

8/11/23

**PORTIONS OF THE RULES IN THIS PACKAGE WERE DISSEMINATED FOR CSI PUBLIC COMMENT ON 4/18/2023. ON 8/7/2023, THE STATE OF OHIO BOARD OF PHARMACY RESCINDED THAT RULE PACKAGE FROM CSI CONSIDERATION.**

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

**New:**

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. Includes requirements to ensure sufficient time and personnel.
- 4729:5-5-02.1 - Prohibits the use of quotas in the provision of ancillary services in an outpatient pharmacy.
- 4729:5-5-02.2 - Provides mandatory rest breaks for pharmacy personnel.
- 4729:5-5-02.3 - Requires outpatient pharmacies to develop a process to address staffing concerns.
- 4729:5-5-02.4 - Defines a significant delay in pharmacy services and creates a process whereby an outpatient pharmacy must address such delays.
- 4729:5-5-02.5 - Provides the requirements for managing pharmacy access points in an outpatient pharmacy.

**Rescind:**

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy.

To submit comments, please use the following online form:

<https://www.surveymonkey.com/r/MINSTAND> (NOTE: All responses will be forwarded to CSI).

Comments on the proposed rules will be accepted until **close of business on September 12, 2023.**

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## Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Joseph Baker**, Director

### Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information:

Cameron McNamee, [cameron.mcnamee@pharmacy.ohio.gov](mailto:cameron.mcnamee@pharmacy.ohio.gov)

Regulation/Package Title (a general description of the rules' substantive content):

Minimum Standards in an Outpatient Pharmacy

Rule Number(s): 4729:5-5-02; 4729:5-5-02.1; 4729:5-5-02.2; 4729:5-5-02.3; 4729:5-5-02.4; 4729:5-5-02.5

Date of Submission for CSI Review: 8/11/23

Public Comment Period End Date: 9/12/23

**Rule Type/Number of Rules:**

New/ 6 rules

No Change/      rules (FYR?     )

Amended/      rules (FYR?     )

Rescinded/ 1 rules (FYR? Y)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies

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should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

### **Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☐ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☒ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

### **Regulatory Intent**

2. Please briefly describe the draft regulation in plain language.

*Please include the key provisions of the regulation as well as any proposed amendments.*

**New:**

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. Includes requirements to ensure sufficient time and personnel.
- 4729:5-5-02.1 - Prohibits the use of quotas in the provision of ancillary services in an outpatient pharmacy.
- 4729:5-5-02.2 - Provides mandatory rest breaks for pharmacy personnel.
- 4729:5-5-02.3 - Requires outpatient pharmacies to develop a process to address staffing concerns.
- 4729:5-5-02.4 - Defines a significant delay in pharmacy services and creates a process whereby an outpatient pharmacy must address such delays.

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- 4729:5-5-02.5 - Provides the requirements for managing pharmacy access points in an outpatient pharmacy.

**Rescind:**

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy.

**3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rule is authorized by sections 4729.26, 4729.55, and 3719.28 of the Ohio Revised Code.

**4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

These rules do not implement a federal requirement.

**5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

These rules exceed federal requirements because the regulation of the pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy.

**6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy. Additionally, ORC 4729.55(D) requires a pharmacy to ensure the following: *Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.*

As part of the Board's mission to ensure adequate safeguards are maintained by a pharmacy, the Board issued two surveys gauging the general working conditions of pharmacists and pharmacy personnel. The results indicated significant issues related to working conditions in

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outpatient pharmacies (see a sample of survey responses below). More information on the survey and results can be found here: [www.pharmacy.ohio.gov/PWAC](http://www.pharmacy.ohio.gov/PWAC).

### **Quotas**

*Ohio Survey: I feel pressure by my employer or supervisor to meet standards or metrics that may interfere with safe patient care.*

Setting	2020	2021
Large Chain (Grocer/Standalone)	Strongly Agree/Agree = (1841/2268) 81%	Strongly Agree/Agree = (1403/1921) 73%
Independent / Small Chain	Strongly Agree/Agree = (59/329) 18%	Strongly Agree/Agree = (54/251) 22%
Hospital / Inpatient	Strongly Agree/Agree = (218/756) 29%	Strongly Agree/Agree = (140/465) 30%
Long-Term Care	Strongly Agree/Agree = (35/130) 27%	Strongly Agree/Agree = (28/95) 42%
Mail Order	Strongly Agree/Agree = (66/161) 41%	Strongly Agree/Agree = (23/66) 34%

### **Mandatory Rest Breaks**

*Ohio Survey: I am given the opportunity to take lunch breaks or other breaks throughout the workday:*

Setting	2020	2021
Large Chain (Grocer/Standalone)	Strongly Agree/Agree = (448/2268) 20%	Strongly Agree/Agree = (554/1921) 29%
Independent / Small Chain	Strongly Agree/Agree = (167/329) 51%	Strongly Agree/Agree = (126/251) 50%
Hospital / Inpatient	Strongly Agree/Agree = (451/756) 60%	Strongly Agree/Agree = (250/465) 54%
Long-Term Care	Strongly Agree/Agree = (106/130) 82%	Strongly Agree/Agree = (68/95) 72%
Mail Order	Strongly Agree/Agree = (151/161) 94%	Strongly Agree/Agree = (58/66) 88%

### **Staffing Concerns**

*Ohio Survey: I feel safe voicing any workload concerns to my employer:*

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Setting	2021
Large Chain (Grocer/Standalone)	Strongly Agree/Agree = (355/1921) 18%
Independent / Small Chain	Strongly Agree/Agree = (152/251) 61%
Hospital / Inpatient	Strongly Agree/Agree = (214/465) 46%
Long-Term Care	Strongly Agree/Agree = (43/95) 45%
Mail Order	Strongly Agree/Agree = (35/66) 53%

