released in the law.
L — See Section 1330.750 of the Rules.
M — Self-referral prohibited; limits ownership.
N — Contact Board for specific requirements.
O — No legislation but Board rules prohibit any activity that negates patient freedom of choice.
P — In hospital settings only.
Q — For durable medical equipment.
R — As of May 2, 2013, legislation was signed eliminating the pharmacist requirement for device/DME only pharmacies.
S — 12 AAC 52.560.
T — However, it shall be unlawful for one or more medical practitioners to have a proprietary or beneficial interest sufficient to permit them to exercise supervision or control over the pharmacist in his or her professional responsibilities or duties.
U — If board approved.
V — Must comply with Board rules regarding centralized dispensing (MA – Must comply with Board policy regarding shared pharmacy services).
W — Encouraged, but not mandated at this time.
X — Must have technician help if filling more than 15 prescriptions/hour on average.
Y — Consulting purpose only.
Z — Not specifically addressed; must follow laws and regulations governing all pharmacies.
AA — Statutory requirements for unused drug program, disposal, and cancer drug repository program in MCL 333.17775 to MCL 333.17780. (PA 329 of 2004 – effective September 23, 2004).
BB — EPA and Occupational Safety and Health Administration guidelines are applicable to legend drugs; DEA guidelines apply for controlled substances.
CC — Under some circumstances.
DD — Board recommends that such programs be addressed in the pharmacy policy and procedure manual.
EE — Board may approve technician ratio variances.
FF — Refer to Board Rules, Chapter 2, Section 15.
GG — Administered through the Department of Social Services.
HH — At the pharmacist's discretion, non-controlled substances may be returned from a LTCF for a credit and reuse if they have been in the control of the LTCF at all times, are in unit dose tamper-evident packaging, and the labels bear the expiration date or calculated expiration date and lot number. Similar provisions also exist for community health centers, correctional facilities, and jails.
II — Amendments to rules and regulations allow for greater use of technology and unlicensed personnel.
JJ — Board has established policy on allowing pharmacist work breaks without closing the pharmacy.
KK — Meal break provisions. (AL – Meal and break. See Board Rule 680-X-2.28 and Code of Alabama (1975) §34-23-70(a).)
LL — Charitable clinics may reuse unused nursing home medications under a specific permit and regulations. Certain medications defined by regulations sent to a LTCF or correctional facility and returned to the pharmacy within 72 hours may also be reused if the package has not been opened or partially used by the returning facility.
MM — However, Board has a 12-hour per day work limit.
NN — Per Board Rule 480-10-.17 and Chapter 480-50 and DPH Rule 511-5-12.
OO — Unless performing the practice of pharmacy.
PP — Under O.C.G.A. §26-4-110.1(b).
QQ — Pharmacists may not be required to work more than 12 continuous hours in a single workday.

29. Miscellaneous State Pharmacy Laws (cont.)

Legend cont.

RR — Permit reuse and return in specific cases.
SS — Only under very limited conditions set forth in 856 IAC 1-21-1 and IC-25-26-13-25.
TT — Controlled substances only.
UU — Excluding controlled substances.
VV — Institutional setting compounding pharmacies.
WW — Licensed pharmacist shall destroy deteriorated, outdated, unused, or discontinued drugs and biologicals at nursing home in the presence of one witness who is an RN. KAR 28-39-156.
XX — Limited circumstances.
YY — MCL 333.16283 - MCL 333.16288.
ZZ — In hospitals/clinics, policy of Department of Public Health – Drug Control Program.
AAA — If returns from patient – no; returns from nursing home, assisted living facilities, and jails are available under certain circumstances.
BBB — See OAC 4729-5-14.
CCC — Handled by the Department of Health and Senior Services.
DDD — Return and reuse of medication is allowed only for items in manufacturer's sealed packages or unit-dose packages if pharmacist determines they have been properly stored and handled. (GU – In health care facility.)
EEE — Long-term care regulations allow for two nurses or pharmacist and nurse to view disposal of medication. Any pharmacy accepting medication from individuals for disposal is required to register with the Board under the Prescription Drug Repository Program and comply with federal law if collecting controlled dangerous substances for disposal. Regulations pending.
FFF — Allowed in limited circumstances (only if drugs are repackaged as required by current regulations; if ultimate user is a patient in a hospital, nursing home, or assisted living facility).
GGG — Only applies to drugs in LTCF; may be donated to indigent clinics and cancer drug repositories.
HHH — For certain cancer and immunosuppressant drugs.
III — For controlled substances and drugs in LTCFs.
JJJ — Return and reuse permitted only in certain facilities with approved systems for medication storage.
KKK — Restricted to LTCFs and repositories in which drugs are stored appropriately and meet USP Class B packaging requirements or better.
LLL — Refer to 902 KAR 55:065. Although drug repository programs are not licensed, return and reuse of certain drugs are permitted if certain circumstances are met.
MMM — Only under very strict conditions.
NNN — Only in long-term care pharmacies and supervised living groups where drugs have remained in the control of health care provider and are packaged.
OOO — Limited circumstances of certain institutional distribution and cancer drug donation program.
PPP — Voluntary drug donation and redistribution program. The law allows practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, patients or their representatives to donate specific drugs and supplies to participating pharmacies for redispensing. Drugs must meet specific conditions to be eligible to donate. Does not include controlled substances. No drug repository.
QQQ — State drug repository program is not permitted; however, return and reuse of medications are allowed with pharmacist's professional judgment.
RRR — Under very limited conditions; contact the Board for specific requirements.

NABP*LAW* Online Search Terms

Miscellaneous State Pharmacy Laws *(type as indicated below)*

- absence security
- central fill
- continuous quality improvement
- destruction disposal
- drug donation program
- drug repository
- "freedom of choice"
- pharmacy benefit manager
- pharmacist breaks
- pharmacist present security
- pharmacist workload
- practitioner pharmacy owner
- prohibited ownership
- return reuse
- self-inspection

29. Miscellaneous State Pharmacy Laws (cont.)

Legend cont.

SSS — The board has rules regarding the destruction of drugs dispensed to patients in nursing homes, drugs returned to a pharmacy, and the disposal of stock prescription drugs.

TTT — Refer to 54.1-3411.1. Prohibition on Returns, Exchanges, or Re-dispensing of Drugs; Exceptions.

UUU — If a pharmacist-in-charge wishes to dispose of unwanted drugs, he or she shall use one of the following procedures: (1) Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or (2) Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through Schedule V drugs are to be destroyed, additional procedures apply. Disposal of drugs by authorized collectors is allowed following conditions found in Regulation 18VAC110-20-211.

VVV — TCA 63-10 Part 5.

WWW — Secure Drug Take Back Act passed in 2018 (ESHB 1047) mandates that the Department of Health establish a comprehensive drug take-back program that will be fully funded by the pharmaceutical industry.

XXX — OAR 855-041-1170.

YYY — Only remote medication order entry services for health care facility pharmacies.

ZZZ — Cancer drugs only.

A4 — For controlled substances.

B4 — The Department of Public Safety, Narcotics Enforcement Division, has a drug repository program for controlled substances. Return of prescription drugs dispensed or distributed by a pharmacy for administration to patients in an institutional facility allowed under certain conditions. The Department of Health (Chapter 328 C, HRS) allows for the donation of prescription drugs previously dispensed to patients in an institutional facility to be donated to needy persons.

C4 — With Board-approved central fill designation on pharmacy drug outlet registration.

D4 — Pharmacists may not be required to work more than 12 continuous hours in a single workday and are entitled to a 30-minute meal break and another 15-minute break if working more than six continuous hours.

E4 — A pharmacist may accept back and redistribute a drug that was dispensed for a patient in a nursing care facility, ICFMR, state prison, county jail, or state hospital and the drug was returned to the original dispensing pharmacist and is in a unit pack or in the manufacturer's sealed container.

F4 — In accordance with Rules at 21 NCAC 46.2513 and N.C.-GS 90-85.44(c).

G4 — Regulations pending.

H4 — The Minnesota Board of Pharmacy is creating a medication drug repository program through which donors may donate a drug or medical supply for use by an individual who meets certain eligibility criteria.

I4 — See OK Rules 535, Chapter 12. Allowed unused drugs in LTCF to be dispensed in charitable pharmacies and mental health facilities.

J4 — See Code of Alabama 1975 34-23-6 and as mandated by DEA for controlled substances and 680-X-2-.42 for drug disposal receptacles.

K4 — Only as it pertains to prescription laws.

L4 — Unless a drug outlet without an on-site pharmacist or prescriber, then monthly self-inspections are required.

M4 — For Alabama-licensed pharmacies only.

N4 — Centralized prescription processing; Chapter 2, Section 32(e)(iii)(E).

O4 — For pharmacies approved for central fill processes.

P4 — See §22-1915.11.

Q4 — Rules are specific to pharmacies storing, dispensing, and delivering drugs to patients without a pharmacist on site.

R4 — Allows return of drugs if for destruction.

S4 — Pharmacists serving long-term care facilities and/or correctional facilities may accept for return and reuse medications returned to the pharmacy within 72 hours that meet stipulations included in 04-00-0004.

T4 — Charitable pharmacy program. No controlled substances. OAR 855-044.

U4 — Return and reuse allowed only in hospital and correctional pharmacies.

V4 — Pharmacists can provide designated non-dispensing activities remotely or electronically, but cannot remotely supervise pharmacy technicians or perform final product/label verification.

W4 — Charitable pharmacies may reuse unused long-term care facility medications under a specific permit and regulations.

29. Miscellaneous State Pharmacy Laws (cont.)

Legend cont.

X4 — No pharmacist shall work more than eight hours without a meal/rest break.

Y4 — Except that the Board regulates the practice of pharmacy into the state; for example if a PBM was conducting MTM into the state.

Z4 — See §1330.560(b)(1)(E)(vi).

A5 — Regulated by the Department of Insurance.

B5 — §22B-502: Safe Disposal of Unused Pharmaceuticals in Health Care Facilities.

C5 — For entities not licensed in Nebraska, if pharmacist practice impacts Nebraska patients, then pharmacist must hold a Nebraska pharmacist license.

D5 — Must be registered with the Insurance Division in the Department of Consumer and Business Services.

E5 — §22-1501.1.

F5 — For initial pharmacy permit application only.

G5 — As a precursor to the inspection by a compliance officer for verification.

H5 — Yes, for in-state pharmacies. For out-of-state pharmacies, only if home state inspection is two years or older.

I5 — Sterile compounding.

J5 — 18VAC110-20-110(B) – Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day 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.

K5 — See Chapter 4729-8 of the Ohio Administrative Code.

L5 — Self-assessment form must be completed by July 1 of each odd-numbered year.

M5 — Reviewed with inspector upon annual inspection.

N5 — Compounders only (gap analysis).

O5 — In process.

P5 — Michigan Administrative Code R 338.477(5) requires applicants for new license or relocation to complete a self-inspection form.

Q5 — Colorado Department of Public Health and Environment.

R5 — Pharmaceutical Task Force has provided recommendations.

S5 — Limited and specific in statutes. See California Business and Professions Code 4046 and 4169.5 and California Health and Safety Code 150204.

T5 — The Board's prescription drug take-back program became effective on June 6, 2017. See California Code of Regulations Title 16, Article 9.1, including Sections 1776-1776.6.

U5 — Per Board approval, a pharmacy may obtain a remote processing designation on pharmacy registration (see OAR 855-041-3100 to 855-041-3130); per Board approval, a remote distribution facility registration allows supervision of technicians preparing drugs for clinic administration by means of live audio-visual connection (see OAR 855-041-5050 to 855-041-5055).

V5 — Remote dispensing site pharmacy is allowed in medically underserved areas (See CA BPC 4130, 4131, 4132, 4134, and 4135).

W5 — Only in federally qualified health centers.

X5 — See Minnesota Rule 6800.2160, Pharmacy Work Conditions.

Y5 — Requires pharmacies to perform and complete a self-inspection worksheet in March of each year. A new self-inspection form is also required within 30 days of a change in pharmacy's responsible manager.

Z5 — Drug Take Back Law will establish a statewide drug take back program for the safe disposal of drugs, effective 2019.

A6 — The specific practice of "telepharmacy" is not specifically addressed in statute or rule. Section 465.035, F.S., provides that it is lawful for a pharmacy to dispense medicinal drugs, including controlled substances authorized under subsection (2), based on reception of an electronic facsimile of the original prescription if certain conditions are met. Section 465.0235, F.S., also provides that a pharmacy may provide pharmacy services to a long-term care facility or hospice or a state correctional institution through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.

B6 — Under review.

C6 — If PBMs conduct audits, they are subject to the requirements of Indiana Code 25-26-22.

D6 — May be dispensed by a pharmacy or medical equipment supplier. See §54.1-3435.2, §54.1-3435.02, and 18VAC110-20-680.

E6 — For telepharmacy locations only.

29. Miscellaneous State Pharmacy Laws (cont.)

Legend cont.

F6 — Licensure required for Medical Device Manufacturers and Retailers in CA; license is issued by the CA Department of Public Health.
G6 — See §22-1911.2.
H6 — Licensed by the Department of State Health Services.
I6 — Board of pharmacy.
J6 — Under the jurisdiction of the Home Medical Equipment and Services Board, the Board of Orthotics, Prosthetics, and Pedorthics, and the Board of Pharmacy.
K6 — Set forth in 856 IAC 1-39.
L6 — Medical oxygen and medical devices.
M6 — Addressed in the Pharmacy Practice Act.
N6 — As of June 1, 2014, entities that dispense only prescription devices or prescription durable medical equipment are no longer required to obtain a pharmacy permit.
O6 — If the device or oxygen bears the federal legend, the Massachusetts regulations would treat them as Schedule VI controlled substances.
P6 — Same as federal regulations.
Q6 — State board of pharmacy.
R6 — Prohibits a wholesale distributor to sell a prescription device directly to ultimate consumer.
S6 — ORC 4752 and OAC 4729.11.
T6 — Department of Health regulates through the Drug, Device, and Cosmetic Program.
U6 — See BPC 4113.5 Community Pharmacies: Required Staffing.
V6 — Jurisdiction: State Department of Health.
W6 — State law and rules are silent; however, pharmacies have a duty to deliver lawfully prescribed medication in a timely manner within reasonable expectations for filling – rule provides exceptions.

Rules for Pharmacist Working Conditions

NABP*LAW* Search Results –July 2021

Alabama

AL BReg 680-X-2-.28.
Temporary Absences of Pharmacists During Break and Meal Period.

(1) This rule is to allow pharmacists to have breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.
(2) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy area or department, temporarily, for breaks and meal periods without closing the pharmacy and removing interns/externs and technicians from the pharmacy, if the pharmacist reasonably believes that the security of the controlled substances will be maintained in his or her absence.
(a) If, in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should be closed during his or her absence, then the pharmacist shall close the pharmacy area or department and remove all interns/externs and technicians from the pharmacy during his or her absence.
(3) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a new or refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.
(4) During such times that the pharmacist is temporarily absent from the pharmacy area or department, the interns/externs and technicians may continue to perform the non-discretionary duties authorized to them by any applicable law or rule. However, any duty performed by an intern/extern or technician shall be reviewed by a pharmacist upon his or her return to the pharmacy.
(5) The temporary absence authorized by this rule shall be limited to thirty (30) minutes. The pharmacist shall remain within the facility during the break period and be available to handle all emergency situations.
(6) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy area or department during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of interns/externs and technicians, the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.

NABP*LAW* 10/2016

California

CA BReg 1714.5.
Dangerous Drugs and Devices Exempt from the Provisions of Chapter 9, Division 2 of the Business and Professions Code.

This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.
(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.
If in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.
(b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.
(c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.
(d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist.
(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission, and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.
(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours.
(g) For the purposes of this section, ancillary staff includes: an intern pharmacist, a pharmacy technician, non-licensed personnel as defined in Section 1793.3 of Title 16 of the California Code of Regulations and a pharmacy technician trainee as defined in Section 4115.5(a) of the Business and Professions Code.

Georgia

GA Policy 5.
Guidelines to Ensure Safe Pharmacy Practice.

Purpose: The Georgia State Board of Pharmacy has developed these guidelines to ensure the protection of the health, safety and welfare of Georgia's citizens as related to the scope and quality of Pharmacy Care and Services provided by the licensed Pharmacies and Pharmacists under the Board's jurisdiction.

