

## **Comments Summary**

**Total Comments: 122**

<b>ANSWER CHOICES</b>	<b>RESPONSES</b>	
<b>Pharmacist</b>	61.48%	75
<b>Pharmacy Technician</b>	20.49%	25
<b>Pharmacy Intern</b>	0%	0
<b>Terminal Distributor of Dangerous Drugs</b>	1.64%	2
<b>Patient/Caregiver</b>	4.10%	5
<b>Organization (please specify)</b>	12.30%	15
<b>TOTAL</b>		122

## **Comment Letters**

1. Animal Policy Group
2. The Ohio State University College of Pharmacy
3. Ohio Pharmacists Association
4. Anonymous (Pharmacy Manager)
5. Independent Pharmacy Cooperative (IPC)
6. Kroger
7. Unite for Safe Medications
8. Ohio Northern University
9. Walgreens
10. Ohio Hospital Association
11. CenterWell Pharmacy
12. Ohio Council of Retail Merchants
13. National Community Pharmacists Association
14. Ohio State Wexner Medical Center
15. CVS Health
16. Kathryn Fletcher (Public)

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

**Answered: 87**

**Skipped: 35**

<b>Answer Choices</b>	<b>Responses</b>	
<b>Proponent</b>	72.41%	63
<b>Opponent</b>	14.94%	13
<b>Interested Party</b>	12.64%	11
<b>Total</b>		<b>87</b>

**Please submit any comments you may have on the proposed rule. (NOTE: Comments were optional, not everyone who answered above provided a comment. Comments that included phrases such as "see attached" or "see letter" were excluded).**

<b>Pro/Op/IP?</b>	<b>Comment</b>
<b>Interested Party</b>	It's like getting blood out of a turnip or beating a dead horse. Unless the state board has what it takes to stand up to insurance companies and big pharma and right alongside with these standards provide the financial means to bring them to fruition, they are just words on a page. But we know from the past as the state board bows down to the CDC and FDA and big pharma by overlooking the truth about Covid 19 ( the shot neither protects the person getting Cov 19 or prevents transmission; masks have been proven to be useless) they will follow suit and not assure to the pharmacy, that there will be a way for them to charge either the patient directly or via the insurance company in order to implement the minimum standards. If you increase the standards, then you must give the pharmacy/ pharmacist the ability to pay for it. But we know that won't happen. You (BOP) are held blameless but just put another burden on pharmacy. These are excellent standards which are definitely needed, that is not the question. But how does one pay for it. But you certainly won't go there.
<b>Interested Party</b>	Appropriate staffing and scheduling needs to be established in conjunction with local pharmacy management. There is significant variety in the type of work seen at different pharmacies, often within the same company. The pharmacy manager should have the ability to adjust corporate staffing models accordingly based on pharmacy needs. If chain pharmacies are forced into increasing staffing to certain levels, a likely outcome is a decrease in pay to employees of the pharmacy. This cannot be allowed, or we will continue to see the decline in the profession that has been occurring.
<b>Interested Party</b>	These rules totally miss the mark. They are too broad and unenforceable. This will not impact retail drug chains.
<b>Interested Party</b>	Pharmacies need to be held accountable if they lack the personal to properly take care of their customers. Pharmacies need to be required to have a minimum number of pharmacy technicians working at all times. I think the minimum should be 3 or 4 at all times depending on size. I should not have to go into work and be the only technician working because corporate cuts our hours so much that we can only have 1 tech working. I travel to different stores all the time and it's just one big mess after another. Customers lives are at risk because we aren't properly staffed at all times.
<b>Interested Party</b>	I understand part of the rules being considered would place a time limit on filling a prescription. In theory this sounds good, but in practice would be impossible to not violate. Medications go on back order constantly and meds require prior authorization from doctors that don't perform that task in a timely manner. These simple scenarios would violate the "fill