These issues are further reinforced through inspections detailing significant staffing issues at outpatient pharmacies, including patient delays and the loss of controlled substances:

- “Corners are cut to dispense prescriptions,” CVS employee tells Ohio Board of Pharmacy: <https://ohiocapitaljournal.com/2023/07/07/corners-are-cut-to-dispense-prescriptions-cvs-employee-tells-ohio-board-of-pharmacy/>
- Problems at understaffed CVS pharmacies are said to be widespread. The Ohio AG is taking a look: <https://ohiocapitaljournal.com/2023/08/03/problems-at-understaffed-cvs-pharmacies-are-said-to-be-widespread-the-ohio-ag-is-taking-a-look/>

It should be further noted that additional state and national surveys also indicate staffing issues in outpatient (community) pharmacy settings throughout the country (this includes data points pre and post COVID-19):

#### **NATIONAL STATE-BASED PHARMACY WORKPLACE SURVEY (April 2021)** ([link](#))

- The survey was launched in April 2021. A preliminary analysis of the data represents the timeframe between April and November 2021.
- This preliminary report represents responses from 4,482 pharmacy personnel.
- Approximately, 75% responded in the negative to questions regarding enough time and personnel to safely perform or meet duties.
- Over 60% indicated that workflow, payment for pharmacy services and employee policies that allow pharmacy personnel to perform clinical and non-clinical duties safely were also responded to in the negative.
- Telephone Interruptions (90%), inadequate staff (88%), patient demands/expectations (80%), inadequately trained staff (75%), the inability to practice in a patient-focused manner (76%) and harassment and bullying from customers/patients (69%) are stressors that contribute the most to medication errors and near misses.

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**National Study: Perceptions of Working Conditions and Safety Concerns in Community Pharmacy (2021) ([link](#))**

- Respondents working in national chains had significantly more fear of being disciplined for following policies to promote safety and addressing patient safety concerns than respondents in independent ( $P < 0.001$ ) and grocery and big box stores ( $P < 0.001$ ), when controlling for years of experience in community pharmacy, degree, and prescription volume. Most participants ( $n = 805$ , 96.9%) indicated organizational or company level factors were the most substantial threat to safety, with work design and quality emphasis being the second most frequently mentioned hazards.

**Ohio (The Ohio State University – February/March 2019) ([link](#))**

- 977 community pharmacists (68.56%) reported professional burnout.
- When asked to self-identify their top 3 workplace stressors, respondents primarily described stressors that aligned with the Workload, Control, and Reward dimensions of the Areas of Worklife Survey:

**Table 3. – Self-Identified Stressors by AWS Dimension**

Dimension	Number and percent of responses	Examples
Workload	873 (36%)	“short staffed”; “meetings”; “busy work”
Control	798 (32.9%)	“change”; “goals”; “metrics”; “reimbursement”
Reward	522 (21.6%)	“recognition”; “appreciation”
Community	150 (6.2%)	“communication”; “colleagues”
Fairness	51 (2.1%)	“distribution of workload”; “accountability”
Values	28 (1.6%)	“lack of congruence/alignment with organization values”

*N=2422 (response to this question was optional, and respondents were not limited to one item/stressor)*

**Nebraska Survey (May 2022)**

Overall, I feel I can practice pharmacy safely at my current pharmacy practice site:

Practice Setting	Agree/Strongly Agree	Disagree/Strongly Disagree
Community (Chain)	26.7%	73.3%
Community (Independent)	84.3%	15.7%

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<b>Hospital (Inpatient)</b>	77.5%	22.5%
<b>Hospital (Outpatient)</b>	81.8%	18.2%
<b>Others</b>	88.2%	11.8%

- Compared to pharmacists working at other practice settings, chain community pharmacists were more likely to feel emotionally exhausted (85.7%), physically exhausted (84.8%), and experience burnout (86.7%).
- Only 26.7% of chain community pharmacists felt they could practice safely.
- Ordinal logistic regression identified predictors that impacted workforce conditions and work stress. Practice setting was a significant predictor for all response variables. Chain community pharmacists were 1.94 to 15.07 times more likely to have negative thoughts on their workforce conditions or feel burnout at work.

### **Missouri (2019):**

I have adequate time to complete my job in a safe and effective manner:

<b>Agree/Strongly Agree</b>	<b>Disagree/Strongly Disagree</b>	<b>Neutral</b>
38%	52%	11%

I feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care at my practice site (e.g., mandatory dispensing or immunization requirements):

<b>Agree/Strongly Agree</b>	<b>Disagree/Strongly Disagree</b>	<b>Neutral</b>
60%	28%	13%

### **Kansas (February 2022) ([link](#))**

I feel I have adequate time to complete my job in a safe and effective manner:

<b>Agree/Strongly Agree</b>	<b>Disagree/Strongly Disagree</b>
43%	57%

<b>Impact of COVID</b>	<b>Responses</b>
Pharmacy workplace conditions have improved during the pandemic	2
Pharmacy workplace conditions were fine before the pandemic but have gotten worse during the pandemic	117
Pharmacy workplace conditions were poor before the pandemic and have continued to worsen during the pandemic	420
The pandemic has not had any impact on pharmacy workplace conditions	10
<b>Total</b>	<b>549</b>