General Guidelines: The following guidelines constitute what the Board feels is necessary to ensure Safe Pharmacy Practice:

• Each individual workplace should be designed to provide adequate space and workflow design that will accommodate the workplace in an organized fashion.

• Computers and other automated equipment should be of a design that drug interactions and contraindications MUST BE REVIEWED BY THE PHARMACIST. Further, the computer system should be of a design to support counseling, DUR documentation and other safeguards to meet legal and regulatory requirements. Adequately trained or experienced professional and supportive staff levels should be maintained to meet the demands of the practice site, workload and clientele served. It should be noted that both the number and the training or experience level of all staff are important. Other factors that could increase staffing levels include demand for OTC recommendations by customers, telephone interruptions, patient teaching and demands of managed care organizations and other third party programs.

• Staff should have the opportunity to take periodic "breaks" and/or meal periods to relieve fatigue and mental and physical stress. Staff should also have opportunities for training and education to keep them abreast of new information and changes in the field.

• Workload quotas or formulas such as strictly using the number of prescriptions or orders processed to set staffing patterns must include other considerations such as peak workload periods, workplace design, training of staff on duty, etc. to adequately meet the needs of the public.

Discussion: Ensuring that practicing pharmacists and pharmacies serving the public are providing accurately filled prescriptions, accurate and timely information for the use of the prescriptions filled and that the desired outcome of the therapy is achieved is the essence of Pharmacy Care. In today's competitive marketplace, the issues related to achieving this should provide the opportunity to succeed.

Institution of quotas and/or additional regulations would be difficult and hard to enforce but might be required. Liability, responsibility and sanctions must be shared equitably by the owner or management of the pharmacy and the individual practitioner. In addition to the 8 above guidelines, the Board officers below, indicators that workload is too great for the staff or the Safe Pharmacy Practice Guidelines are not being followed and disciplinary action may be in order.

Indicators:
- An inordinate number of filling errors occur
- Patients are not properly counseled
- Patient or customer complaints

- Continuing pharmacist complaints related to working conditions
- Failure to comply with patient counseling or other rules and regulations
- Inadequate supervision and training of supportive personnel

History: Adopted: October 22-23, 1997. Amended: May 13, 2003.

Illinois

IL Law 85-15.1.
Pharmacy working conditions.

§ 15.1. Pharmacy working conditions.

(a) A pharmacy licensed under this Act shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subsection (b).

(b) A pharmacist who works 6 continuous hours or longer per day shall be allowed to take, at a minimum, one 30-minute uninterrupted meal break and one 15-minute break during that 6-hour period. If such pharmacist is required to work 12 continuous hours per day, at a minimum, he or she qualifies for an additional 15-minute break. A pharmacist who is entitled to take such breaks shall not be required to work more than 5 continuous hours, excluding a 15-minute break, before being given the opportunity to take a 30-minute uninterrupted meal break.

If the pharmacy has a private break room available, or if there is a private break room in the establishment or business in which the pharmacy is located, a pharmacist who is entitled to breaks must be given access to that private break room and allowed to spend his or her break time in that room.

(c) A pharmacy may, but is not required to, close when a pharmacist is allowed to take a break under subsection (b). If the pharmacy does not close, the pharmacist shall either remain within the licensed pharmacy or within the establishment in which the licensed pharmacy is located in order to be available for emergencies. In addition, the following applies:

(1) pharmacy technicians, student pharmacists, and other supportive staff authorized by the pharmacist on duty may continue to perform duties as allowed under this Act;

(2) no duties reserved to pharmacists and student pharmacists under this Act, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians or other supportive staff; and

(3) only prescriptions that have received final verification by a pharmacist may be dispensed while the pharmacist is on break, except those prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which

a pharmacist has determined that counseling is necessary, may be dispensed only if the following conditions are met:

(i) the patient or other individual who is picking up the prescription on behalf of the patient is told that the pharmacist is on a break and is offered the chance to wait until the pharmacist returns from break in order to receive counseling;

(ii) if the patient or other individual who is picking up the prescription on behalf of the patient declines to wait, a telephone number at which the patient or other individual who is picking up the prescription on behalf of the patient can be reached is obtained;

(iii) after returning from the break, the pharmacist makes a reasonable effort to contact the patient or other individual who is picking up the prescription on behalf of the patient and provide counseling; and

(iv) the pharmacist documents the counseling that was provided or documents why counseling was not provided after a minimum of 2 attempts, including a description of the efforts made to contact the patient or other individual who is picking up the prescription on behalf of the patient; the documentation shall be retained by the pharmacy and made available for inspection by the Board or its authorized representatives for at least 2 years.

(d) In a pharmacy staffed by 2 or more pharmacists, the pharmacists shall stagger breaks so that at least one pharmacist remains on duty during all times that the pharmacy remains open for the transaction of business.

(e) A pharmacy shall keep and maintain a complete and accurate record showing its pharmacists' daily break periods.

(f) Subsections (a) and (b) shall not apply when an emergency, as deemed by the professional judgment of the pharmacist, necessitates that a pharmacist, student pharmacist, or pharmacy technician work longer than 12 continuous hours, work without taking required meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.

History: P.A. 85-796, § 15.1, added by P.A. 101-621, § 10, eff. Jan. 1, 2020.

Iowa

IA BReg 657-13.9(155A).
General requirements for managing pharmacy.

13.9(1) Distance to telepharmacy site. The managing pharmacy shall be located in Iowa and within a 200-mile radius of a telepharmacy site to ensure that the telepharmacy site is sufficiently supported by the managing pharmacy and that necessary personnel or supplies may be delivered to the telepharmacy site within a reasonable period of time of an identified need.

13.9(2) Emergency preparedness plan. A managing pharmacy shall develop and include in both the managing pharmacy's and the telepharmacy site's policies and procedures a plan for continuation of pharmaceutical services provided by the telepharmacy site in case of an emergency interruption of the telepharmacy site's services. The plan shall address the timely arrival at the telepharmacy site of necessary personnel or the delivery to the telepharmacy site of necessary supplies within a reasonable period of time following the identification of an emergency need. The plan may provide for alternate methods of continuation of the services of the telepharmacy site including, but not limited to, personal delivery of patient prescription medications from an alternate pharmacy location or on-site pharmacist staffing at the telepharmacy site.

13.9(3) Pharmacist in charge. The pharmacist in charge of the managing pharmacy shall be the pharmacist in charge of the telepharmacy site.

13.9(4) Adequate audiovisual connection. The pharmacist in charge shall ensure adequate audiovisual connection with the telepharmacy site during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.9(5) Monthly inspection. The pharmacist in charge or delegate pharmacist shall be responsible for performing a monthly inspection of the telepharmacy site. Inspection reports shall be signed by the individual pharmacist who performed the inspection. Inspection records and reports shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy. The monthly inspection shall include, but may not be limited to, the following:

a. Audit and reconciliation of controlled substances perpetual and physical inventories.

b. Audit of electronic entry system and records.

c. Verification that the video recording system is functioning properly and that the recordings are maintained and available for at least 60 days past the date of the recording.

d. Compilation of a record of the number of prescriptions filled, the number of on-site pharmacist hours, and the number of hours the pharmacy site was open for business during the preceding month.

e. Review of written policies and procedures and verification of compliance with those policies and procedures.

f. Ensuring compliance with and review of records in the continuous quality improvement program, following up with responsible personnel to address issues identified by incident reports to prevent future incidents.

g. Review of records of the receipt and disbursement of prescription drugs, including controlled substances, to ensure compliance with record-keeping requirements.

h. Inspection of drug supplies and storage areas to ensure removal and quarantine of outdated drugs.

i. Inspection of stock drug supplies and storage areas to ensure drugs are maintained in a manner to prevent diversion and maintain the integrity of the drugs, verifying that the temperatures of storage areas are appropriate for the stored drugs and equipment.

j. Inspection of pharmacy and storage areas and shelves to ensure areas and shelves are clean and free of pests and other contaminants.

13.9(6) On-site pharmacist staffing. In an effort to promote public health, the telepharmacy site shall be staffed by a pharmacist for at least 16 hours per month. While on site, the pharmacist shall make available to the community general health care services, which may include, but not

necessarily be limited to, immunizations, medication therapy management, or health screenings, as deemed necessary and appropriate by the pharmacist in charge and as provided by policies and procedures.
a. If a pharmacist will be available at the telepharmacy site to provide in-person patient services, a consistent schedule of the pharmacist's availability shall be established and published.
b. Signage identifying the days and times when a pharmacist is on site and available to patients shall be conspicuously posted at the telepharmacy site and may be published by other means, as deemed appropriate.
c. Notice that the pharmacist will not be present at the telepharmacy site during any routinely scheduled and posted on-site availability shall be provided to the public in advance of the absence except as provided in the emergency preparedness plan.
d. If the average number of prescriptions dispensed per day by the telepharmacy site exceeds 150 prescriptions, the telepharmacy site shall provide on-site pharmacist staffing 100 percent of the time the pharmacy is open for business and shall, within ten business days, apply to the board for licensure as a general pharmacy. The average number of prescriptions dispensed per day shall be determined by averaging the number of prescriptions dispensed per day over the previous 90-day period.

NABP*LAW* 12/2017

Massachusetts

MA Policy 2000-03
Policy on Pharmacy Operations During the Temporary Absence of a Pharmacist

Board Regulations at 247 CMR § 6.02(9)(a) state:
" A registered pharmacist shall be on duty and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy department"
This requirement shall not apply during the temporary absence of a pharmacist as set forth below provided that the following requirement is strictly adhered to at all times during the temporary absence of the pharmacist.

This policy is adopted to ensure that pharmacists are able to have necessary and appropriate duty free breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.

a. **In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for necessary and appropriate breaks and meal periods without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.**
If in the professional judgment of the pharmacist, for reasons of security or otherwise, the

pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

b. During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked; and determined not to require the consultation of a pharmacist; prior to being released for furnishing to the patient.
A new prescription which has been previously prepared, visibly checked by a pharmacist and had a drug utilization performed by a pharmacist, may be picked up by a patient provided that a log, including the patients phone number, of all such transactions is kept. The pharmacist, upon return from break, and within a reasonable time, shall call the patient to review any pertinent counseling deemed appropriate.

c. During such times that the pharmacist is temporarily absent from the pharmacy, the pharmacy technical support staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

d. Pharmacist managers, at their discretion, may develop a written policy for allowing Pharmacy Technician Certification Board ("PTCB") and/or Board approved certified technicians and pharmacy interns to receive telephone prescription orders from practitioners, unless otherwise prohibited by law.

e. In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not left without a pharmacist for a temporary period.

f. The temporary absence authorized by this section shall not exceed 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period, however the pharmacist shall be required to remain on the premises, licensed by the Board. The total temporary absence shall not exceed more than 30 minutes absence during any work period of at least six consecutive hours.

g. The pharmacy shall have written policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.

A pharmacist who temporarily leaves the pharmacy for a break or meal period in compliance with this section shall not be subject to Massachusetts Board of Registration in Pharmacy disciplinary action or for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence.

Minnesota

MN BReg 6000.2160.
Pharmacy work conditions.

Subpart 1. Limitation on continuous hours worked. A pharmacy licensed under Minnesota Statutes, section 151.19, subdivision 1, which is located within Minnesota, shall not require a pharmacist, pharmacist-intern, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subpart 2.
Subp. 2. Requirements for breaks.
A. A pharmacist, pharmacist-intern, or pharmacy technician working longer than six continuous hours per day shall be allowed during that time period to take a 30-minute, uninterrupted break.
B. A pharmacist, pharmacist-intern, or pharmacy technician shall be allowed adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.
C. A pharmacy may, but is not required to, close when a pharmacist is on a break. If the pharmacy does not close, the pharmacist shall either remain within the licensed pharmacy or within the establishment in which the licensed pharmacy is located in order to be available for emergencies. In addition, the following apply:
(1) pharmacy technicians, pharmacist-interns, and other supportive staff, authorized by the pharmacist on duty, may continue to perform duties as allowed under this chapter;
(2) no duties reserved to pharmacists and pharmacist-interns under any part of this chapter, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians or other supportive staff; and
(3) only prescriptions that have been certified by a pharmacist, as required by part 6800.3100, may be dispensed while the pharmacist is on break; except that prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may be dispensed only if the following conditions are met:
(a) the pharmacy develops a list of drugs that may not be dispensed while a pharmacist is taking an allowed break, without the patient receiving counseling from a pharmacist, when counseling would normally be required;
(b) the patient, or other individual who is picking up the prescription on behalf of the patient, is told that the pharmacist is on a break and is offered the chance to wait until the pharmacist returns from break in order to receive counseling;
(c) if the patient or caregiver declines to wait, a telephone number at which the patient or a caregiver can be reached is obtained;
(d) after returning from the break, the pharmacist makes a reasonable effort to contact the patient or a caregiver by telephone and provides counseling; and
(e) the pharmacist documents the counseling that was provided or documents why counseling was not provided, including a description of the efforts made to contact the patient or caregiver. The documentation shall be retained by the pharmacy, and be made available for inspection by the board or its authorized representatives, for a period of at least two years.
D. In pharmacies staffed by two or more pharmacists, the pharmacists shall stagger breaks so that at least one pharmacist remains on duty at all times that the pharmacy remains open for the transaction of business.

Subp. 3. Exceptions for emergencies. Subpart 1 and subpart 2, item A, shall not apply in the event that an emergency necessitates that a pharmacist, pharmacist-intern, or pharmacy

technician work longer than 12 continuous hours, work without taking required meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.

Mississippi

MS Rule 30-20-3001:VII.
Responsibility of Pharmacist-In-Charge (PIC).

1. The person who signs the application for a pharmacy permit or the renewal of a pharmacy permit shall be the pharmacist-in-charge (PIC) for that facility.

A. Authority. The PIC of the pharmacy shall be responsible for complete supervision, management and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy in the entire prescription department. He/She shall have the cooperation and support of all pharmacy staff in carrying out these responsibilities. The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted.

A pharmacist shall not be the PIC at more than one Community Pharmacy or Institutional I Pharmacy (unless the Board grants a waiver upon presentation of good cause) and shall not be the pharmacist-in-charge or have personal supervision of more than one facility which is open to the general public on a full-time basis.

B. Recommended Guidelines:

(1) That each individual work space is designed to provide space and a work flow design that will accommodate the workload in an organized fashion; and

(2) That the computer's software should be of a design so that drug interactions and contraindications must be reviewed by the pharmacist. Further, the computer system should support counseling and drug utilization review documentation; and

(3) That trained supportive staff should be maintained to meet the demands of the practice site, workload and the clientele served; and

(4) That all staff should have the opportunity to take periodic breaks and/or meal periods to relieve fatigue and mental and physical stress. Nothing in this paragraph suggests closing the pharmacy; and

(5) That all staff should be afforded and encouraged to participate in training and continuing education in order to keep them abreast of new information and changes in the field; and

(6) That if quotas or formulas such as prescription volume are used to set staffing, conditions such as peak workload periods, workplace design and the training of staff must be taken into consideration.

C. Circumvention. It is a violation of this section for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department for the compliance with federal and state drug or pharmacy laws and regulations. Any such circumvention may result in charges being filed against the pharmacy permit.

Montana

MT BReg 24.174.411.
Pharmacist meal/rest breaks.

(1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.
(2) The time of the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area.
(3) In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.
(4) The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.
(5) When authorized by the pharmacist, only registered technicians and interns directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.
(6) Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.
(7) In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.
(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.
(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.
(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.
(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.
(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.

NABP*LAW* 11/2016

Nevada

NV Rule 639.556.
Meal periods and rest periods for employees of pharmacy. NRS 639.070, 639.220.