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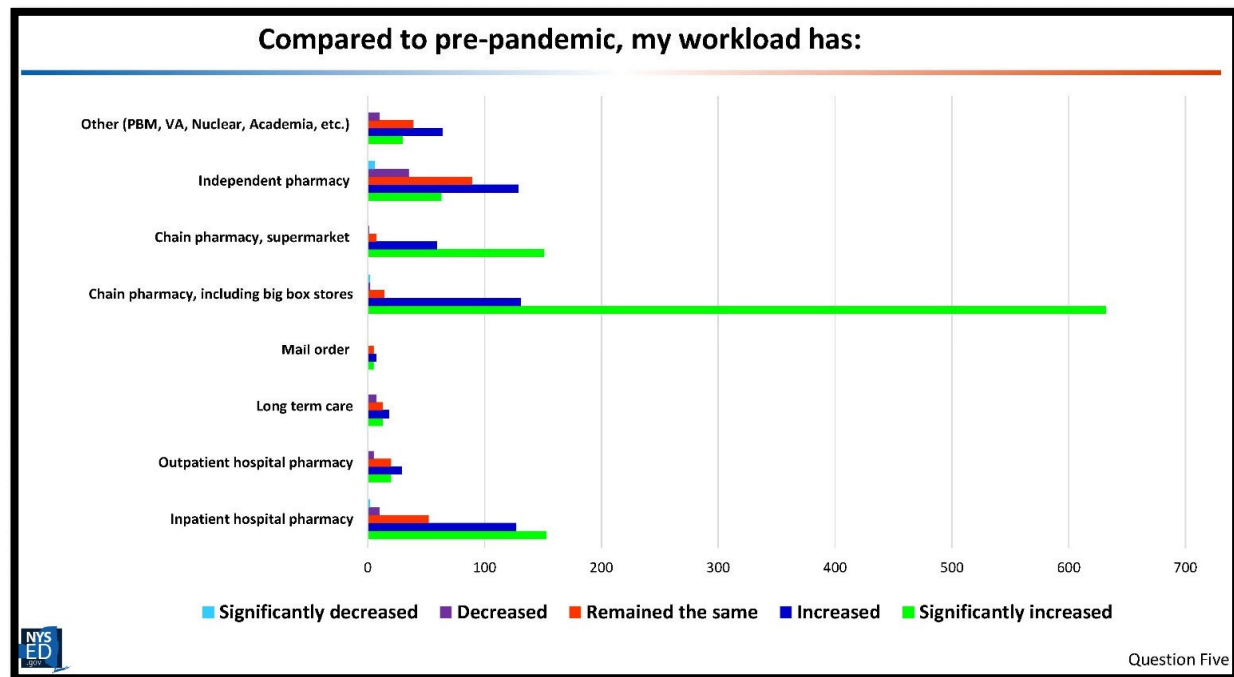
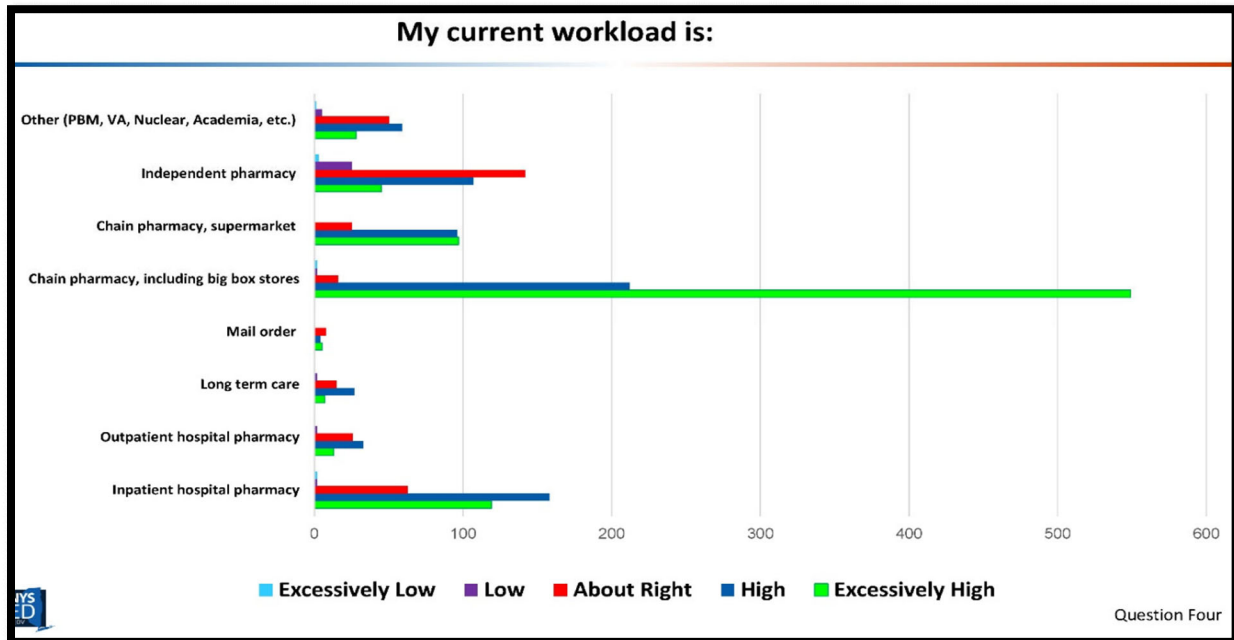
**Tennessee (2019) ([link](#))**

- Actively licensed Tennessee pharmacists were recruited from January 1 and June 30, 2019 to complete a 13-item survey of workplace patient safety perceptions (N=1391).
- Descriptive statistics were calculated, and nonparametric statistical tests employed to compare differences in perceptions across practice setting type, pharmacist roles, and hours worked per shift and per week.
- Generally, pharmacists practicing in compounding and independent community pharmacy settings reported the most favorable perceptions of patient safety.
- Whereas approximately 60% of chain community pharmacists disagreed or strongly disagreed that they have adequate time to complete their job in a safe and effective manner, at least two-thirds of pharmacists in every other practice setting agreed or strongly agreed with the statement.
- The extent to which pharmacists agreed/strongly agreed that their employer provides a work environment that allows for safe patient care ranged from 29.7% of chain community pharmacists to 85% of compounding pharmacists.
- When asked about adequate staffing to provide a safe environment for patient care, 23.2% of community chain pharmacists agreed or strongly agreed they have adequate pharmacy technician staffing; alternatively, about 55% of inpatient hospital pharmacists and 88% of independent community pharmacists agreed that they have adequate pharmacy technician staffing.
- About two-thirds (64.7%) of chain community pharmacists agreed or strongly agreed that they feel pressured or intimidated to meet standards or metrics that may interfere with safe patient care at their practice sites. The percentage of pharmacists who responded similarly in other settings ranged from 17.1% in independent community to 38.2% in mail order pharmacy settings.

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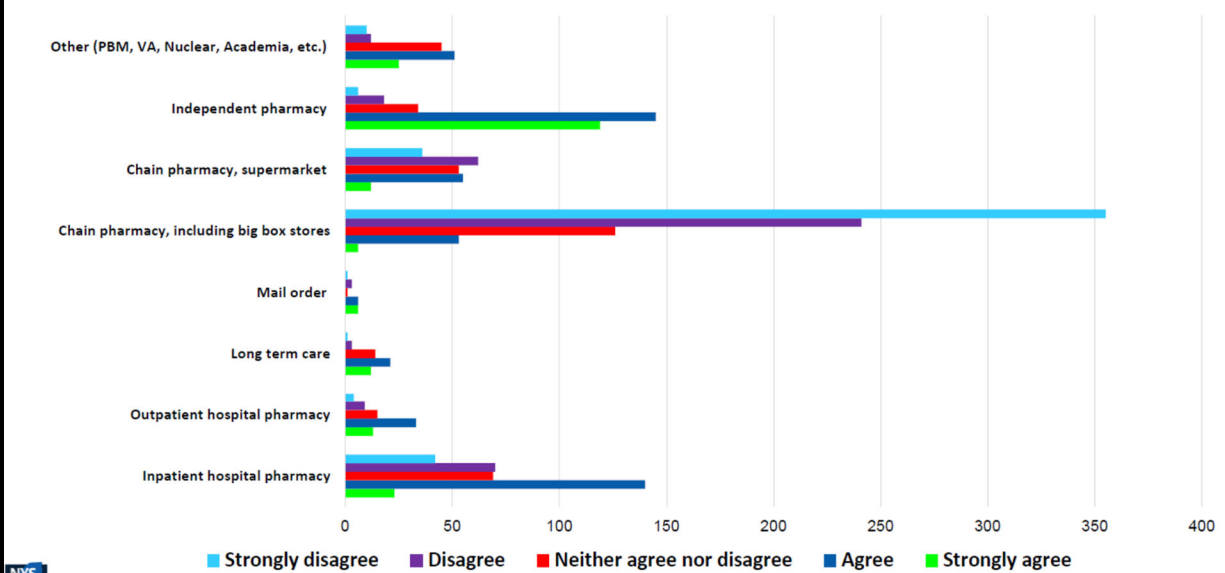
New York (June 2022) ([link](#))



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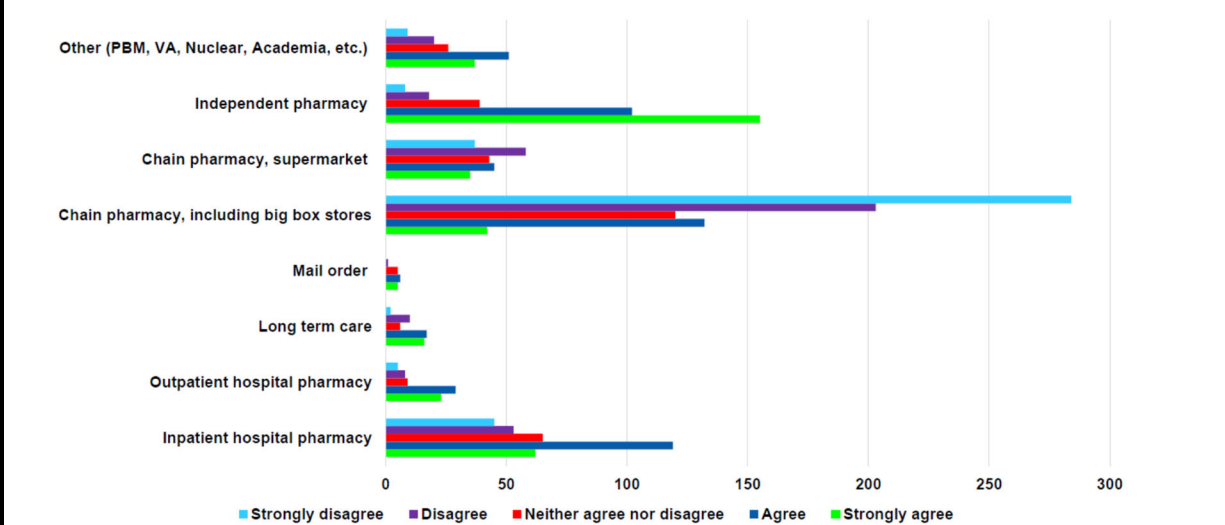
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### Overall, my employer provides a work environment that allows for safe patient care.



Question Ten

### I feel safe voicing any workplace concerns to my employer.



Question 13

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**7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules. Additionally, the Board will be deploying future surveys of pharmacists and pharmacy personnel to see how the rule is impacting working conditions.