1. Except as otherwise provided in this section and NRS 639.220:
(a) The owner of a pharmacy shall permit each employee of the pharmacy to take meal periods and rest periods as required by NRS 608.019 or any applicable collective bargaining agreement; and
(b) A pharmacy may schedule a regular time during which a pharmacist employed by the pharmacy may take a meal period.
2. If there is more than one pharmacist on duty at the time that a pharmacist takes a meal period, the pharmacist who is taking the meal period may, at his or her discretion, remain on the premises of the pharmacy or leave the premises of the pharmacy.
3. Except as otherwise provided in NRS 639.220, if a pharmacist is the only pharmacist on duty at the time he or she takes a meal period, the pharmacist may, at his or her discretion, remain on the premises of the pharmacy or leave the premises of the pharmacy. If the pharmacist chooses to remain on the premises of the pharmacy, the pharmacist may not be interrupted or disturbed to conduct his or her work as a pharmacist, unless the pharmacist has agreed to such an interruption. If the pharmacist chooses to leave the premises of the pharmacy, the pharmacist shall:
(a) Close and secure the pharmacy pursuant to NAC 639.520; and
(b) Post a sign that is visible to the public stating the time the pharmacist will return from the meal break.
4. A pharmacy that is closed and secured during the meal period of a pharmacist pursuant to subsection 3 may accept a prescription during the meal period if:
(a) The prescription is placed by the patient or the patient's agent or representative in a secure container or receptacle that ensures that the prescription cannot be seen, removed or damaged until it is retrieved by a pharmacist or other authorized employee of the pharmacy; or
(b) An authorized employee of the pharmacy personally accepts and secures the prescription from the patient or the patient's agent or representative outside the closed and secured premises of the pharmacy.
5. A pharmacy may require a pharmacist to remain on the premises of the pharmacy during a rest period, but may not require the pharmacist to serve the public during the rest period. The pharmacist may, at the discretion of the pharmacist, agree to have his or her rest period interrupted.
6. The provisions of this section do not affect any other provision of law regarding the practice of pharmacy.

History: Added to NAC by Bd. of Pharmacy by R152-05, eff. 12-29-2005.

NABP*LAW* 07/2019

New Hampshire

NH Rule Ph 704.01.
Presence of Pharmacists.

(a) No pharmacist shall work more than 8 hours without a rest break of 30 minutes. Breaks shall be scheduled as close as possible to the same time each day so that patients may become familiar with the approximate break times.

(b) Whenever the prescription department is staffed by a single pharmacist, the pharmacist may take a rest break for a period of 30 minutes without closing the pharmacy and removing support personnel from the pharmacy, provided that the pharmacist reasonably believes that the security of the prescription drugs will be maintained in the pharmacist's absence.

(c) Pharmacy technicians, NH certified pharmacy technicians and pharmacy interns may remain in the pharmacy if the pharmacist on duty reasonably believes that the security of the prescription drugs will be maintained in his or her absence and in accordance with the following:

(1) Rest breaks shall be scheduled as close as possible to the same time each day in order for the patients to become familiar with the approximate times of breaks;

(2) The pharmacist shall remain on the premises, within the building, during the rest break and be available for emergencies. Emergencies shall be defined by the pharmacist;

(3) Whenever the pharmacist temporarily leaves the prescription department for a rest break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in full view of patients approaching the prescription department service area. The signage shall also indicate the time when the pharmacist is to return;

(4) Only pharmacy technicians or pharmacy interns authorized by the pharmacist on duty may remain in the pharmacy while the pharmacist is on break;

(5) During such times that the pharmacist is temporarily absent from the pharmacy, only pharmacy technicians or pharmacy interns duly authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. However, all duties performed by the technicians or interns shall be reviewed by the pharmacist upon his or her return from break;

(6) When a pharmacist is not in the pharmacy, there shall be no dispensing or sale of new prescriptions that the pharmacist has checked and are waiting to be picked up nor shall counseling be provided by the pharmacy technician or pharmacy intern;

(7) New, written prescriptions, presented in person by the patient or his agent, may be accepted by the pharmacy technician or pharmacy intern and the processing of that prescription, up to the final check, may occur during the absence of the pharmacist. However, no new prescriptions

may be dispensed or sold until the final check is completed by the pharmacist on his or her return;

(8) New prescriptions conveyed by telephone shall be accepted by a NH certified pharmacy technician or pharmacy intern or when authorized by the pharmacist or the caller shall be instructed to call back, or a telephone number obtained for the pharmacist to call upon his or her return;

(9) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or his agent. If the patient has no questions, the sale may proceed as normal with the patient signing a statement indicating the refusal of counseling by the pharmacist. If the patient desires counseling, he or she shall be asked to wait for the pharmacist to return from break or, alternatively, asked to leave a telephone number for the pharmacist to call later that day; and

(10) Telephone refill orders as well as refill requests presented, in person, by the patient or his agent, may be accepted by the pharmacy technician or intern and such refill orders may be processed by the technician or intern up to the final check. However, no such refill orders shall be dispensed or sold until the final check is completed by the pharmacist on his or her return from break.

(d) A pharmacist who takes a rest break in compliance with this section shall continue to be responsible for the operation and security of the pharmacy department. Therefore, if in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy. All pharmacy technicians, NH certified pharmacy technicians, and pharmacy interns shall leave the pharmacy during his or her absence. A sign informing the public of the pharmacist's return shall be conspicuously posted.

(e) Pharmacists shall follow company protocols in leaving the pharmacy department unattended for any reason, such as but not limited to counselling patients, giving immunizations, or rest room breaks.

New Jersey

NJ BReg 13:39-6.4.
Meal or restroom breaks.

(a) A sole pharmacist on duty may take restroom breaks and 30-minute meal breaks while working in a pharmacy consistent with the following requirements:

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;

2. The pharmacy shall remain open during the restroom or meal breaks, provided a pharmacy employee remains present in the pharmacy, for patient related services, which include, but are not limited to, the following:

i. The receipt of new written prescriptions; and

ii. The dispensing of prescription medications which have been checked by the pharmacist; and

3. A sign shall be posted in the prescription dispensing area stating "Pharmacist on break, but available for emergencies and counseling."

NABP*LAW* 11/2016

North Carolina Part I

NC BReg 2512.
Pharmacist work conditions.

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.

NABP*LAW* 01/2018

North Carolina Part II

NC BReg .1811.
Excessive dispensing of prescription drugs.

Pharmacists shall not dispense and permit holders shall not allow a pharmacist to dispense prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety.

Oklahoma

OK Rule 535-15-3-16.
Adequate staffing rules for pharmacists and pharmacies.

(a) 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.

(b) In order to ensure adequate staffing levels a staffing form shall be available in each pharmacy. A copy of this form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection.

(1) Such form shall include, but not be limited to the following:

(A) Date and time the inadequate staffing occurred;

(B) Number of prescriptions filled during this time frame;

(C) Summary of events; and

(D) Any comments or suggestions.

(2) Such forms are not to be sent to the Board.

(c) A pharmacist shall complete the staffing report form when:

(1) A pharmacist is concerned regarding staffing due to:

(A) inadequate number of support persons (cashiers, technicians, auxiliary supportive personnel, etc.); or,

(B) excessive workload;

(2) Filling out the form may enable management to make a better decision concerning staffing.

(d) If the pharmacy manager feels that the situation warrants earlier Board review, the pharmacy manager shall inform the Board.

(e) Each pharmacy shall review completed staffing reports and address any issues listed as well as document any corrective action taken or justification for inaction to assure continual self-improvement. If the issue is not staffing related, measures are being taken to address the issue should be described.

(f) 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.

(g) 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 good faith.

History: Reserved at 14 Ok Reg 3024, eff 7-1-97; Added at 22 Ok Reg 2172, eff 7-1-05; Amended at 32 Ok Reg 1229, eff 8-27-15.

Oregon

OR BReg 855-041-1170
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(1) Unprofessional conduct as defined in OAR 855-006-0005;

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:

(A) Drug Utilization Review;

(B) Immunization;

(C) Counseling;

(D) Verification of the accuracy of a prescription; and

(E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.

(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

(5) Incenting or inducing the transfer of a prescription absent professional rationale.

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Pennsylvania

PA Rule 27.11.
Pharmacy permit and pharmacist manager.

(a) A permit to conduct a pharmacy issued under section 4 of the act (63 P. S. § 390-4) shall show the name and address of the pharmacy, the name of the current owner and the name of the current pharmacist manager.

(b) A pharmacy may not display, advertise or use any name other than the name in which it is registered.

(c) The prescription area of a pharmacy may not be open without a licensed pharmacist on duty at all times. A sole pharmacist on duty may take up to a 30-minute break while the pharmacy remains open consistent with the following:

(1) The pharmacist shall remain in the pharmacy, or in the case of a pharmacy located within a retail establishment or institution, in the immediate building containing the pharmacy, and shall be accessible for emergencies or for counseling, if requested. For purposes of this paragraph, the term "immediate building" means the physical structure that contains the pharmacy. A pharmacy located at a complex consisting of multiple retail and other business establishments, such as a mall, is not considered to be "located within a retail establishment." In that case, the entire store containing the pharmacy is licensed, and the pharmacist shall remain in the store during a break.

(2) The pharmacy may remain open during the pharmacist's break for patient-related services, including:

(i) The receipt of new written prescriptions.

(ii) The preparation of prescriptions for final verification by the pharmacist.

Rhode Island

RI Rule 40-15-1.5.
Pharmacies: Licensure Requirements.

1.5.1 Licensure Requirements: Pharmacies

A. Pursuant to R.I. Gen. Laws § 5-19.1-9, no person shall conduct, maintain, or operate a pharmacy in the State of Rhode Island without first obtaining and having in force a pharmacy license in accordance with the statutory provisions of the Act and the regulatory requirements of this Part.

B. Restricted Pharmacies: Pursuant to R.I. Gen. Laws § 5-19.1-10, upon application of the plan administrator or trustee of any trust, fund, pension plan, combination plan, or profit sharing plan, which is subject to the provisions of the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.*, the Board may license a facility, hereinafter called a restricted pharmacy, for the purpose of dispensing pharmacy services to beneficiaries; provided, however, that no such license shall be granted unless the said trust, fund or plan demonstrates to the satisfaction of the Board that it is associated with another such trust, fund or plan already licensed in another State to own and operate a restricted pharmacy for the purpose of dispensing pharmacy services to its beneficiaries. Charges for such serviced shall be determined by the trustee or plan administrator. A restrictive pharmacy may, after written notice to the Board, limit its operation to a specific schedule of drugs.

1. Nothing in this section shall prohibit a restricted pharmacy from accepting or filling prescriptions by mail; provided, that the prescribing physician is verified, according to the procedures established by R.I. Gen. Laws Chapter 5-37, as licensed to practice in the State of Rhode Island or in any New England State.

C. Any pharmacy that utilizes latex gloves shall do so in accordance with the provisions of the Rules and Regulations pertaining to the Use of Latex Gloves by Healthcare Workers, in Licensed Healthcare Facilities, and by Other Persons, Firms, or Corporations Licensed or Registered by the Department (Part 20-15-3 of this Title).

D. A mechanism shall be in place to verify current licensure for every individual within the pharmacy who is licensed, certified, or registered by the State of Rhode Island. Documentation of current licensure shall be maintained by the pharmacy.

E. All pharmacies shall maintain an adequate number of pharmacists and pharmacy technicians to meet pharmacy workload demands, provide for adequate rest periods for personnel, and maintain public safety. Pharmacy staffing information shall be provided to the Department upon request, including but not limited to number of pharmacists and pharmacy technicians, prescription volume, pharmacy hours of operation, and staff schedules.

Vermont

VT BReg 20-4-1400:9.21.
Pharmacist Meal/Rest Breaks

(a) Whenever the prescription department is staffed by a single pharmacist, the pharmacist may take a meal/rest break for a period of up to 30 minutes without closing the pharmacy and removing support personnel from the pharmacy, provided that the pharmacist reasonably believes that the security of the prescription drugs will be maintained in the pharmacist's absence.

(b) No pharmacist shall work more than 8 hours without a meal/rest break. Breaks should be scheduled as close as possible to the same time each day, so that patients may become familiar with the approximate time of the breaks

(c) The pharmacist shall remain on the premises of the drug outlet during the meal/rest break and shall be available for emergencies.

(d) If two or more pharmacists are on duty in the prescription department, the pharmacists shall stagger their meal/rest breaks so that the prescription department is not left without a pharmacist on duty.

(e) Whenever the pharmacist temporarily leaves the prescription department for a meal/rest break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed. The sign shall also indicate the time when the pharmacist will return.

(f) Only support personnel directly involved in the prescription dispensing process and authorized by the pharmacist on duty may remain in the prescription department while the pharmacist is on a meal/rest break.

(g) When the pharmacist is temporarily absent from the prescription department, support personnel authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. All such duties performed by support personnel shall be reviewed by the pharmacist upon return from the meal/rest break.

(h) When a pharmacist is not in the prescription department, there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by support personnel.

(i) New, written prescriptions presented by the patient or the patient's agent may be accepted by support personnel. The processing of such prescriptions, up to the final check, may occur in the absence of the pharmacist. However, no prescription may be dispensed until the final check is completed by the pharmacist after return to the prescription department.

(j) New prescriptions conveyed by telephone shall not be accepted by support personnel. The caller should be instructed to call back, or a telephone number should be obtained for the pharmacist to call upon return to the prescription department.

(k) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or the patient's agent. Support personnel must offer the patient counseling by the pharmacist. If the patient has no questions, dispensing may proceed as usual, with the patient signing for the counseling refusal. If the patient desires counseling, the patient should be asked to wait for the pharmacist to return from

the meal/rest break. Alternatively, the patient may be asked to leave a telephone number for the pharmacist to call later the same day.

(l) Telephone refill orders and refill requests presented in person by the patient or the patient's agent may be accepted by support personnel. Such refill orders may be processed by support personnel up to the final check. However, no such refill orders shall be dispensed until the final check is completed by the pharmacist after return from the meal/rest break.

(m) Under this rule, the pharmacist-manager remains responsible for the direct management, supervision, and control of the prescription department.

(n) If, for security reasons or otherwise, the pharmacist determines that the prescription department should close during the pharmacist's absence, the pharmacist shall close the prescription department and remove all support personnel from the prescription department during the pharmacist's absence. A sign informing the public of the pharmacist's temporary absence and time of return shall be conspicuously posted.

(o) Using this rule as a guide, the pharmacist-manager, in conjunction with the pharmacy license holder, should develop written policies and procedures regarding operation of the prescription department while the pharmacist is temporarily absent on a meal/rest break.

(1) The policies and procedures should include authorized duties of support personnel and should define the pharmacist's responsibilities for checking all work performed by support personnel and for maintaining security of the prescription department. The pharmacist-manager should review the policies and procedures with support personnel.

(2) After review, each support person should be requested to initial the policies and procedures to indicate that the policies and procedures are understood.

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Virginia

VA Rule 18 VAC 110-20-110.
Pharmacy Permits Generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day 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.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

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Article IV
Discipline

Introductory Comment to Article IV

At the very heart of any Pharmacy Act is the enforcement power of the Board of Pharmacy. The Board must have authority to discipline and/or prohibit Pharmacies, Pharmacists, Pharmacy Interns, Certified Pharmacy Technicians, or Certified Pharmacy Technician Candidates who violate this Act or Rules from continuing to threaten the public if it is to fulfill its responsibilities. The Board must have the ability to stop wrongdoers, either permanently or temporarily, discipline them, and, where appropriate, to guide and assist errant licensees in rehabilitating themselves.

The Model Act *disciplinary provisions are contained in Article IV. They were drafted with the purpose of granting to the Board the widest possible scope within which to perform its disciplinary functions. Standardized disciplinary action terms and definitions were developed to facilitate the accurate reporting of disciplinary actions taken by Boards of Pharmacy and to avoid confusion associated with state-to-state variations in terms and definitions. The grounds for disciplinary action were developed to ensure protection of the public, while reserving to the Board the power to expand upon them and adapt them to changing or local conditions as necessary. The penalties permitted under the* Model Act *will afford the Board the flexibility to conform and relate discipline to offenses.*

Section 401. Disciplinary Action Terms.

The following is a list of disciplinary actions that may be taken, issued, or assessed by the Board of Pharmacy: Revocation, Summary Suspension, Suspension, Probation, Censure, Reprimand, Warning, Cease and Desist, Fine/Civil Penalty, Costs/Administrative Costs.[1]

Section 402. Grounds, Penalties, and Reinstatement.[2]

(a) The Board of Pharmacy may refuse to issue or renew, or may Revoke, Summarily Suspend, Suspend, place on Probation, Censure, Reprimand, issue a Warning against, or issue a Cease and Desist order against, the licenses or the registration of, or assess a Fine/Civil Penalty or Costs/Administrative Costs against any Person Pursuant to the procedures set forth in Section 403 herein below, upon one or more of the following grounds:

(1) unprofessional conduct as that term is defined by the rules of the Board;[3]

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[1] Guidelines for the imposition of sanctions for certain designated offenses can be found in Appendix C: Guidelines for Disciplinary Sanctions of the *Model Act*.

[2] The penalties provided in Section 402 give the Board wide latitude to make the disciplinary action fit the offense. The "reasonable intervals" in 402(c) would be determined by the Board.

[3] It is particularly important to emphasize the need for specificity in defining the grounds upon which a Pharmacist's or Pharmacy Intern's license to practice Pharmacy, or a Certified Pharmacy Technician's or Certified Pharmacy Technician Candidate's registration to assist in the Practice of Pharmacy, may be Revoked or Suspended. The term "unprofessional conduct" is particularly susceptible to judicial challenge for being unconstitutionally vague. Each offense included within the meaning of this term must be capable of being understood with reasonable

(2) incapacity that prevents a licensee from engaging in the Practice of Pharmacy or a registrant from assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public;[4]

(3) being guilty of one (1) or more of the following:
   (i) a felony; or
   (ii) violations of the Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;[5]

(4) disciplinary action taken by another state or jurisdiction against a license or other authorization to Practice Pharmacy based upon conduct by the licensee similar to conduct that would constitute grounds for actions as defined in this section, which involves or may result in direct patient impact or harm in states other than that of the initiating Board;

(5) failure to report to the Board any adverse action taken by another licensing jurisdiction (United States or foreign), government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this section;

(6) failure to report to the Board one's surrender of a license or authorization to Practice Pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this section;

(7) failure to report to the Board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this section;

(8) knowing or suspecting that a Pharmacist or Pharmacy Intern is incapable of engaging in the Practice of Pharmacy or that a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate is incapable of assisting in the Practice of Pharmacy, with reasonable skill, competence, and safety to the public, and failing to report any relevant information to the Board of Pharmacy;

(9) misrepresentation of a material fact by a licensee in securing the issuance or renewal of a license or registration;

(10) fraud by a licensee in connection with the Practice of Pharmacy;

(11) affiliating with websites that may deceive or defraud patients or that violate Pharmacy or Drug laws of this State or rules and regulations pertaining thereto; or of laws, rules, and regulations of any other state; or of the Federal government;

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precision by the Persons regulated so that it can be readily enforced and relied upon during disciplinary proceedings, and so that those regulated by it may easily conform their professional conduct to its meaning(s).

These potential problems make it essential for Boards to issue appropriate rules making the grounds for disciplinary action specific, understandable, and reasonable. In addition, the Boards must ensure that such rules are published for the benefit of all licensees within their jurisdiction. Only by doing so can Boards be assured of authority to take successful and meaningful disciplinary actions that will not later be overturned by the courts.

This section must be examined in light of other state laws since some states, for example, restrict the circumstances under which a license may be denied to an individual because of the commission of a felony. In addition, an individual who has been convicted of a felony and who has paid his debt to society has restored constitutional protections that may curtail a strict application of Section 402(a)(3).

[4] Boards need to consider the issue of impairment if a registrant or licensee tests positive for a substance of misuse and/or abuse.

[5] It is contemplated that Boards of Pharmacy will consider state and federal law, including any discrepancies between state and federal law, when evaluating complaints against a registrant or licensee related to a positive result on a cannabinoid Drug test. It is also contemplated that any complaint of this nature will be assessed on a case-by-case basis.

(12) engaging, or aiding and abetting an individual to engage in the Practice of Pharmacy without a license; assisting in the Practice of Pharmacy or aiding and abetting an individual to assist in the Practice of Pharmacy without being licensed by the Board of Pharmacy; or falsely using the title of Pharmacist, Pharmacy Intern, Certified Pharmacy Technician, or Certified Pharmacy Technician Candidate;

(13) requiring Pharmacy personnel to meet production and/or performance metrics and/or quotas that negatively impact patient safety.[6]

(14) failing to pay the costs assessed in a disciplinary hearing pursuant to Section 213(c)(9);

(15) engaging in any conduct that subverts or attempts to subvert any licensing examination or the Administration of any licensing examination;[7]

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Model Rules for the Practice of Pharmacy

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Section 3. Personnel.

(a) Duties and Responsibilities of the Pharmacist-in-Charge

(1) No Person shall operate a Pharmacy without a Pharmacist-in-Charge. The Pharmacist-in-Charge of a Pharmacy shall be designated in the application of the Pharmacy for license, and in each renewal thereof. A Pharmacist may not serve as Pharmacist-in-Charge unless he or she is physically present in the Pharmacy a sufficient amount of time to provide supervision and control. A Pharmacist may not serve as Pharmacist-in-Charge for more than one Pharmacy at any one time except upon obtaining written permission from the Board.

(2) The Pharmacist-in-Charge has the following responsibilities:

(i) Developing or adopting, implementing, and maintaining:[8]

(A) Policies and procedures addressing the following:

(-a-) the provision of Pharmacy services;[9]

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[6] This is not intended to include performance metrics that may be related to the ability and competency of Pharmacy personnel.

[7] It is recommended that the following rule be adopted defining subversion or the attempt to subvert any licensing examination.

(a) Conduct which subverts or attempts to subvert any licensing examination or the administration of any examination shall include, but not be limited to, the following:

(1) Conduct which violates the security of the examination materials; removing from the examination room any examination materials without authorization; the unauthorized reproduction by any means of any portion of the actual licensing examination; aiding by any means the unauthorized reproduction of any portion of the actual licensing examination; paying or using professional or paid examination takers for the purpose of reconstructing any portion of the licensing examination; obtaining examination questions or other examination materials, except by specific authorization either before, during, or after an examination; or selling, Distributing, buying, receiving, or having unauthorized possession of any portion of a future, current, or previously administered licensing examination.

(2) Unauthorized communication of examination information with any other examinee during the administration of a licensing examination; copying answers from another examinee or permitting one's answers to be copied by another examinee; having in one's possession during the administration of the licensing examination any books, equipment, notes, written or printed materials, or data of any kind other than the examination materials Distributed, or otherwise authorized to be in one's possession during the examination; or impersonating any examinee or having an impersonator take the licensing examination on one's behalf.

[8] The owner and/or pharmacy permit holder, along with the Pharmacist-in-Charge, are responsible for these policies and procedures.

[9] The Pharmacist-in-Charge, as part of the responsibilities to manage as effectively as possible a patient's therapy to avoid a harmful interruption of therapy because of a shortage or limited Distribution of medications, can proactively improve Pharmacy operations by developing a systematic approach to address such circumstances. References such as the American Society of Health-System Pharmacists

(-b-) the procurement, storage, security, and disposition of Drugs and Devices, particularly controlled substances and Drugs of Concern;

(-c-) computerized record-keeping systems;

(-d-) Automated Pharmacy Systems;

(-e-) preventing the illegal use or disclosure of Protected Health Information, or verifying the existence thereof and ensuring that all employees of the Pharmacy read, sign, and comply with such established policies and procedures;

(-f-) operation of the Pharmacy in the event of a fire, flood, pandemic, or other natural or man-made disaster or emergency, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed. Such policies and procedures shall include reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence[10];

(-g-) the proper management of Drug recalls which may include, where appropriate, contacting patients to whom the recalled Drug Product(s) have been Dispensed;

(-h-) the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their education, training, and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(-i-) actions to be taken to prevent and react to pharmacy robberies and thefts, including but not limited to coordinating with law enforcement, training, mitigation of harm, and protecting the crime scene.

(-j-) the PIC shall have policies and procedures in place that restrict and monitor control over and access to the locks, barriers, and systems used to secure the pharmacy and pharmacy systems in accordance with state laws and regulations.

(B) Policies and procedures that address the following activities related to prescription medication shipment by mail or common carrier:

(-a-) properly transferring prescription information to an alternative Pharmacy of the patient's choice in situations where the medication is not Delivered or Deliverable;

(ASHP) Guidelines in Managing Drug Product Shortages could be used as resources for developing policies and procedures if appropriate. Additionally, Food and Drug Administration maintains a list of current and resolved Drug shortages, as well as discontinued Drugs on the agency's Drug Shortages Web page at www.fda.gov/cder/drug/shortages.

[10] States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed pharmacy area to accommodate the need to store emergency supplies.

(-b-) verifying that common carriers have in place security provisions, such as criminal background checks and random drug screens on its employees who have access to prescription medications;

(-c-) tracking all shipments; and

(-d-) ensuring that Drugs do not become adulterated in transit

(C) Quality assurance programs addressing the following:

(-a-) Pharmacy services. The quality assurance program should be designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(-b-) Automated Pharmacy Systems. The quality assurance program should monitor the performance of the Automated Pharmacy System, ensure the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed, while maintaining appropriate record keeping and security safeguards; and

(-c-) The prevention and detection of Drug diversion.[11]

(ii) Ensuring that:

(A) all Pharmacists, Pharmacy Interns, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates employed at the Pharmacy are currently licensed by the Board of Pharmacy.

(iii) Notifying the Board of Pharmacy, immediately and in writing, of any of the following[12] changes:

(A) change of employment or responsibility as the Pharmacist-in-Charge;

(B) the separation of employment of any Pharmacist, Pharmacy Intern, Certified Pharmacy Technician Candidate, or Certified Pharmacy Technician for any confirmed Drug-related reason, including but not limited to, Adulteration, abuse, theft, or diversion, and shall include in the notice the reason for the termination: if it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall notify the Board of Pharmacy;

(C) change of ownership of the Pharmacy;

(D) change of address of the Pharmacy;

(E) permanent closing of the Pharmacy;

(F) Significant Quality-Related Events;

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[11] As part of a quality assurance program designed to prevent and detect drug diversion, the Pharmacist-in-Charge, if the practice setting warrants, may also consider implementing diversion prevention and detection policies and procedures that address the following: periodic reviews of employee access to any secure controlled substance storage areas, which may include:

- alarm codes and lock combinations;
- passwords; and
- keys and access badges.

[12] If states require the Pharmacist-in-Charge or other Person in charge of the Pharmacy to submit information regarding the separation of employment of licensees, especially in circumstances of suspected or confirmed abuse, theft, or diversion of Drugs, states should also be aware of confidentiality and employment laws that may restrict the release of information and be cautioned that the release of such information may create a liability for the reporting Pharmacy.

In instances where the Pharmacist-in-Charge and the owner and/or pharmacy permit holder are the same person and that person is no longer employed or designated as the Person in charge, then the Board must take action to cease operation of the Pharmacy.

(G) the installation or removal of Automated Pharmacy Systems. Such notice must include, but is not limited to:

(-a-) the name and address of the Pharmacy;

(-b-) the location of the Automated Pharmacy System; and

(-c-) the identification of the responsible Pharmacist.

(-d-) Such notice must be must occur prior to the installation or removal of the system.

(iv) Making or filing any reports required by state or federal laws and rules.

(v) Reporting any theft, suspected theft, diversion, or other Significant Loss of any Prescription Drug within one business day of discovery to the Board of Pharmacy and as required by Drug Enforcement Administration (DEA) or other State or federal agencies for Prescription Drugs and controlled substances.

(vi) Responding to the Board of Pharmacy regarding any minor violations brought to his or her attention.

(3) The Pharmacist-in-Charge shall be assisted by a sufficient number of Pharmacists, Certified Pharmacy Technicians, and Certified Pharmacy Technician Candidates as may be required to competently and safely provide Pharmacy services.

(i) The Pharmacist-in-Charge shall maintain and file with the Board of Pharmacy, on a form provided by the Board, a current list of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates assisting in the provision of Pharmacy services.

(ii) The Pharmacist-in-Charge shall develop or adopt, implement, and maintain written policies and procedures to specify the duties to be performed by Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates. The duties and responsibilities of these personnel shall be consistent with their education, training, and experience and shall address the method and level of necessary supervision specific to the practice site. These policies and procedures shall, at a minimum, specify that Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates are not assigned duties that may be performed only by a Pharmacist. Such policies and procedures shall also specify that Certified Pharmacy Technician Candidates shall not be assigned duties that may be performed only by Certified Pharmacy Technicians.

(iii) The Pharmacist-in-charge shall develop or adopt, implement, and maintain a Certified Pharmacy Technician training program that is site-specific to the practice setting of which he or she is in charge for all individuals employed by the Pharmacy who will assist in the Practice of Pharmacy. The Pharmacist-in-Charge shall utilize a Certified Pharmacy Technician training manual as part of the training program. The Pharmacist-in-Charge shall be responsible for maintaining a record of all Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates successfully completing a site-specific training program and an objective assessment mechanism. The Pharmacist-in-Charge shall attest to the Board of Pharmacy, in a timely manner, those persons who, from time to time, have met the training requirements necessary for licensure by the Board.[13]

(b) Professional Performance Evaluation

[13] All training programs should be subject to approval by the Board of Pharmacy.

Each Pharmacist who performs any of the acts described within the definition of "Practice of Pharmacy" is responsible for ensuring that he or she is the subject of a Professional Performance Evaluation at least once each year. Each Pharmacy is responsible for ensuring that every Pharmacist who practices at the Pharmacy for more than 40 hours during any twelve (12)-month period and who performs any of the acts described within the definition of "Practice of Pharmacy" is the subject of a Professional Performance Evaluation at least once each year.

(c) If any action of the Pharmacy is deemed to contribute to or cause a violation of any provision of this section, the Board may hold the owner and/or Pharmacy permit holder responsible and/or absolve the Pharmacist-in-Charge from the responsibility of that action.

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Section 16. Unprofessional Conduct.

Unprofessional conduct shall include, but is not limited to, the following acts of a Pharmacist or Pharmacy:

(a) the publication or circulation of false, misleading, or otherwise deceptive statements concerning the Practice of Pharmacy;

(b) unreasonably refusing to Compound or Dispense Prescription Drug Orders that may be expected to be Compounded or Dispensed in Pharmacies by Pharmacists;

(c) attempting to circumvent the Patient Counseling requirements, or discouraging the patient from receiving Patient Counseling concerning their Prescription Drug Orders;

(d) the illegal use or disclosure of Protected Health Information;

(e) failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of Protected Health Information;

(f) failure to maintain adequate records to account for disclosures of Protected Health Information;

(g) selling, giving away, or otherwise disposing of accessories, chemicals, or Drugs or Devices found in illegal Drug traffic when the Pharmacist knows or should have known of their intended use in illegal activities;

(h) engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the Standards of Care ordinarily exercised by a Pharmacist, with proof of actual injury not having to be established;

(i) selling a Drug for which a Prescription Drug Order from a Practitioner is required, without having received a Prescription Drug Order for the Drug;

(j) willfully and knowingly failing to maintain complete and accurate records of all Drugs received, Dispensed, or disposed of in compliance with the Federal laws and regulations and State laws and rules;

(k) obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's Pharmacist Care Services, absent a clear benefit to the patient, solely in response to promotion or marketing activities;

(l) willfully and knowingly completing and submitting inaccurate due diligence questionnaires and attestation documents regarding the purchase or receipt of Drugs from Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors.

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Quarles & Brady LLP

Publications & Media

New Limitations on Chain Pharmacy Quotas in California

Health & Life Sciences
10/22/21
Simone Colgan Dunlap, Michael French, Luis Lanz, Nicholas Meza

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Retail chain pharmacies should be aware of California's recent passage of SB 362, signed into law by Governor Gavin Newson late last month, and the potential impact of the law on how chains evaluate their pharmacy staff and track individual productivity. At a high level, the law bars using "quota" metrics that track the number of times individual pharmacists and

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pharmacy technicians perform tasks or provide services while on duty. These quota systems have historically been used by various national retail pharmacy chains to track staff productivity and inform business operations. The bill cites various rationales for instituting quota prohibitions, including "overwhelming workloads" for pharmacists expected to meet certain fixed quotas and the associated negative impact on patient care. Of note, the bill noted that the Board of Pharmacy lacks the ability to determine whether to discipline non-compliant individual licensees or penalize pharmacies for created work environments that "leave little choice but noncompliance."

The new law updates the California Business and Professions Code by adding two new Sections-- 4113.7 and 4317. Section 4113.7 prohibits chain community pharmacies from establishing, utilizing, or communicating a quota. A "quota" is defined as a "fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required, against which the chain community pharmacy or its agent measures or evaluates the number of times either an individual pharmacist or pharmacy technician performs tasks or provides services while on duty related to any of the following:

- Prescriptions filled;
- Services rendered to patients;
- Programs offered to patients; and
- Revenue obtained."