**8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

**Development of the Regulation**

**9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

Most of the rules in this package, except for OAC 4729:5-5-02.4, were distributed for initial public comment by posting the rule package to the Board's proposed rules website. Additionally, portions of the rules in this package were disseminated for CSI public comment on 4/18/2023. On 8/7/2023, the Board rescinded that filing with CSI and is replacing it with this package. OAC 4729:5-5-02.4 was primarily developed from Board inspection reports detailing pharmacies that were experiencing significant staffing issues and delays in the provision of patient care as well as previous meetings of the Board's Pharmacist Workload Advisory Committee (including the discussion of the implementation of dark hours).

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

**10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

The initial public comment period for this rule was split into two rules. The first rule addressed the use of quotas and the second rule addressed meal breaks. The input provided during these two initial rounds of stakeholder feedback that were incorporated into the rule includes:

- The Board did not include a prohibition on quotas related to the volume of prescriptions dispensed.

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- The Board opted to allow a pharmacist to voluntarily work more than 12 hours.
- The Board created some flexibility for independent pharmacies to allow them to remain open while still giving staff an appropriate rest break.

Additionally, the Board submitted a previous version of this rule for CSI review in April 2023. That rule package was withdrawn on 8/7/23 and was replaced by this package. However, the Board did incorporate some comments provided during that comment period, including the exemption of closed-door pharmacies from certain requirements of the rules.

#### **11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

In addition to the data provided in Q6 of this BIA, the Board surveyed Ohio Pharmacists (N=2,012) to assess how the policy proposals in this rule package would improve working conditions:

- **Quotas (4729:5-5-02.1):** Majority of ALL pharmacists surveyed indicated that eliminating quotas would be likely or extremely likely to improve working conditions (~88%). Addressing quotas was the highest rated policy option (87.92%) by Ohio pharmacists.
  - This figure increases to 91% when looking at [responses](#) from pharmacists working in large chain settings.
- **Rest Breaks (4729:5-5-02.2):** Majority of ALL pharmacists surveyed indicated that mandatory rest breaks would be likely or extremely likely to improve working conditions (~84%). Addressing rest breaks was the fourth highest rated policy option (83.85%) by Ohio pharmacists.
- **Staffing Concerns (4729:5-5-02.3):** Majority of ALL pharmacists surveyed indicated that reports of understaffing would be likely or extremely likely to improve working conditions (~60%).
- **Managing Touchpoints (4729:5-5-02.5):** Majority of ALL pharmacists surveyed indicated that policies to address pharmacy touchpoint would be likely or extremely likely to improve working conditions (~87%). Addressing touchpoints was the second highest rated policy option (86.86%) by Ohio pharmacists.
  - This figure increases to 91% when looking at [responses](#) from pharmacists working in large chain settings.

#### **12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives? *Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

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Several rules incorporate performance-based regulations, including:

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. Includes required outcome to ensure sufficient personnel.
- 4729:5-5-02.4 - Defines a significant delay in pharmacy services and creates a process whereby an outpatient pharmacy must address such delays. Provides flexibility for the pharmacy to develop a remediation plan in consultation with an agent of the Board.
- 4729:5-5-02.5 - Provides the requirements for managing pharmacy access points in an outpatient pharmacy. Permits a pharmacy to develop their own policies regarding pharmacy access points.

**13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

**14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rules will be posted on the Board of Pharmacy's website, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications and feedback from the Board's legal department for every citation submitted.

**Adverse Impact to Business**

**15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

- a. Identify the scope of the impacted business community:**
- Outpatient pharmacies licensed as terminal distributors of dangerous drugs;

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- Pharmacists;
- Pharmacy Interns;
- Pharmacy Technicians.

**b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.*

**New:**

- **4729:5-5-02** - Establishes minimum standards in an outpatient pharmacy. Includes requirements to ensure sufficient time and personnel. While this is a new rule, the only new requirements, when compared to the existing rule, include:
  - A requirement to ensure sufficient personnel to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Requires staffing levels shall not be solely based on prescription volume but shall consider any other requirements of pharmacy personnel during working hours.
  - A requirement to provide Board inspectors with the contact information for the pharmacy's security system vendor.
  - A requirement to provide pharmacists sufficient time to perform their professional duties.

Violation of the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

To ensure sufficient staffing, an outpatient pharmacy may have to hire additional pharmacy personnel. According to [Indeed.com](https://www.indeed.com):

- The average cost per hour for an Ohio Pharmacist is \$52.44.
- The average cost per hour for an Ohio Pharmacy Intern is \$17.43.
- The average cost per hour for an Ohio Pharmacy Technician is \$ 18.54.

Based upon the 2021 Ohio survey data, the need to onboard additional staff may primarily impact large chain settings:

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**2021: I feel that the workload to staff ratio allows me to provide for patients in a safe manner:**

Setting	Pharmacist	Pharmacy Technician
<b>Large Chain (Grocer/Standalone)</b>	<b>Strongly Disagree/Disagree = (1711/1921) 89%</b>	<b>Strongly Disagree/Disagree = (1174/1571) 75%</b>
<b>Independent / Small Chain</b>	<b>Strongly Disagree/Disagree = (66/251) 26%</b>	<b>Strongly Disagree/Disagree = (82/292) 28%</b>

Using an assumption that at least 50% of all large chain outpatient pharmacies operating in this state may require additional pharmacist staffing, the following is an example of the estimated cost of compliance for some of the large chains operating in Ohio:

Large Chain Pharmacy	Number of Ohio Stores (as of 8/10/23)	Cost of Compliance (Assuming Hiring of Additional Pharmacist <sup>1</sup> at 50% of Stores)	Compliance Cost as a % of Net Income
<b>CVS Health</b>	356	$(\$142,888 \times 178)^1 =$ <b>\$25,434,064</b>	Estimated compliance cost assuming 50% of stores understaffed: $(\$142,888 \times 175) =$ <b>\$25,434,064</b>  Estimated compliance costs as a percentage of Net Income <sup>2</sup> : $(\$25,434,064 / \$4,149,000,000) =$ 0.6%.
<b>Walgreens</b>	236	$(\$142,888 \times 118)^1 =$ <b>\$16,860,784</b>	Estimated compliance cost assuming 50% of stores understaffed: $(\$142,888 \times 118) =$ <b>\$16,860,784</b>  Estimated compliance costs as a percentage of Net Income <sup>2</sup> : $(\$16,860,784 / \$4,336,000,000) =$ 0.4%.
<b>Kroger</b>	191	$(\$142,888 \times 96)^1 =$ <b>\$13,717,248</b>	Estimated compliance cost assuming 50% of stores

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			understaffed: (\$142,888 x 97) = <b>\$13,717,248</b>  Estimated compliance costs as a percentage of Net Income <sup>2</sup> : (\$13,717,248/\$2,224,000,000) = 0.6%.
<b>Wal-Mart</b>	143	(\$142,888 x 72) <sup>1</sup> = <b>\$10,287,936</b>	Estimated compliance cost assuming 50% of stores understaffed: (\$142,888 x 97) = <b>\$10,287,936</b>  Estimated compliance costs as a percentage of Net Income <sup>2</sup> : (\$10,287,936/\$2,224,000,000) = 0.6%.

<sup>1</sup>Estimated Cost for 1 additional full-time pharmacist: Salary (\$52.44\* x 40 X 52) = \$109,075, Benefits (31%+) = \$33,813,  
Total Cost Per Store = \$142,888

<sup>2</sup>Source: <https://www.wsj.com/market-data/>

\*Source: <https://www.indeed.com/career/pharmacist/salaries/OH>

<sup>+</sup>Source: [https://www.bls.gov/regions/southwest/news-release/employercostsforemployeecompensation\\_regions.htm](https://www.bls.gov/regions/southwest/news-release/employercostsforemployeecompensation_regions.htm)

- **4729:5-5-02.1** - Prohibits the use of quotas in the provision of ancillary services in an outpatient pharmacy.

Pharmacies that currently implement quotas will experience an increase in administrative costs to redesign or alter systems to avoid the imposition of such quotas. It should be noted that at least one large chain, Walgreens, has [publicly committed](#) to the elimination of all “task-based metrics.”

Violation of the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

- **4729:5-5-02.2** - Provides mandatory rest breaks for pharmacy personnel.

Large chain pharmacies may experience a loss of revenue from having to close the pharmacy for required breaks (if there is no cross coverage). It should be noted that the Board is [aware of several large chains](#) (CVS, Walgreens) that already close the pharmacies to offer an uninterrupted lunch break. The Board attempted to mitigate any negative financial impact on small businesses by offering flexibility to independent pharmacies and small chains.

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Additionally, some pharmacies may have to onboard additional staff if a pharmacist refuses to work in excess of twelve hours.

Violation of the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

- **4729:5-5-02.3** - Requires outpatient pharmacies to develop a process to address staffing concerns.

Outpatient pharmacies that do not have an existing process to address staffing concerns will experience an increase in administrative costs to establish such a process. Once such a process is established the cost of the rule is dependent on the staffing levels of the pharmacy.

A pharmacy that is appropriately staffed should not experience significant costs to implement the provisions of this rule. Pharmacies that are understaffed will experience increased costs to comply with the requirements of the rule. The Board estimates that the completion of the required reporting form, to be developed by the Board, will take 10-15 minutes to complete.

Violation of the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

- **4729:5-5-02.4** - Defines a significant delay in pharmacy services and creates a process whereby an outpatient pharmacy must address such delays.

Outpatient pharmacies that can dispense medications within 72-hours (e.g., not experiencing a significant delay) will not experience any adverse impact from this rule. Those pharmacies that are unable to provide patients medications in a timely manner may experience significant costs depending on the number of prescriptions that are experiencing a significant delay and the remediation measures required. For example, an understaffed pharmacy experiencing a delay may have to surge additional staff to that store or may have to implement “dark hour” to catch up on any backlog.

Violation of the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

- **4729:5-5-02.5** - Provides the requirements for managing pharmacy access points in an outpatient pharmacy.

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An outpatient pharmacy that seeks to develop an organizational policy in accordance with this rule will experience an increase in administrative costs to develop and implement such a policy. Additionally, pharmacies that are experiencing staffing shortages may see a reduction in revenue if a pharmacist determines that certain services provided by the pharmacy cannot be offered safely. The impact of this requirement is dependent on the outpatient pharmacy's staffing levels and therefore the financial impact could be minimal or significant depending on the pharmacy's existing staffing.

Violation of the rule may result in administrative licensure discipline for an outpatient pharmacy licensed as a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty (\$1,000) and/or revocation of a license.

**Rescind:**

- 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. This rule is being rescinded with most of the text being incorporated into the proposed new rule. As this rule is being rescinded, it should not have an adverse impact.

**16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).**

No.

**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by:

- Ensuring proper staffing levels in outpatient pharmacies;
- Establishing a process for pharmacies that are experiencing significant delays to ensure patients access;
- Mandating rest and meal breaks and eliminating quotas to ensure that pharmacy personnel can operate in a safe and effective manner; and
- Addressing touch points to reduce opportunities for distraction and fatigue in the practice of pharmacy.

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### **Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

These rules do provide exemptions or alternative means of compliance for small businesses. In this case, small chains and independent pharmacies are offered flexibility regarding the implementation of meal breaks (see OAC 4729:5-5-02.2(B)(2)).