CA BUS & PROF § 4113.7(c)(1)(A-D).

Section 4317 grants the California Board of Pharmacy authority to take enforcement action against a violating pharmacy unless the pharmacy can show clear and convincing evidence that the quotas were used contrary to its policy.

Importantly, there are certain limiting factors to this quota prohibition. First, the restrictions only apply to "chain community pharmacies," defined by California as "a chain of 75 or more stores in California under the same ownership." *CA BUS & PROF § 4001(c).* Second, the following are not considered "quotas" and are therefore still permissible activities for applicable pharmacies:

- Revenue measurements for a particular pharmacy that are not calculated or measured by tasks performed/services provided by individual pharmacy staff;

- Evaluations of pharmacy staff competence, performance, or quality of care provided to patients so long as quotas are not used;

- Any performance metric required by state or federal regulators that does not use quotas; and

- Pharmacy policy and procedures that assist with assessing pharmacy staff competency and performance so long as quotas are not used.

CA BUS & PROF § 4113.7(c)(2)—(d).

In sum, large pharmacy chains may need to evaluate changes to their tracking and evaluation process for California-based pharmacy staff. However, it is important to note that SB 362 still gives California chain pharmacies room to evaluate employees and quantify productivity so long as the evaluation procedure falls in line with the delineated exceptions. Additionally, the law appears to only bar quotas used for individual pharmacy staff, meaning that pharmacy chains could arguably still use quota-type metrics to track performance on a pharmacy or entity level.

For more information about how California's new quota prohibitions may affect your business, please contact your Quarles & Brady attorney or:

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SENATE BILL No. 362

Introduced by Senator Newman

February 10, 2021

An act to add Sections 4113.7 and 4317 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 362, as introduced, Newman. Community pharmacies: quotas.

Under the Pharmacy Law, the California State Board of Pharmacy licenses and regulates the practice of pharmacy and the conduct of a pharmacy in this state. The Pharmacy Law refers to various types of pharmacies, including community pharmacies, as specified. Existing law prohibits a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless another employee, as specified, is made available to assist the pharmacist at all times.

This bill would prohibit a community pharmacy from establishing a quota, defined as a fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required, against which the community pharmacy or its agent measures or evaluates the pharmacist or pharmacy technician's performance of those duties in the community pharmacy. The bill would also prohibit a community pharmacy, through employees, contractors, or third parties, from communicating the existence of quotas to pharmacists or pharmacy technicians who are its employees or with whom it contracts. For an initial violation of this provision, the bill would require the community pharmacy to be assessed a fine not exceeding one million dollars and a 30-day suspension of the licenses of its pharmacies in the state. For a second violation, the bill would require the revocation of the licenses of its pharmacies in the state. The bill would provide that a community

pharmacy is not subject to these penalties if it demonstrates by clear and convincing evidence that the violation was contrary to its policy.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) California's pharmacists and pharmacy technicians employed by multibillion dollar, publicly-traded, pharmacy chain stores will imminently be called upon to accomplish something unprecedented: to vaccinate tens of millions of California patients on top of their already overwhelming workloads.

(b) However, widespread, profit-driven, and long-decried performance quotas imposed by these chains upon their licensed professional employees place at risk the ability of pharmacists and pharmacy technicians safely to vaccinate Californians properly while at the same time performing their already life-or-death duties.

(c) Documents and data obtained by investigative reporters, public prosecutors, and researchers have established that large, publicly-traded pharmacy chains impose performance quotas on licensed pharmacists and pharmacy technicians that place at risk the health and well-being of patients. For example:

(1) More than one-half of the chain and retail pharmacists reported high stress work environments from "having to meet quotas."

(2) Eighty-three percent of pharmacists reported in one survey that "performance metrics contributed to dispensing errors."

(3) Another survey by the California State Board of Pharmacy found that about 85 percent of the pharmacists surveyed indicated "workload" was "too high." Prescription errors can be found and corrected 89 percent of the time during such consultations. However, performance quotas such as timed metrics inhibit consistent consultations.

(4) An investigative report by The Los Angeles Times documented enormous pressure placed upon pharmacy employees by vast drug chains to meet quotas. One pharmacist is quoted as saying, "Everyone knows that if we don't hit our quotas, people can lose their jobs," and The Times writes "[c]ompany documents

. . . have shown that CVS workers are expected to enroll at least 40% of patients into the [automatic prescription renewal] program. Failure to do so can result in loss of raises or bonuses. Other drugstores, notably Target, Rite Aid and Walgreens, have similar quotas [.]"

(5) In 2011, the California State Board of Pharmacy brought to three District Attorneys' offices information about the three biggest retail chains failing to properly provide needed personal consultation to prescription drug customers. All three of these major retailers were forced to pay huge fines and were permanently enjoined to comply with California's standards for patient consultations. Indeed, major drug store chains have been forced to pay millions to settle claims brought by the United States Department of Justice and other public agencies for overzealous and unlawful profit-increasing practices.

(d) Performance quotas in normal times pose a risk to the public health. When implemented during a time when pharmacists and pharmacy technicians will have imposed upon them for an indefinite period significant new and vital public health duties, quotas are unacceptable.

SEC. 2. Section 4113.7 is added to the Business and Professions Code, to read:

4113.7. (a) A community pharmacy shall not establish a quota related to the duties for which a pharmacist or pharmacy technician license is required.

(b) A community pharmacy shall not, through employees, contractors, or third parties, communicate the existence of quotas related to the duties for which a pharmacist or pharmacy technician license is required to pharmacists or pharmacy technicians who are employees of the community pharmacy or with whom the community pharmacy contracts.

(c) (1) For purposes of this section, "quota" means a fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required, against which the community pharmacy or its agent measures or evaluates the pharmacist or pharmacy technician's performance of those duties in the community pharmacy. "Quota" includes a fixed number or formula related to any of the following:

(A) Prescriptions filled.

(B) Services rendered to patients.

(C) Programs offered to patients.

(D) Revenue obtained.

(2) For purposes of this section, "quota" does not mean any measurement communicated on an annual basis to a pharmacist or a pharmacy technician by a community pharmacy that documents the items sold, prescriptions filled, or services rendered during the preceding 12 months compared to other pharmacists and pharmacy technicians during the same period.

(d) A community pharmacy that violates this section may be assessed an administrative penalty in accordance with Section 4317.

SEC. 3. Section 4317 is added to the Business and Professions Code, immediately following Section 4316, to read:

4317. A community pharmacy that violates Section 4113.7 shall be assessed an administrative penalty unless by clear and convincing evidence the community pharmacy demonstrates that the violation was contrary to its policy.

(a) An initial violation shall result in both of the following:

(1) A fine not exceeding one million dollars ($1,000,000.00).

(2) A suspension of the licenses of pharmacies in the state owned or controlled by the community pharmacy for 30 days.

(b) A second violation shall result in revocation of the licenses of pharmacies in the state owned or controlled by the community pharmacy.

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MEMORANDUM

TO: The Honorable JB Pritzker, Governor
Deborah Hagan, Secretary of the Department of Financial and Professional Regulation
The Illinois General Assembly

FROM: **The Illinois Collaborative Pharmaceutical Task Force**

Philip P. Burgess, MBA, DPh, RPh, Chairperson
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Thomas Stiede

SUBJECT: Illinois Collaborative Pharmaceutical Task Force Report and Recommendations

On behalf of the Illinois Collaborative Pharmaceutical Task Force, chaired by Philip P. Burgess, this Report and Recommendations regarding pharmacies, pharmacists and pharmacy technicians in the State of Illinois is hereby submitted in compliance with the Illinois Pharmacy Act, 225 ILCS 85/4.5.

Illinois Collaborative Pharmaceutical Task Force Report and Recommendations

Mandated by 225 ILCS 85/4.5
October 11, 2019

Table of Contents

Collaborative Pharmaceutical Task Force Authorizing Statute

Public Act 100-497 amended the Illinois Pharmacy Practice Act [225 ILSC 85/4.5] (the "Act") to create an eleven-person Collaborative Pharmaceutical Task Force made up of various representatives appointed by the Department of Financial and Professional Regulation, the President of the Senate, the Minority Leader of the Senate, the Speaker of the House and the Minority Leader of the House. The voting members of the Collaborative Pharmaceutical Task Force was charged with voting on recommendations concerning the standards in the Section and the Illinois Department of Financial and Professional Regulation was directed to propose rules for adoption that are consistent with the Collaborative Pharmaceutical Task Force's recommendations or recommend legislation to the General Assembly, concerning the standards in the section. 225 ILCS 85/4.5 reads in full:

> In order to protect the public and provide quality pharmaceutical care, the Collaborative Pharmaceutical Task Force is established. The Task Force shall discuss how to further advance the practice of pharmacy in a manner that recognizes the needs of the healthcare system, patients, pharmacies, pharmacists, and pharmacy technicians. As a part of its discussions, the Task Force shall consider, at a minimum, the following:
>
> (1) the extent to which providing whistleblower protections for pharmacists and pharmacy technicians reporting violation of worker policies and requiring pharmacies to have at least one pharmacy technician on duty whenever the practice of pharmacy is conducted, to set a prescription filling limit of not more than 10 prescriptions filled per hour, to mandate at least 10 pharmacy technician hours per 100 prescriptions filled, to place a general prohibition on activities that distract pharmacists, to provide a pharmacist a minimum of 2 15-minute paid rest breaks and one 30-minute meal period in each workday on which the pharmacist works at least 7 hours, to not require a pharmacist to work during a break period, to pay to the pharmacist 3 times the pharmacist's regular hourly rate of pay for each workday during which the required breaks were not provided, to make available at all times a room on the pharmacy's premises with adequate seating and tables for the purpose of allowing a pharmacist to enjoy break periods in a clean and comfortable environment, to keep a complete and accurate record of the break periods of its pharmacists, to limit a pharmacist from working more than 8 hours a workday, and to retain records of any errors in the receiving, filling, or dispensing of prescriptions of any kind could be integrated into the Pharmacy Practice Act; and
>
> (2) the extent to which requiring the Department to adopt rules requiring pharmacy prescription systems contain mechanisms to require prescription discontinuation orders to be forwarded to a pharmacy, to require patient verification features for pharmacy automated prescription refills, and to require that automated prescription refills notices clearly communicate to patients the medication name, dosage strength, and any other information required by the Department governing the use of automated dispensing and storage systems to ensure that discontinued medications are not dispensed to a patient by a pharmacist or by any automatic refill dispensing systems whether prescribed through electronic prescriptions or paper prescriptions may be integrated into the Pharmacy Practice Act to better protect the public.

In developing standards related to its discussions, the Collaborative Pharmaceutical Task Force shall consider the extent to which Public Act 99-473 (enhancing continuing education requirements for pharmacy technicians) and Public Act 99-863 (enhancing reporting requirements to the Department of pharmacy employee terminations) may be relevant to the issues listed in paragraphs (1) and (2).

The voting members of the Collaborative Pharmaceutical Task Force shall be appointed as follows:

(1) the Speaker of the House of Representatives, or his or her designee, shall appoint: a representative of a statewide organization exclusively representing retailers, including pharmacies; and a retired licensed pharmacist who has previously served on the Board of Pharmacy and on the executive committee of a national association representing pharmacists and who shall serve as the chairperson of the Collaborative Pharmaceutical Task Force;

(2) the President of the Senate, or his or her designee, shall appoint: a representative of a statewide organization representing pharmacists; and a representative of a statewide organization representing unionized pharmacy employees;

(3) the Minority Leader of the House of Representatives, or his or her designee, shall appoint: a representative of a statewide organization representing physicians licensed to practice medicine in all its branches in Illinois; and a representative of a statewide professional association representing pharmacists, pharmacy technicians, pharmacy students, and others working in or with an interest in hospital and health-system pharmacy; and

(4) the Minority Leader of the Senate, or his or her designee, shall appoint: a representative of a statewide organization representing hospitals; and a representative of a statewide association exclusively representing long-term care pharmacists.

The Secretary, or his or her designee, shall appoint the following non-voting members of the Task Force: a representative of the University of Illinois at Chicago College of Pharmacy; a clinical pharmacist who has done extensive study in pharmacy e-prescribing and e-discontinuation; and a representative of the Department.

The Department shall provide administrative support to the Collaborative Pharmaceutical Task Force. The Collaborative Pharmaceutical Task Force shall meet at least monthly at the call of the chairperson.

No later than September 1, 2019, the voting members of the Collaborative Pharmaceutical Task Force shall vote on recommendations concerning the standards in paragraphs (1) and (2) of this Section.

No later than November 1, 2019, the Department, in direct consultation with the Collaborative Pharmaceutical Task Force, shall propose rules for adoption that are consistent with the Collaborative Pharmaceutical Task Force's recommendations, or

recommend legislation to the General Assembly, concerning the standards in paragraphs (1) and (2) of this Section.

This Section is repealed on November 1, 2020.

Task Force Votes and Rationales Regarding Recommended Standards

The Collaborative Pharmaceutical Task Force made the following recommendations regarding the standards delineated in Section 4.5 of the Act, as well as other recommendations regarding changes to the Pharmacy Practice Act, the rules promulgated thereunder and the renumeration for pharmaceutical services.

Whistleblower Protections

Regarding the standard contained in Section 4.5 of the Act involving a consideration of "the extent to which providing whistleblower protections for pharmacists and pharmacy technicians reporting violations or worker policies," the Task Force's recommendation was that a new section listing "Grounds for Discipline" should be included in the Act, or rules promulgated thereunder, and that one of these grounds would include the following provision:

(5) Anyone reporting violations of this section to the Department of Financial and Professional Regulation are specifically protected under the Illinois Whistleblower Act" (740 ILCS 174/15(b)).

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of seven in favor, none opposed, no abstentions and one absent.

The Task Force is aware that the Illinois Whistleblower Act (740 ILCS 174/15(b)) protections already apply to pharmacists and pharmacy technicians; however, the Task Force unanimously recommended placing the above reference provision in either the Pharmacy Practice Act or the rules promulgated thereunder to reemphasize and reinforce the pharmacist's or pharmacy technician's ability to file a complaint, without repercussion, when they identify a violation of the Pharmacy Practice Act or the rules thereunder which the pharmacy and/or Pharmacist-In-Charge refuses to address or correct.

Requiring Pharmacies to Employ at Least One Pharmacy Technician

Section 4.5 of the Act provided another standard that the Task Force considered, which was "requiring pharmacies to have at least one pharmacy technician on duty whenever the practice of pharmacy is conducted." The Task Force recommended against the adoption of any language within the Act, or the rules promulgated thereunder, regarding this standard by a vote of five in favor, one opposed, one abstention and one absent.

The majority believed that it would be unduly costly to require all pharmacies in the State of Illinois to employ a pharmacy technician whenever the practice of pharmacy is being conducted, as there are various

types of pharmacies across the State that have no need or use for a pharmacy technician in general or during specific times of the day or week. For example, there are pharmacies, which could not afford to employ and would not have sufficient work to be required to employ a pharmacy technician. In addition, there are pharmacies which do not fill enough prescriptions, either all day or at particular times, to justify employing a pharmacy technician. Finally, there are often clinical and administrative tasks a pharmacist undertakes that have no need for a pharmacy technician. A requirement that pharmacies in the State employ a pharmacy technician whenever it is operational would be costly and unduly burdensome.

Rationale Provided by Dissenter

While I agree with the majority that it may be "unduly costly to require that all pharmacies" employ a pharmacy technician whenever the practice of pharmacy is being conducted, the same does not hold true in retail pharmacy settings. As an important reminder, the issues before this Task Force arose from the voice of Unionized pharmacists working exclusively in the retail setting. It is this particular practice of pharmacy that is the most vulnerable to technician understaffing and prescription errors. In fact, the Chicago Tribune's investigation highlighted errors found only in retail pharmacy settings (as opposed to hospital and long-term care facilities mentioned by the majority). Retail pharmacies, unlike small independent pharmacies or long-term care facilities, can most certainly afford to employ at least one pharmacy technician at all times. Additionally, as made clear by the Tribune's study, the rate of prescription errors in the retail setting (referred to as "chain" pharmacies in the Tribune story) are much higher than other settings, further amplifying the need for a pharmacy technician at all times. The workload in the retail setting is also undisputedly higher than other settings, making pharmacists working alone vulnerable to fatigue and errors unlike slower settings. Additionally, while overnight pharmacists who work in small hospitals and long-term care facilities may not "fill enough prescriptions" during that time to justify employing a pharmacy technician, the same cannot be said for retail pharmacists. The majority has failed to take these key differences into consideration and has not provided a basis as to why technicians should not be mandated solely in the retail setting. Accordingly, the Pharmacy Practice Act should be amended to require a pharmacy technician be on duty at all times in retail pharmacies such as Walgreens, Walmart, Target, CVS, Osco, and Marianos.

Limits on the Number of Prescriptions Filled and Mandated Pharmacy Technician Hours

Regarding the standards contained in Section 4.5 of the Act, which required a consideration whether "to set a prescription limit of not more than ten (10) prescriptions filled per hour," and whether "to mandate at least 10 pharmacy technician hours per 100 prescriptions filled," the Task Force recommended a modification of these standards. The Task Force's recommendation was that a new section listing "Grounds for Discipline" should be included in the Act, or rules promulgated thereunder, and that one of these grounds would include the following provision:

> (2) Failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient which includes, but is not limited to:
>
> . . . .

(c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:
  (A) Drug Utilization Review;
  (B) Immunization;
  (C) Counseling;
  (D) Verification of the accuracy of a prescription; and
  (E) All other duties and responsibilities of a pharmacist as specified in the Pharmacy Practice Act Administrative Rules Part 1330.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, regarding this standard by a vote of seven in favor, none opposed, no abstentions and one absent.

The Task Force reached this recommendation by balancing the need to allow a pharmacist sufficient time to effectively complete his or her job against the establishment of arbitrary numerical limits on the prescriptions that are filled. Several Members of the Task Force recognized that it may be unduly costly and unworkable to require that all pharmacies in the State of Illinois only fill a specified number of prescriptions over a set time and require a specific number of pharmacy technicians based on an arbitrary number of prescriptions filled by the pharmacy. Again, some the Task Force Members recognized that there are many types of pharmacies with a variety of technological capabilities throughout Illinois, which causes the establishment of a specific limit on the number of prescriptions filled over a certain time to be unworkable in some settings. The Task Force's recommendation is based on a recognition that a restriction based on an arbitrary absolute number of prescriptions filled cannot be fairly applied, while basing restrictions on the overall work burdens of a pharmacist is a much more meaningful method of evaluating overall patient safety. The Task Force determined that monitoring the working environment of pharmacists and establishing a disciplinary action if the work load is excessive or the environment is too distracting as to prevent a pharmacist from properly completing all of his or her duties and obligations is a more reasonable and rational approach.

Prohibitions on Distractions

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration whether "to place a general prohibition on activities that distract pharmacists," the Task Force recommended a modification of this standard. The Task Force's recommendation was that a new section listing "Grounds for Discipline" should be included in the Act, or rules promulgated thereunder, and that one of these grounds would include the following provision:

(2) Failure to provide a working environment for all pharmacy personnel that protects that health, safety and welfare of a patient which includes, but is not limited to:
  (a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, regarding this standard by a vote of seven in favor, none opposed, no abstentions and one absent.

The Task Force strongly believes that activities that distract pharmacists from their jobs are harmful and could affect the safety of the public. The Task Force noted that activities creating distractions could include requiring pharmacists to: solicit new business; meet productivity or production quotas; or induce the transfer of prescriptions. However, the Task Force decided that it would be impossible to define and list all possible activities which could cause distractions for pharmacists and which may or may not result from distractions based on volume, time of day, staffing, technology, etc. They recommended the addition of the language under Grounds for Discipline, which would afford flexibility to the pharmacist and the Board of Pharmacy.

No Work During Break

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration whether to require that a pharmacy "to not require a pharmacist to work during a break period," by modifying the standard in recommending that the Pharmacy Practice Act or the rules promulgated thereunder to add a new section entitled "Grounds for Discipline," which would include the following provisions:

> (2) Failure to provide a working environment for all pharmacy personnel that protects that health, safety and welfare of a patient which includes, but is not limited to:
>
> . . . .
>
> (b) Appropriate opportunities for uninterrupted rest periods and meal breaks.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of seven in favor, none opposed, no abstentions and one absent.

The Task Force also believes that pharmacists generally need to have uninterrupted rest periods and meal breaks throughout the work day to ensure that they can effectively carry out their job responsibilities and to protect the safety of the public. However, the Task Force recognized that flexibility is necessary for addressing emergencies which would occasionally require the interruption of a pharmacist's rest breaks and lunch periods. The Task Force recommended the addition of the language under Grounds for Discipline because it would afford flexibility to the pharmacists, while allowing for generally uninterrupted breaks and lunch periods for the pharmacists.

Triple Pay for No Breaks

Section 4.5 of the Act also provided the standard that the Task Force considered, which required pharmacies "to pay the pharmacist 3 times the pharmacist's regular hourly rate of pay for each workday during which the required breaks were not provided." The Task Force recommended against the adoption

of any language within the Act or the rules promulgated thereunder regarding this standard by a vote of five in favor, one opposed, one abstention and one absent.
The majority of the Task Force determined that it would be overly broad and unduly burdensome to require that pharmacies make mandated payment of three times the amount of a pharmacist's wages for an entire day for the failure of a pharmacy to permit the pharmacist to receive breaks during that workday. The majority noted that the proposed standard failed to account for different types and sizes of pharmacies, workflow, technology, etc. The majority believed that it is a professional obligation for a pharmacist to serve his or her patients in a timely and safe manner and that pharmacists are medical professionals who should be trusted to manage their responsibilities as are other medical professionals. The enactment of the other changes overwhelmingly recommended by the Task Force would remove any ambiguity that the pharmacist is empowered to protect patients.

Rationale Provided by Dissenter

I agree with the majority that pharmacists have a professional obligation to serve patients in a "timely and safe manner." The problem, however, is that retail pharmacies have prevented this from happening. As made clear by reports and numerous examples presented to the Task Force Members during this process, the current state of retail pharmacy is unsafe. Retail Pharmacists simply are not provided the time or adequate coverage to actually take breaks. Furthermore, having clear monetary penalties with strict liability for each violation would alleviate the necessity for long drawn-out investigations and hearings by the IDFPR or Board of Pharmacy on penalties after a violation has occurred. Additionally, having a clear penalty will act as both a sword and a shield, as it will shield pharmacists from undue interference with their breaks by Employers in the retail setting (a fact which has gone largely unrebutted during Task Force Meetings) and will also act as a sword by penalizing Employers who do not comply. This will have a direct impact on protecting patient safety as it will incentivize Employers to provide the mandated breaks, much like speeding or traffic violations operate to incentivize safe driving.

Required Break Room

Section 4.5 of the Act provided the standard that the Task Force considered, which required pharmacies "to make available at all times a room on the pharmacy's premises with adequate seating and tables for the purpose of allowing a pharmacist to enjoy break periods in a clean and comfortable environment." The Task Force recommended against the adoption of any language within the Act or the rules promulgated thereunder regarding this standard by a vote of five in favor, one opposed, one abstention and one absent.

The majority of the Task Force noted that many pharmacists already have access to areas which would be considered break rooms or areas. For example, pharmacies in hospitals and long-term nursing facilities have cafeterias or sequestered vending areas for pharmacists to take their breaks or lunch periods. The majority also considered that a requirement for a separate break room with seating tables could be unduly burdensome for some retail pharmacies because of space limitations, and a requirement that all pharmacies maintain a clean break room would not provide a significant contribution to public safety but could add significant unreimbursed costs.

Rationale Provided by Dissenter

As was correctly pointed out by several majority members, it may be an OSHA violation to require pharmacists to take their break in the pharmacy given the drugs that are stored therein. Furthermore, failing to provide a breakroom forces a pharmacist to store his/her food in the same refrigerator where pharmacy drugs are stored. While small retail pharmacies may not have the space for it, larger retailers like Walmart, Osco, Target, CVS, Walgreens and Marianos simply have no excuse. Providing a separate breakroom and access to the breakroom is the only way to ensure that pharmacists in the retail setting actually receive an "uninterrupted" break. Pharmacists in the retail setting have no way to shield themselves from the viewing public if they are forced to take their break in the pharmacy, unlike other settings. Because of this there is no physical way to prevent a member of the public from accessing the pharmacists while he or she was on their uninterrupted break (something that this Task Force has agreed is vital for patient safety).

Required Break Records

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration whether to require that a pharmacy "to keep a complete and accurate record of the break periods of its pharmacists," by recommending that the legislature enact a provision in the Pharmacy Practice Act under a new Section entitled "Pharmacy Work Conditions," which states the following:

> The Employer shall keep and maintain a complete and accurate record of the daily break periods of its pharmacists.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of four in favor, two opposed, one abstention and one absent.

The majority of the Task Force determined that records of the breaks taken by pharmacists was necessary to ensure that pharmacists are provided the rest breaks and lunch periods that the Act or rules require. Without a requirement that records of breaks and lunch periods be maintained, pharmacists may not be able to establish that they are not being permitted to take the rest and lunch time to which they are entitled under separate recommendations of the Task Force.

The dissenters were given an opportunity to provide an explanation for their vote but chose not to submit a rationale.

Required 8-Hour Work Day

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration whether to require a pharmacy to "limit a pharmacist from working more than 8 hours a workday," the Task Force considered a motion to recommend that the legislature enact a provision in the Pharmacy Practice Act under a new Section entitled "Pharmacy Work Conditions," which states as follows:

> A pharmacy licensed under Illinois Statutes, which is located within Illinois, shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than eight (8) continuous hours per day, inclusive of the breaks.

The Task Force did not approve a motion recommending the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of one in favor, six opposed, and one abstention.

However, a majority of the Task Force determined to modify this standard to limit the hours worked by a pharmacist to 12 hours a workday, and recommending that the legislature enact a provision in the Pharmacy Practice Act under a new Section entitled "Pharmacy Work Conditions," which states as follows:

> A pharmacy licensed under Illinois Statutes, which is located within Illinois, shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than twelve (12) continuous hours per day, inclusive of the breaks.

The Task Force recommended the adoption of this language within the Act, in response to this standard by a vote of five in favor, one opposed, one abstention and one absent.

Most of the Task Force noted that currently many pharmacies in Illinois regularly use a ten or twelve-hour workday. The majority recognized that there was a need to be flexible regarding the length of the workday and by setting the length of the workday at twelve hours would not preclude any pharmacy from permitting a shorter workday. The majority further determined that requiring pharmacists to work over twelve hours a workday on a consistent basis could create public health safety concerns. They determined that allowing an exception to the number of hours that a pharmacist can work when there is, in the judgment of the pharmacist, an emergency or other situation, would protect the safety of the public while offering some flexibility.

Rationale Provided by Dissenter

While I agree with the majority that hospitals, home pharmacies, and smaller community pharmacists may regularly use a ten or twelve-hour workday, the impact to patient safety is not the same in those settings as it is in the retail setting where far more prescriptions are filled on a daily basis. In fact, it is the retail setting that had the highest error rate and it is in this setting that a twelve-hour day should be banned absent emergencies. The work of a retail pharmacist, in terms of prescription count and administrative duties, varies greatly from a pharmacist working in a hospital, home pharmacy, or community pharmacy. Retail pharmacists are held to unsafe quotas, performance standards, and high prescription fill rates making the work they perform in an 8-hour window exhausting. The rate of prescription errors in Illinois in the retail setting has never been analyzed from a work hour perspective, thus it is impossible and negligent to assume that this factor is not vital to patient safety. At the very least, the State should consider carving out retail pharmacies to limit the workday to 8 hours.

Mandatory Breaks and Lunch Period

Regarding the standard contained in Section 4.5 of the Act, which required that the Task Force consider whether to require a pharmacy to "provide a pharmacist a minimum of 2 15-minute paid rest breaks and one 30-minute meal period in each working day on which the pharmacist works at least 7 hours," by modifying this standard in recommending that the legislature enact a new Section in the Pharmacy Practice Act entitled "Pharmacy Work Conditions," which would include the following provision:

> A. A pharmacist working longer than six (6) continuous hours per day shall be allowed during that time period to take a 30-minute uninterrupted meal break and (1) 15-minute break. The pharmacist qualifies for an additional 15-minute break if working twelve (12) continuous hours per day. No pharmacist shall be required to work longer than five (5) continuous hours per day without the opportunity to take an uninterrupted meal break.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of six in favor, none opposed, one abstention and one absent.[1]

The Task Force determined that this was a reasonable accommodation which provided sufficient minimal rest periods for a pharmacist, based on the majority's decision to limit the pharmacist's workday to a maximum of twelve hours. This recommendation recognizes that: pharmacies may require pharmacists to work twelve-hour shifts; and to ensure public safety, the pharmacists working those shifts on a regular basis need to have specified rest breaks and lunch periods to practice effectively.

Maintaining Error Records

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration whether to require a pharmacy "to retain records of any errors in the receiving, filling, or dispensing of prescriptions of any kind," by modifying this standard to establish a Continuous Quality Improvement ("CQI") Program and recommending that the legislature enact a provision in the Pharmacy Practice Act under a new Section entitled "Continuous Quality Improvement Program," which states the following:

> Each pharmacy shall implement a program for continuous quality improvement, for the purpose of detecting, documenting, assessing, and preventing Quality-Related Events (QREs). At a minimum, a CQI Program shall include provisions to:
>
> (i) designate an individual or individuals responsible for implementing, maintaining, and monitoring the CQI Program, which is managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form;

[1] The Task Force only considered provisions related to recommended breaks and lunch period based on a twelve-hour work day, because as discussed above, it separately determined that a pharmacy licensed under Illinois Statutes, which is located within Illinois, shall not require that a pharmacist, student pharmacist, or pharmacy technician work longer than twelve continuous hours per day, inclusive of the breaks, rather than eight continuous hours per day.

(ii) initiate documentation of QREs as soon as possible, but no more than seven days, after determining their occurrence;
(iii) analyze data collected in response to QREs to assess causes and any contributing factors;
(iv) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients;
(v) provide ongoing CQI education at least annually to all pharmacy personnel

Any pharmacy that contracts with a federally-listed Patient Safety Organization (PSO) and has developed and implemented a Patient Safety Evaluation System in order to advance the goal of continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) shall be deemed in compliance with this Section.

All information, communication, data, reports, deliberations and analyses of any pharmacy which satisfies the CQI Program requirements set forth that have the potential to improve quality and/or patient safety and are maintained as a component of a pharmacy CQI Program are privileged and confidential and shall not be subject to discovery or admissible into evidence in a state or federal proceeding nor subject to a judicial subpoena.

These protections shall not prevent the review of a pharmacy's CQI Program materials, policies, procedures and corrective actions taken pursuant to their Program. In addition, the Department may collect information of any adverse event or error that is maintained outside of a PSO's Patient Safety Evaluation System or outside of a CQI program, in response to a subpoena. The disclosure of documents or information under subpoena does not constitute a waiver of the privilege or confidentiality protections associated with a CQI Program.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of seven in favor, none opposed, and one abstention.

In reaching this unanimous (with one abstention) recommendation, the Task Force determined that in order to maintain effective error records, there must be continuous quality improvement ("CQI") to build a "just" culture and improve overall safety and quality of patient care. The Task Force believed that this proposal provides the Department and other oversight authorities with access to pharmacies' processes in monitoring and preventing quality-related events, while protecting the documentation of the errors from discovery in litigation and disciplinary actions – which discourage addressing errors. The Task Force believed that this provision gives pharmacies and pharmacists an incentive to strive toward providing accurate prescriptions and reports of adverse incidents without fear of litigation. The Task Force determined that the amendments would open any CQI process to review, but not the documentation involving the specific incident. Documentation of specific adverse events are intended to be used to improve systems and processes for the purpose of better patient safety.

In its review of this provision, the Task Force also considered Section 30.1 of the Pharmacy Practice Act (225 ILCS 85/30.1), which requires the reporting of any termination of a pharmacist or pharmacy

technician for actions which may have threatened patient safety. The Task Force determined that the proposed provision plus Section 30.1 would afford the Department the ability to determine whether any safety concerns are systemic within the pharmacy or are related to a single individual's unprofessional behavior.