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a licensee to comply with the licensure requirements of the state is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

**20. What resources are available to assist small businesses with compliance of the regulation?**

To assist our licensees, including those representing small business, the Board developed inspection guides. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board. The guides may be accessed by visiting: [www.pharmacy.ohio.gov/inspection](http://www.pharmacy.ohio.gov/inspection)

Additionally, the Board has dedicated licensing staff to field questions from licensees regarding initial licensure and renewal applications.

**4729:5-5-02 - Minimum Standards for the Operation of an Outpatient Pharmacy  
(RESCIND CURRENT RULE AND FILE NEW)**

(A) As used in this rule, “pharmacy personnel” means any of the following licensed or registered in accordance with Chapter 4729. of the Revised Code:

- (1) Pharmacist;
- (2) Pharmacy intern;
- (3) Certified pharmacy technician;
- (4) Registered pharmacy technician;
- (5) Pharmacy technician trainee.

(B) In accordance with division (D) of section 4729.55 of the Revised Code, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall:

(1) Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume but shall consider any other requirements of pharmacy personnel during working hours.

(2) Provide sufficient tools and equipment in good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner. All tools and equipment shall be housed in a suitable, well-lit, and well-ventilated room or department and maintained in a clean, sanitary, and orderly condition.

(3) Provide pharmacy personnel with access to the following:

(a) All current federal and state laws, regulations, and rules governing the practice of pharmacy and legal distribution of drugs in Ohio, including internet access to:

(i) The board's website ([www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov));

(ii) LAWriter Ohio laws and rules (<http://codes.ohio.gov/>);

(iii) The code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC); and

(iv) The code of federal regulations.

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- (b) References necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws, this shall include hard copy or internet access to appropriate pharmacy reference materials.
- (c) The telephone number of a poison control center.
- (4) Ensure pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties.
- (5) Maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered by the pharmacy.
- (6) Maintain a stock of prescription containers necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.
- (7) Ensure all areas where drugs and devices are stored and prepared are dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.
- (8) For outpatient pharmacies open to the public, publicly post the operating hours of the pharmacy department.
- (9) Ensure all employees of the pharmacy are identified by a name tag that includes the employee's job title.
- (10) Provide adequate security for all dangerous drugs in accordance with the requirements of agency 4729 of the Administrative Code. A pharmacy shall maintain the current contact information for the pharmacy's security system vendor and shall immediately provide this information upon the request of an agent, inspector, or employee of the board.
- (11) Provide sufficient time for pharmacists to complete professional duties and responsibilities, including:
  - (a) Drug utilization review;
  - (b) Immunization;
  - (c) Patient counseling;

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(d) Dispensing of prescriptions;

(e) Patient testing; and

(f) All other duties of a pharmacist as authorized by Chapter 4729. of the Revised Code.

**4729:5-5-02.1 - Provision of Ancillary Services in an Outpatient Pharmacy.**

(A) As used in this rule, “ancillary services” are those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs as set forth in this chapter of the Revised Code. Examples of such services include, but are not limited to, immunizations, medication therapy management, disease state management, and refill reminders.

(B) In accordance with division (D) of section 4729.55 of the Revised Code, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not establish any productivity or production quotas relating to the provision of ancillary services.

(1) For purposes of this rule, “quota” means a fixed number or formula related to the duties of pharmacy personnel, against which the pharmacy or its agent measures or evaluates the number of times either an individual performs tasks or provides services while on duty.

(2) For purposes of this rule, “quota” does not mean any of the following:

(a) A measurement of the revenue earned by a pharmacy not calculated in relation to, or measured by, the tasks performed, or services provided by pharmacy personnel.

(b) Any evaluation or measurement of the competence, performance, or quality of care provided to patients of pharmacy personnel if the evaluation does not use quotas.

(c) Any performance metric required by state or federal regulators.

(C) The limitations in this rule do not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies).

#### **4729:5-5-02.2 - Mandatory Rest Breaks for Pharmacy Personnel**

(A) Except in a documented emergency that would endanger the health and safety of patients, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not require pharmacy personnel to work longer than twelve continuous hours in any workday and shall allow at least eight hours of off time between consecutive shifts.

(1) Except as provided in paragraph (A)(2) of this rule, a pharmacist may volunteer to work longer than twelve continuous hours.

(2) An outpatient pharmacy shall not retaliate or discipline a pharmacist for refusing to work longer than twelve continuous hours. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

- (a) Removing or suspending the employee from employment;
- (b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- (c) Transferring or reassigning the employee;
- (d) Denying the employee a promotion that otherwise would have been received;
- (e) Reducing the employee in pay or position.

(B) Pharmacy personnel working longer than six continuous hours shall be allowed to take a thirty-minute break. Breaks, including uninterrupted rest periods and meal breaks, shall be provided as follows:

(1) For an outpatient pharmacy licensed as a terminal distributor of dangerous drugs that is owned or operated by a company with twelve or more outpatient pharmacies operating in this state, either:

- (a) The outpatient pharmacy shall close for the required thirty-minute break. The pharmacy shall implement a regular break schedule and communicate the break schedule to customers wherever pharmacy hours are publicly posted or communicated.
- (b) The outpatient pharmacy shall not be required to close for rest periods and meal breaks in accordance with paragraph (B)(1)(a) of this rule if there is more than one pharmacist working at the pharmacy that can provide coverage.

(2) For an outpatient pharmacy licensed as a terminal distributor of dangerous drugs that is owned or operated by a company with eleven or fewer outpatient pharmacies operating in this state:

(a) A pharmacy may close when a pharmacist is on break based on the professional judgment of the pharmacist on duty;

(b) If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking their break within the pharmacy or on the premises. The pharmacist on duty must determine if pharmacy personnel may continue to perform duties and if the pharmacist is able to provide adequate supervision; and

(c) If the pharmacy remains open, only prescriptions dispensed by a pharmacist pursuant to this chapter of the Administrative Code may be sold when the pharmacist is on break. An offer to counsel any person filling a prescription shall be offered pursuant rule 4729:5-5-09 of the Administrative Code. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling.

(d) In lieu of meeting the requirements of paragraph (B)(2) of this rule, a pharmacy licensed as a terminal distributor of dangerous drugs that is owned or operated by a company with eleven or fewer outpatient pharmacies operating in this state may comply with the requirements of paragraph (B)(1) of this rule.

(3) The requirements of paragraph (B) of this rule do not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies). An outpatient pharmacy that is not open to the public shall still be required to allow all pharmacy personnel working longer than six continuous hours to take a thirty-minute uninterrupted rest period and meal break.

#### **4729:5-5-02.3 - Staffing Requests or Concerns in an Outpatient Pharmacy**

(A) Staffing requests or concerns shall be communicated by the responsible person or pharmacist on duty to the terminal distributor using a form developed by the board and accessible via the board's website ([www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)).

(1) Executed staffing forms or reports shall be provided to the immediate supervisor of the responsible person or pharmacist on duty, with one copy maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

(2) The responsible person or pharmacist on duty shall report any staffing issues directly to the board if the responsible person or pharmacist on duty believes the situation warrants immediate board review because it presents an immediate danger to the health and safety of the public.

(B) Outpatient pharmacies licensed as terminal distributors of dangerous drugs shall review completed staffing reports and shall:

(1) Respond to the reporting staff member to acknowledge receipt of the staffing request or concern;

(2) Resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff and appropriate medication access for patients;

(3) Document any corrective action taken, steps taken toward corrective action as of the time of inspection, or justification for inaction, which documentation shall be maintained on-site for a period of three years for immediate inspection by an agent, inspector, or employee of the board; and

(4) Communicate corrective action taken or justification for inaction to the responsible person or reporting pharmacist.

(C) An outpatient pharmacy shall not retaliate or discipline a pharmacist who, in good faith, reports staffing concerns in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

(1) Removing or suspending the employee from employment;

(2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(3) Transferring or reassigning the employee;

(4) Denying the employee a promotion that otherwise would have been received;

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(5) Reducing the employee in pay or position.

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#### **4729:5-5-02.4 - Significant Delays in the Provision of Pharmacy Services**

(A) An outpatient pharmacy has a duty to properly dispense lawful prescriptions for dangerous drugs or devices without significant delay.

(1) For purposes of this rule, “significant delay” means a prescription that was submitted to the pharmacy for processing by a prescriber, patient, or caregiver and has yet to be dispensed (e.g., final verification) by a pharmacist within seventy-two hours of receiving the prescription. Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy.

(2) For purposes of this rule, “significant delay” does not mean any of the following:

(a) A prescription that has been submitted to the pharmacy but where there is a documented drug shortage, or the pharmacy documents the drug is not available from the pharmacy’s drug distributor.

(b) A prescription that has been submitted to the pharmacy that requires clarification or consultation by the issuing prescriber.

(c) A prescription that has been submitted to the pharmacy that requires a prior-authorization or is otherwise delayed because of the patient’s prescription insurance coverage.

(d) A prescription that is for a compounded drug product.

(e) A prescription that the pharmacist, using their professional judgement, determines is of doubtful, questionable, or suspicious origin.

(B) Each prescription that experiences a significant delay, as defined in paragraph (A) of this rule, shall be considered a violation of this rule and shall subject the outpatient pharmacy to disciplinary action in accordance with rule 4729:5-4-01 of the Administrative Code.

(C) Immediately upon discovery or at the request of an agent, inspector, or employee of the board, a pharmacy experiencing a significant delay shall implement one or more of the following remediation measures to dispense all prescriptions that are experiencing a significant delay:

(1) Limiting pharmacy hours (e.g., dark hours);

(2) Transferring prescriptions to another pharmacy, upon patient consent;

(3) Increasing pharmacy staff; or

(4) Any other strategy that is mutually agreed upon by the outpatient pharmacy and the agent, inspector, or employee of the board.

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(D) As part of the remediation process required in paragraph (C) of this rule, the outpatient pharmacy shall implement a process that triages lifesaving and life-sustaining medications that are experiencing a significant delay.

#### **4729:5-5-02.5 - Outpatient Pharmacy Access Points**

(A) Except as provided for in paragraph (B) of this rule, a pharmacy shall develop and implement an organizational policy that permits a pharmacist to do all the following:

(1) Limit the provision of ancillary services if, in the pharmacist's professional judgment, the provision of such services cannot be safely provided or may negatively impact patient access to medications; and

(2) Limit pharmacy access points, if, in the pharmacist's professional judgment, limiting such access points will prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety.

(B) In the absence of an organizational policy in paragraph (A), an outpatient pharmacy shall not override the control of the pharmacist on duty as follows:

(a) A pharmacist's decision not to administer or supervise immunizations or provide other ancillary services if, in the pharmacist's professional judgment, the provision of such services cannot be provided safely or may negatively impact patient access to medications. The pharmacy shall offer to make an appointment for the patient or may refer the patient to another location offering immunizations.

(b) A pharmacist's decision to limit pharmacy access points if, in the pharmacist's professional judgment, limiting such access points will prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety. Such limitations shall not interfere with a patient's ability to drop off or receive dispensed prescriptions during the pharmacy's posted hours of operation.

(C) Organizational policies developed in accordance with paragraph (A) of this rule shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

(D) The requirements in this rule do not apply to outpatient pharmacies that are not open to the public (e.g., closed door pharmacies).