Report of Prescription Discontinuation

Regarding the standard contained in Section 4.5 of the Act, which involved a consideration of "the extent to which . . . the Department [should be required] to adopt rules requiring pharmacy prescription systems contain mechanisms to require prescription discontinuation orders to be forwarded to a pharmacy," by recommending that the Pharmacy Practice Act, or the rule promulgated thereunder, be amended to state as follows:

A. Effective January 1, 2021, all pharmacies that use the SCRIPT standard for receiving electronic prescriptions must enable, activate, and maintain the ability to receive transmissions of electronic prescription cancellation and to transmit cancellation response transactions.

B. Within two (2) business days of receipt of a prescription cancellation transaction, pharmacy staff must either review the cancellation transaction for deactivation or provide that deactivation occurs automatically.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of eight in favor, none opposed, and no abstentions.

In reviewing the background information for this standard, the Task Force noted that the "CancelRx" function, which provides electronic notifications to cancel a prescription, was not included in the original meaningful use program which provided incentives for implementing the e-prescribing program. If the "CancelRx" function is not enabled, the prescriber is required to call the pharmacy on the telephone to discontinue the refills. Failure to notify the pharmacy of cancelled prescriptions could lead to patients continuing to take medications which the prescriber has determined are no longer necessary, potentially causing adverse drug events and increasing overall health care costs. Therefore, enabling the "CancelRx" function would permit the prescriber to electronically transmit instructions to prevent the issuance of refills for any discontinued medication.

Patient Verification and Detailed Automated Prescription Refill Notices

The Collaborative Pharmaceutical Task Force also considered the appropriate response to the provisions contained in Section 4.5 of the Pharmacy Practice Act, which stated that:

> [T]he extent to which requiring the Department to adopt rules requiring pharmacy prescription systems contain mechanisms:
>
> (1) To require patient verification features for pharmacy automated prescription refills; and
>
> (2) To require that automated prescription refills notices clearly communicate to patients the medication name, dosage strength, and any other information required

> by the Department governing the use of automated dispensing and storage systems to ensure that discontinued medications are not dispensed to a patient by a pharmacist or by any automatic refill dispensing systems whether prescribed through electronic prescriptions or paper prescriptions may be integrated into the Pharmacy Practice Act to better protect the public.

In response to these provisions, the Collaborative Pharmaceutical Task Force recommended an amendment to the Pharmacy Practice Act, or the rules promulgated thereunder, which states that:

> Prior to a prescription that has a refill on file from a prescribing practitioner being included in an auto-refill program, a patient or patient's agent must enroll each prescription medication in an auto-refill program. Prescriptions without a refill on file are not eligible for auto-refill.

The Task Force recommended the adoption of this requirement within the language of the Act, or the rules promulgated thereunder, in response to this provision of the Act by a vote of seven in favor, one opposed, and no abstentions.

The majority of the Task Force considered that the patient's approval to be placed in an auto-refill program was necessary to prevent the patient from receiving prescription medication which had not been approved by the patient's medical provider.

The dissenter was given an opportunity to provide an explanation for his vote but chose not to submit a rationale.

Duties of Pharmacy Technicians and Their Continuing Education Requirements

Regarding the direction contained in Section 4.5 of the Act, which stated that in "developing standards related to its discussions, the Collaborative Pharmaceutical Task Force shall consider the extent to which Public Act 99-473 (enhancing continuing education requirements for pharmacy technicians) may be relevant to the issues listed in Section 4.5 of the Pharmacy Practice Act," the Committee recommended amendments to Sections of the Act and the Controlled Substance Act. These amendments are intended to accomplish the following:

A. Require that pharmacy technicians be specifically trained for the tasks which they are assigned to accomplish, while retaining the exception that certain tasks cannot be delegated to pharmacy technicians;
B. Require that pharmacy technicians obtain documentation from a Pharmacist-In-Charge verifying that he or she has successfully completed a standardized nationally accredited education and training program with an objective assessment mechanism to be licensed, if they have not graduated from a pharmacy technician training program meeting the requirements of the Act;
C. Permit pharmacy technicians to administer vaccinations/immunizations to persons, as long as they successfully complete a course of training on the administration of vaccines approved by the Department and are directly supervised by a pharmacist; and

D. Permit student pharmacists and registered pharmacy technicians to transfer prescriptions between pharmacies for the purpose of original or refill dispensing, and to receive prescriptions for controlled substances from an employee or agent of the individual practitioner pursuant to the directions and order of that practitioner.

The Task Force recommended the adoption of this language within the Act, and the Controlled Substance Act, in response to this standard by a vote of eight in favor, none opposed, and no abstentions.

In reaching this unanimous recommendation, the majority of the Task Force concluded that there should be one standardized education and training program for all new pharmacy technicians. The amendments also clarified that a new pharmacy technician should obtain documentation from the Pharmacist-In-Charge, who verifies that the pharmacy technician has successfully completed a standardized nationally accredited education and training program to remain licensed. Furthermore, the majority of the Task Force recognized that there were certain tasks that appropriately trained and supervised pharmacy technicians can effectively undertake, thereby allowing the pharmacist to focus on more critical tasks. The amendments also recommend clarification in the current Act to specifically identify the only tasks that pharmacy technicians are prohibited from carrying out. This will allow a pharmacist to delegate any other task to an appropriately trained and supervised pharmacy technician.

Employee Terminations

The Task Force also considered the direction contained in Section 4.5 of the Act, which stated that in "developing standards related to its discussions, the Collaborative Pharmaceutical Task Force shall consider the extent to which . . . Public Act 99-863 (enhancing reporting requirements to the Department of pharmacy employee terminations) may be relevant to the issues listed in paragraphs (1) and (2)." After considering the standard, the Task Force recommended against the adoption of any language within the Act or the rules promulgated thereunder regarding this provision by a vote of eight in favor, none opposed, and no abstentions.

The Task Force noted that Section 30.1 of the Pharmacy Practice Act (225 ILCS 85/30.1) mandates that pharmacies or Pharmacists-In-Charge file a report with the Department's Chief Pharmacy Coordinator in every instance where a pharmacist, registered certified pharmacy technician, or registered pharmacy technician is terminated for actions which may threaten patient safety. The Task Force determined that these provisions were sufficient to protect public safety without unfairly harming the reputation of pharmacists or pharmacy technicians, as the Staff's investigations are confidential. The Task Force recommends that the Board of Pharmacy and State pharmacy professional organizations remind all Illinois licensed pharmacists of this requirement and emphasize the importance of submitting such reports. Also, these organizations should remind all pharmacists that no information about the individual named in a report is disclosed unless formal disciplinary action is taken against that person.

Grounds for Discipline

In response to several standards contained in Section 4.5 of the Act (225 ILCS 85/4.5), the Task Force recommended overall changes to the provisions which define unprofessional and unethical conduct,

contained in Administrative Rule Section 1330.30. The proposed additional definitions of unprofessional and unethical conduct would include the following provisions:

(1) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:
   (a) Is false, fraudulent, deceptive, or misleading;
   (b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee; or
   (c) Requiring pharmacists to participate in such activities.

(2) Failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient which includes but is not limited to:
   (a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care.
   (b) Appropriate opportunities for uninterrupted rest periods and meal breaks.
   (c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:
      (A) Drug Utilization Review;
      (B) Immunization;
      (C) Counseling;
      (D) Verification of the accuracy of a prescription; and
      (E) All other duties and responsibilities of a pharmacist as specified in the Pharmacy Practice Act Administrative Rules Part 1330.

(3) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

(4) Incenting or inducing the transfer of a prescription absent professional rationale.

(5) Anyone reporting violations of this section to the Department of Financial and Professional Regulation are specifically protected under the Illinois Whistle Blower Act (740 ILCS 174/15(b)).

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of seven in favor, none opposed, no abstentions and one absent.

The Task Force recognized that this motion included a number of standards that had been individually considered. However, a separate vote was taken on all the provisions because they include language that is not a part of the previously considered standards. The Task Force unanimously recommended these provisions to provide reassurance to pharmacists and pharmacy technicians that their work environment should be as free of distractions as possible, and sufficiently staffed so that they are able to provide safe and effective care for their patients. These standards allow the pharmacist to exercise his/her professional medical judgment while also giving the Department and the Board of Pharmacy a means to discipline pharmacists and pharmacy owners who permit unsafe pharmacy practices to occur.

Pharmacy Working Conditions

The Task Force also considered language for inclusion in Illinois statutes or rules, including the votes regarding standards discussed above, with some additional language. The proposed changes involve a new section of the statute or the rules which state the following:

1. Limitation on continuous hours worked.

   A pharmacy licensed under Illinois Statutes, 225 ILCS 85/15, which is located within Illinois, shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than twelve (12) continuous hours per day, inclusive of the breaks required under Subpart 2.

2. Requirements for breaks.

   A. A pharmacist working longer than six continuous hours per day shall be allowed during that time period to take a 30-minute uninterrupted meal break and one 15-minute break. The pharmacist qualifies for an additional 15-minute break if working twelve continuous hours per day. No pharmacist shall be required to work longer than five continuous hours per day without the opportunity to take an uninterrupted meal break.

   B. A pharmacy may, but is not required to, close when a pharmacist is on a break. If the pharmacy does not close, the pharmacist shall either remain within the licensed pharmacy or within the establishment in which the licensed pharmacy is located in order to be available for emergencies. In addition, the following apply:

      (1) Pharmacy technicians, student pharmacists, and other supportive staff, authorized by the pharmacist on duty, may continue to perform duties as allowed under this chapter;

      (2) No duties reserved to pharmacists and student pharmacists under any part of this chapter, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians or other supportive staff; and

      (3) Only prescriptions that have received final verification by a pharmacist may be dispensed while the pharmacist is on break, except those prescriptions that require counseling by a pharmacist, including all new prescriptions as defined in 1330.700 and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may be dispensed only if the following conditions are met:

         (a) The patient, or other individual who is picking up the prescription on behalf of the patient, is told that the pharmacist is on a break and is offered the chance to wait until the pharmacist returns from break in order to receive counseling;

(b) If the patient or caregiver declines to wait, a telephone number at which the patient or a caregiver can be reached is obtained;

(c) After returning from the break, the pharmacist makes a reasonable effort to contact the patient or a caregiver and provide counseling; and

(d) The pharmacist documents the counseling that was provided or documents why counseling was not provided after a minimum of two attempts, including a description of the efforts made to contact the patient or caregiver. The documentation shall be retained by the pharmacy, and be made available for inspection by the board or its authorized representatives, for a period of at least two years.

C. In pharmacies staffed by two or more pharmacists, the pharmacists shall stagger breaks so that at least one pharmacist remains on duty at all times that the pharmacy remains open for the transaction of business.

D. The Employer shall keep and maintain a complete and accurate record of the daily break periods of its pharmacists.

3. Exceptions for emergencies.

Subpart 1 and subpart 2, item A, shall not apply in the event that an emergency, as deemed by the professional judgment of the pharmacist, necessitates that a pharmacist, student pharmacist, or pharmacy technician work longer than 12 continuous hours, work without taking required meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.

The Task Force recommended the adoption of this language within the Act, or the rules promulgated thereunder, in response to this standard by a vote of six in favor, none opposed, one abstention and one absent.

The Task Force recognized that this motion included several standards that had been individually considered. However, a separate vote was taken on all the combined provisions because they include language related to exceptions from the established rule regarding the length of time that a pharmacist can work per day. The Task Force unanimously (with one abstention) recommended these provisions recognizing that there is a need to address the issue of required breaks for meals and restroom use. These newly recommended standards for work conditions provide the pharmacist and pharmacy technician with assurances of fairness and empower the pharmacist and pharmacy technician while providing the pharmacy employer with reasonable flexibility and, most importantly, providing the patient with safe and effective care.

Recommendation and Rationale Regarding Additional Study of the System for Compensating Pharmacists in Illinois

Regarding the language contained in Section 4.5 of the Act, which directed the Task Force to "discuss how to further advance the practice of pharmacy in a manner that recognizes the needs of the healthcare system, patients, pharmacies, pharmacists, and pharmacy technicians," it approved a motion to strongly recommend that the General Assembly establish another task force which:

> Will be charged with studying the issues related to the current system for remunerating pharmacists, and developing alternative methods for remunerating pharmacists for their professional patient care services, separate from the sale of drug products."

A majority of the Task Force believed that despite their formidable education and experience, the most important barrier to pharmacist contributions to safe and effective care in any setting is how they are paid. This is especially true in the setting of community pharmacy. They believed that many of the issues assigned to the task force are symptoms of insufficient reimbursement and virtually non-existent remuneration that exists in the current payment model to pharmacies and pharmacists. Fixing these other parts of pharmacy practice without altering current practices in payment will not solve the problems that drive risks to medication therapy in our patients. Without addressing the payment model for pharmacists, we continue to fail to take advantage of the significant contributions of highly trained healthcare professionals whose specific expertise is exactly what our system needs. Unlike other healthcare professions, no "professional fee" is usually attached to pharmacists' services. Total reimbursement is connected only to a commodity, the drug product. A typical prescription payment consists of reimbursement for the "ingredient cost" (cost of the drug) plus a dispensing fee (payment to cover the cost of providing the drug). The ingredient cost is typically calculated by the payer (insurance company or pharmacy benefits manager [PBM]), and, because of the high cost of drugs, the dispensing fee paid on prescriptions has significantly declined in recent years. It is not uncommon for insurers or PBM organizations to pay as little as 50 cents or nothing at all as a dispensing fee. Therefore, it is not unusual for the pharmacy or pharmacist to be reimbursed at an amount that is lower than the actual acquisition cost of the drug. That is, it is not uncommon for a pharmacy to lose money by filling a prescription.

In addition, payers often invoke other ways to reduce their expenses and their reimbursement to pharmacies. Most insurers or PBMs have formularies composed of preferred or formulary drugs; however, non-formulary drugs differ between insurers and PBMs, requiring the pharmacist to navigate these complexities to ensure the patient can receive the medication. In addition, some drugs require prior approval before dispensing, similar to medical procedures. Still other payers invoke penalties (so called "claw-back fees") for not making performance metrics (e.g., adherence, as judged by refill records). Audits conducted by the payer under the pretense of preventing fraud, waste, and abuse are frequent and time-consuming. Moreover, they often focus specifically on high-cost drugs and administrative errors rather than metrics that more closely improve outcomes for the insured.

So, it is clear that the margins on prescriptions in most community pharmacies are razor-thin and that the reimbursement models imposed by the various payers are incredibly complex. This lack of a viable financial and business model for the provision of patient care services in community pharmacies has prompted a trend of community pharmacy closures (both chain and independent). Recent research has

concluded that these closures can decrease patient adherence and negatively impact health.[2] Importantly, there is no payment for the pharmacist's cognitive services (such as counseling patients, detecting drug interactions, insuring adherence, getting rid of unneeded or duplicate medications, etc.), and without incentivizing these services through reasonable payment, it is unlikely that pharmacists will be able to perform them well, while simultaneously satisfying their important roles in drug distribution and dispensing. To ensure a safe medication use system, the public needs these roles to be appropriately incentivized, reimbursed, and remunerated. Payment models can significantly modulate health care professional behavior and performance. Another significant issue, often overlooked, is the conflict of interest that occurs when the pharmacist's only form of payment is tied to the drug product (i.e., there is no financial incentive to discontinue unneeded drugs). In fact, there is a perverse incentive to use as many drugs as possible in order to enhance revenue. This is out of sync with the needs of the public and payers, and it would greatly benefit from being counterbalanced by incentives toward rationale drug therapy. Clinical pharmacists in a hospital setting can attest that (1) drugs are overused and (2) the first step in the pharmacist's quest to ensure a rational drug regimen for an individual patient is to get rid of unnecessary prescriptions. Thus, in some way, if a pharmacist were paid for cognitive duties, this function and the revenue stream would be separated from the drug product. Pharmacists could and should be incentivized, through payment, for positive patient outcomes (e.g., discontinuing unnecessary medications, preventing a serious drug interaction, detecting adverse events, optimizing dosages) rather than a small or non-existent fee attached to a commodity, the drug product. The reimbursement model for pharmacists must be radically altered and unbundled from the drug product[3] in order to optimize medication therapy outcomes and reduce unnecessary health care spending. This change from volume-based reimbursement to service based and outcome-based reimbursement and population health would certainly be consistent with the current initiatives in organized medicine and health care in general.

It is our contention that paying pharmacists for their patient care services separately from the drug product would improve drug safety, adherence and overall public health for the citizens of Illinois. Other states (e.g., North Carolina, Washington, California, Minnesota and others)[4] have put into place such polices; Illinois should implement these policies as well.

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[2] Qato DM, Alexander GC, Chakraborty A, Guadamuz JS, Jackson JW, *"Association between pharmacy closures and adherence to cardiovascular medications among older US adults,"* JAMA Network Open April 19, 2019. doi:10.1001/jamanetworkopen.2019.2606. (Accessed April 26, 2019).

[3] Stubbings JA, Nutescu E, Durley SF, Bauman JL. *"Payment for clinical pharmacy services revisited,"* Pharmacotherapy 2011;31:1-8.

[4] Guglielmo BJ, Sullivan SD, *"Pharmacists as health care providers: Lessons from California and Washington,"* J Am Coll Clin Pharm 2018;1:32-37.

Collaborative Pharmaceutical Task Force Recommendation Log (225 ILCS 85/4.5)

Short Name	Language in Statute	Task Force's Recommendation	Date of Vote on Recommendation	Change in Statute or Rule
Whistleblower Protection	"The extent to which providing whistleblower protections for pharmacists and pharmacy technicians reporting violations of worker policies,"	Restate whistleblower provisions from Illinois Statutes Chapter 740, Civil Liabilities Section 174/15 into the Pharmacy Practice Act, and revisit whether it needed to be expanded at a later date. Vote was 8-0. Also, recommended a modification to adopt "Grounds for Discipline" to include "Anyone reporting violations of this section to the Department of Financial and Professional Regulation are specifically protected under the Illinois Whistleblower Act" (740 ILCS 174/15(b))." Vote was 7 in favor, 0 against and no abstentions.	11/13/2018 and 06/19/2019	Either Statute or Rule
Pharmacy Tech on Duty	"Requiring pharmacies to have at least one pharmacy technician on duty whenever the practice of pharmacy is conducted,"	Recommended against the adoption of any language within the Pharmacy Practice Act, or the Rules thereunder, addressing standard. Vote was 5 in favor, 1 against, with 1 abstention.	6/19/2019	N/A
Prescription Limit	"To set a prescription limit of not more than 10 prescriptions filled per hour,"	Recommended a modification to adopt "Grounds for Discipline" to include "the Failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient which includes, but is not limited to: (A)Drug Utilization Review; (B)Immunization; (C)Counseling;(D)Verification of the accuracy of a prescription; and (E)All other duties and responsibilities of a pharmacist as specified in the Pharmacy Practice Act Administrative Rules Part 1300." Vote was 7 in favor and 0 against with no abstentions.	6/19/2019	Either Statute or Rule
Pharmacy Tech Hours	"To mandate at least 10 pharmacy technician hours per 100 prescriptions filled,"	Recommended a modification to adopt "Grounds for Discipline" to include "the Failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient which includes, but is not limited to: Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to: (A)Drug Utilization Review; (B)Immunization; (C)Counseling;(D)Verification of the accuracy of a prescription; and (E)All other duties and responsibilities of a pharmacist as specified in the Pharmacy Practice Act Administrative Rules Part 1300. Vote was 7 in favor and 0 against, with no abstentions.	6/19/2019	Either Statute or Rule

Short Name	Language in Statute	Task Force's Recommendation	Date of Vote on Recommendation	Change in Statute or Rule
Prohibit Distractions	"To place general prohibition on activities that distract pharmacists,"	Recommended a modification to adopt "Grounds for Discipline," to include "(2) Failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient which includes, but is not limited to:(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care." Vote was 7 in favor and 0 against with no abstentions.	6/19/2019	Either Statute or Rule
Mandatory Breaks and Lunch Period	"To provide a pharmacist a minimum of 2 15-minute paid rest breaks and one 30-minute meal period in each workday on which the pharmacist works at least 7 hours,"	Recommended a modification to adopt "Pharmacy Work Conditions" which contains "A pharmacist working longer than six continuous hours per day shall be allowed during that time period to take a 30-minute uninterrupted meal break and (1) 15-minute break. The pharmacist qualifies for an additional 15-minute break if working 12 continuous hours per day. No pharmacist shall be required to work longer than 5 continuous hours per day without the opportunity to take an uninterrupted meal break." Vote was 6 in favor, 0 against with 1 abstention.	6/19/2019	Statute
No Work During Break	"To not require a pharmacist to work during a break period,"	Recommended a modification to adopt "Grounds for Discipline," to include "(2) Failure to provide a working environment for all pharmacy personnel that protects the health, safety and welfare of a patient which includes, but is not limited to:(b) Appropriate opportunities for uninterrupted rest periods and meal breaks. Vote was 7 in favor and 0 against with no abstentions.	6/19/2019	Either Statute or Rule
Triple Pay for No Breaks	"To pay the pharmacist 3 times the pharmacist's regular hourly rate of pay for each workday during which the required breaks were not provided,"	Recommended against the adoption of any language within the Pharmacy Practice Act, or the Rules thereunder, addressing this standard. Vote was 5 in favor, 1 against with 1 abstention.	6/19/2019	N/A
Break Room	"To make available at all times a room on the pharmacy's premises with adequate seating and tables for the purpose of allowing a pharmacist to enjoy break periods in a clean and comfortable environment,"	Recommended against the adoption of any language within the Pharmacy Practice Act, or the Rules thereunder, addressing standard. Vote was 5 in favor, 1 against with 1 abstention.	6/19/2019	N/A
Break Records	"To keep a complete and accurate record of the break periods of its pharmacists,"	Recommended a modification to adopt "Pharmacy Work Conditions" which contains "The Employer shall keep and maintain a complete and accurate record of the daily break periods of its pharmacists." Vote was 4 in favor, 2 against, with 1 abstention.	6/19/2019	Statute

Short Name	Language in Statute	Task Force's Recommendation	Date of Vote on Recommendation	Change in Statute or Rule
8-Hour day	"To limit a pharmacist from working more than 8 hours a workday, and"	Failed to approve a motion containing a recommendation that stated "A pharmacy licensed under Illinois Statutes, which is located within Illinois, shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than eight (8) continuous hours per day, inclusive of the breaks required under subpart 2." Vote was 1 in favor, 6 against with 1 abstention. Recommended a modification to adopt "Pharmacy Work Conditions" which contains "A pharmacy licensed under Illinois Statutes, which is located within Illinois, shall not require a pharmacist, student pharmacist, or pharmacy technician to work longer than twelve (12) continuous hours per day, inclusive of the breaks required under subpart 2." Vote was 5 in favor, 1 against, with 1 abstention.	8/13/2019 6/19/2019	Statute
Maintaining Error Records	"To retain records of any errors in the receiving, filling or dispensing of prescriptions of any kind could be integrated into the Pharmacy Practice Act."	Approved a Continuous Quality Improvement ("CQI") program with a vote of 7 in favor, 0 against with 1 abstention.	11/13/2018	Statute
The extent to which requiring the Department to adopt rules requiring pharmacy prescription systems contain mechanisms:				
Report of Prescription Discontinuation	"To require prescription discontinuation orders to be forwarded to a pharmacy,"	Recommended amendments to the Act, or the Rules which state the following: Effective January 1, 2021, all pharmacies that use the SCRIPT standard for receiving electronic prescriptions must enable, activate, and maintain the ability to receive transmissions of electronic prescription cancellation and to transmit cancellation response transactions; and Within two (2) business days of receipt of a prescription cancellation transaction, pharmacy staff must either review the cancellation transaction for deactivation or provide that deactivation occurs automatically. Vote was 7 in favor and 0 against, with no abstentions.	7/9/2019	Either Statute or Rule
Patient Verification	"To require patient verification features for pharmacy automated prescription refills, and"	Recommended amendments to the Act, or the Rules, which state the following: Prior to a prescription that has a refill on file from a prescribing practitioner being included in an auto-refill program, a patient or patient's agent, must enroll each prescription medication in an auto-refill program. Prescriptions without a refill on file are not eligible for auto-refill. Vote was 7 in favor and 1 against, with no abstentions.	8/13/2019	Either Statute or Rule

Short Name	Language in Statute	Task Force's Recommendation	Date of Vote on Recommendation	Change in Statute or Rule
Detailed Automated Prescription Refill Notices	"To require that automated prescription refills notices clearly communicate to patients the medication name, dosage strength, and any other information required by the Department governing the use of automated dispensing and storage systems to ensure that discontinued medications are not dispensed to a patient by a pharmacist or by any automatic refill dispensing systems whether prescribed through electronic prescriptions or paper prescriptions may be integrated into the Pharmacy Practice Act to better protect the public."	Recommend amendments to the Act, or the Rules, which state the following: Prior to a prescription that has a refill on file from a prescribing practitioner being included in an auto-refill program, a patient or patient's agent, must enroll each prescription medication in an auto-refill program. Prescriptions without a refill on file are not eligible for auto-refill. Vote was 7 in favor and 1 against, with no abstentions.	8/13/2019	Either Statute or Rule
		Additional Paragraph		
Pharmacy Technicians Continuing Education and Employee Terminations	"In developing standards related to its discussions, the Collaborative Pharmaceutical Task Force shall consider the extent to which Public Act 99-473 (enhancing continuing education requirements for pharmacy technicians) . . . may be relevant to the issues listed in paragraphs (1) and (2)." "In developing standards related to its discussions, the Collaborative Pharmaceutical Task Force shall consider the extent to which . . . Public Act 99-863 (enhancing reporting requirements to the Department of pharmacy employee terminations) may be relevant to the issues listed in paragraphs (1) and (2)."	Recommended amendments to the Act or the Rules, and the Controlled Substance Act, as shown on the document entitled "Proposed Changes Related to Duties of Pharmacy Technicians." These amendments are intended to accomplish the following: require that pharmacy technicians be specifically trained for the tasks which they are assigned to accomplish, while retaining the exception that certain tasks cannot be delegated to pharmacy technicians; require that pharmacy technicians obtain documentation from a pharmacist-in-charge verifying that he or she has successfully complete a standardized nationally accredited education and training program with an objective assessment mechanism to be licensed, if they have not graduated from a pharmacy technician training program meeting the requirements of the Act; permit pharmacy technicians to administer vaccinations/ immunizations to persons, as long as they successfully complete a course of training on the administration of vaccines approved by the Department and are directly supervised by a pharmacist; and permit student pharmacists and registered pharmacy technicians to transfer prescriptions between pharmacies for the purpose of original or refill dispensing, and to receive prescriptions for controlled substances from an employee or agent of the individual practitioner pursuant to the directions and order of that practitioner. Vote was 7 in favor and 0 against, with no abstentions. Recommended against the adoption of any language within the Pharmacy Practice Act, or the Rules thereunder, addressing standard. Vote was 7 in favor, 0 against with 0 abstentions.	7/9/2019	Either Statute or Rule

Short Name	Language in Statute	Task Force's Recommendation	Date of Vote on Recommendation	Change in Statute or Rule
Additional Recommendation For Further Study				
Review System for Compensating Pharmacists in Illinois	"The Task Force shall discuss how to further advance the practice of pharmacy in a manner that recognizes the needs of the healthcare system, patients, pharmacies, pharmacists, and pharmacy technicians."	Strongly recommended continued efforts to develop alternative methods for remunerating pharmacists for their professional patient care services, separate from sale of drug products, and that another task force be formed to study this critically important issue and product recommended amendments to the Pharmacy Practice Act. Vote was 7 in favor, 0 against and 1 abstention.	8/13/2019	Statute

Potentially Relevant Laws and Regulations

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the

responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs, devices, or controlled paraphernalia in accordance with the provisions of § 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3316. Refusal; revocation; suspension and denial.

The Board may refuse to admit an applicant to any examination; refuse to issue a license, permit, certificate, or registration to any applicant; or reprimand, impose a monetary penalty, place on probation, impose such terms as it may designate, suspend for a stated period of time or indefinitely, or revoke any license, permit, certificate, or registration if it finds that an applicant or a person holding a license, permit, certificate, or registration:

1. Has been negligent in the practice of pharmacy or in any activity requiring a license, permit, certificate, or registration from the Board;

2. Has engaged in unprofessional conduct specified in regulations promulgated by the Board;

3. Has become incompetent to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board because of a mental or physical condition;

4. Uses drugs or alcohol to the extent that he is rendered unsafe to practice pharmacy or to engage in any activity requiring a license, permit, certificate, or registration from the Board;

5. Has engaged in or attempted any fraud or deceit in connection with the practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board, including any application to the Board for such license, permit, certificate, or registration;

6. Has engaged in activities beyond the scope of a license, permit, certificate, or registration or has assisted or allowed unlicensed persons to engage in the practice of pharmacy or perform duties related to the practice of pharmacy for which a license or registration is required;

7. Has violated or cooperated with others in violating any provisions of law or regulation relating to practice of pharmacy or any activity requiring a license, permit, certificate, or registration from the Board;

8. Has had revoked or suspended any registration issued by the United States Drug Enforcement Administration or other federal agency that is necessary to conduct an activity also requiring a license, permit, certificate, or registration from the Board;

9. Has engaged in the theft or diversion of controlled substances or has violated any federal drug law or any drug law of Virginia or of another state;

10. Has had denied, suspended, or revoked in any other state a license to practice pharmacy or any license, permit, certificate, or registration necessary to conduct an activity requiring a license, permit, certificate, or registration from the Board, or has surrendered in another state such license, permit, certificate, or registration;

11. Has been convicted of any felony or of any misdemeanor involving moral turpitude;

12. Has issued or published statements intended to deceive or defraud about his professional service or an activity requiring a license, permit, certificate, or registration from the Board;

13. Has conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public; or

14. Has failed to comply with requirements of this chapter or any regulation of the Board relating to continuing education.

(1972, c. 798, § 54-524.22:1; 1976, c. 614; 1977, c. 86; 1982, c. 401; 1988, c. 765; 1992, c. 868; 1994, c. 296; 2007, c. 662.)

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day 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.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

E. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time.

B. In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

Below from *Regulations Governing the Practice of Pharmacy*:

18VAC110-20-25. Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or the patient's personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Failing to maintain adequate safeguards against diversion of controlled substances;

5. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

6. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

7. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current;

8. Obtaining money or property of a patient or client by fraud or misrepresentation;

9. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

10. Violating any provision of this chapter or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

11. Performing any act likely to deceive, defraud, or harm the public; or

12. Having a restriction of a license, permit, or registration to practice in another jurisdiction in the United States.

Below from *Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians:*

18VAC110-21-40. Unprofessional conduct.

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to providing patient records to another practitioner or to the patient or the patient's personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain the confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against the diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the pharmacist in charge to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current;

10. Failing to exercise professional judgment in determining whether a prescription meets the requirements of law before dispensing;

11. Obtaining money or property of a patient or client by fraud or misrepresentation;

12. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

13. Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

14. Performing any act likely to deceive, defraud, or harm the public; or

15. Having a restriction of a license to practice pharmacy or a registration as a pharmacy technician in another jurisdiction in the United States.

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within 15 days of receipt of this notice. At the conclusion of the 15-day period, the Director or his authorized agent, or any law-enforcement officer in coordination with the Director, shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and the Director shall notify the owner of such seizure. The Director, his authorized agent, or the law-enforcement officer may properly dispose of the seized drugs and devices after 60 days from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board or law-enforcement agency shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Every pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

Each day during which a person is in violation of this section shall constitute a separate offense.

1970, c. 650, § 54-524.31; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1980, c. 288; 1983, c. 286; 1986, c. 207; 1988, cc. 445, 765; 1994, c. 299; 1998, c. 470; 2000, c. 135; 2008, c. 320; 2011, c. 610; 2016, c. 221; 2019, c. 94.

Revised: December 10, 2020
Effective: February 4, 2021

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

Regulations Governing the Practice of Pharmacy

18VAC110-20-110. Pharmacy permits generally.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day 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.

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to, close when a pharmacist is on break. A pharmacist on duty may use professional judgment about whether to close the pharmacy provided notice has been posted at least 14 days in advance of the closure;
- If a pharmacy does not close, the pharmacist must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.