	<p>within 72 hours" rule and place more burden on the pharmacy than they can control. Furthermore, rules that punish the pharmacy staff for things out of their hands is counterproductive. The corporation that owns the pharmacy should be the ones held more accountable for the staffing issues. Staff are forced to cut corners or provide less than perfect care due to the lack of staffing, not necessarily because they are bad pharmacists. Allow wordage in the mandates that require higher level managers to "face the music" for violations. They are largely shielded from any repercussions, yet they are the responsible parties for the understaffing</p>
<b>Opponent</b>	<p>I am worried the Ohio Board of Pharmacy is overstepping their authority in issuing mandates that impact how the profession is managed.</p>
<b>Opponent</b>	<p>I have been a pharmacy technician for over 30 years and never needed to have a lunch break. We have always brought our lunch or snacks to work and ate when needed while working. It's never been an issue. We do not need to close for a half hour and then when getting back be behind and having patients angry. It is just not necessary.</p>
<b>Opponent</b>	<p>Mandatory lunch would put additional stress and pressure on the pharmacists which would result in being further behind and having to stay after hours to catch up.</p>
<b>Opponent</b>	<p>We are making rules that impacts severely 80% of the pharmacies and pharmacy owners who do NOT mistreat or overwork their staff in order to get under control the 20% of the chains and groceries who are severely mistreating and abusing their staff. There should be a requirement that independent pharmacies who employ like 15-20 or less staff do not have to followup these requirements because we already take care of our staff.</p>
<b>Opponent</b>	<p>While I feel that the board should have the ability to place the standards into an outpatient pharmacy, I think it could put unnecessary burden on a pharmacy, when it seems one corporation has taken advantage of the boards previous position. Maybe this could be a remediation strategy for a pharmacy that loses control of their environment, but a pharmacy that is able to operate efficiently with less staffing, should not be handcuffed by this broad stroke policy.</p>
<b>Opponent</b>	<p>Independent pharmacies should be exempt. We are all professionals and sometimes if the demand is there we just need to step up to plate and take care of who's in front of you. Are we to turn people away who have needs? I took an oath to protect my patients and know my limitations.</p>
<b>Proponent</b>	<p>I think the very specific rules and details in these minimum standards are sorely needed especially in the large chain environment. Pharmacists for far to long had no power to change the work environment issues within their pharmacies, since the policies came down from corporate managers who for the most part are not pharmacists and do not pay any consequences for pharmacy errors or risks to patient safety. Pharmacists were afraid to take concerns to non pharmacist supervisors for fear of retaliation. Complaining pharmacists were seen as negative by these nonpharmacist supervisors and they would find a way to get rid of these pharmacists or make their lives miserable so they would quit. These updated rules gives some power back to the on duty pharmacists, especially floaters. I would just hope the BOP staff holds these corporate manager's feet to the fire. It should be the corporate manager that made the policies that led to the unsafe work environment and risk to patient safety that pays the price. Any fines should be assessed to the corporate pharmacist that created the unsafe policies or were informed of the unsafe conditions by the pharmacist and did not do anything about it within a reasonable time frame. \$1000 fines mean nothing to a billion dollar corporation. In their minds it is a cost of doing business. I would suggest the fines should be larger to the corporation or charge \$1000 per incident per store. I do believe the only way for a corporation to take these rules seriously is for the BOP to suspend the terminal distributor license for the store until the problem is rectified. Closing a pharmacy would result is thousands of revenue lost per day per store until the problem is fixed. Also ensure these corporate managers are not able to find another non transparent way to not be compliant with these rules such as finding another way to define ancillary services like asking pharmacy staff to enroll patients in company programs ( like company loyalty or credit card programs or other programs that have nothing to do with improving patient care.) Pharmacists should have sufficient time to counsel patients on</p>

	<p>prescription meds, OTC meds, or the correct uses of devices such as glucose testing machines, inhalers or other devices. I would also ask that any safety concern forms sent to the immediate supervisor should also have to be sent to the district manager or pharmacy supervisor and responded by both individuals. Many chain pharmacists now report to a store manager who is a non pharmacist and typically does not have much power to change an unsafe work situation either. Their reviews also depend on the store attaining budgeted pharmacy hours and other metrics so they will not be willing to give additional hours or other support/resources if they are also not supported by their immediate and regional bosses(likely non pharmacists). These non pharmacist managers suffer no consequences for patient errors that cause harm when the errors was caused by an unsafe pharmacy environment. It is only the pharmacist that made the error that is penalized by the BOP through their license. It is time to hold these corporate decision makers responsible with penalties that have real teeth. I think these proposed rules are a great start to alleviating some of the issues that have created these negative and unsafe work environments.</p>
<b>Proponent</b>	<p>Busy stores should have sufficient overlap hours for pharmacists. One pharmacist working a 13 hour shift and filling 700+ prescriptions is not a safe environment.</p>
<b>Proponent</b>	<p>Understaffing is not only a current risk for all patients in America who need medications, but the future of pharmacy and medication access is impacted as pharmacists leave the profession and students refuse to enter. Thank you for taking the lead in our nation to protect not only patients but pharmacists and the future of the pharmacy profession. These are the types of steps that it will take for America's safe pharmacy and medication access to be saved.</p>
<b>Proponent</b>	<p>(Walgreens CPhT 15+ years) We desperately need safety standards that are mandated by the The Board of Pharmacy. In the past 3-5 years there has been a shift from patient satisfaction to cutting back on any and everything to ensure maximum profits. I have seen management cut staffing to as little as possible, while increasing workloads dramatically. We are told we need to be more efficient with less staff. This has caused an extremely unsafe environment. Technicians are forced to physically work at least 2-3 stations at once. Jumping from filling prescriptions to answering phones to working drive thru to working the front checkout to assisting customers with otc needs then returning to filling prescriptions. We are begging for the board of pharmacies help!!</p>
<b>Proponent</b>	<p>I believe that this has become necessary for the Board to step in to establish minimum standards. It does seem to be overreach into the individual business of, but in the case of the large chains, they have steadily ignored any minimum standards in the pursuit of maximum profit. The time has come to hold their feet to the fire and impose these standards because they never will. They have proved this, beyond a doubt, especially to us as pharmacists and technicians working the front lines.</p>
<b>Proponent</b>	<p>I believe this is appropriate and necessary for our profession.</p>
<b>Proponent</b>	<p>I applaud the Board of Pharmacy for looking into several areas of concern in the profession, but I am concern that the Board would be overstepping in several different areas.</p>
<b>Proponent</b>	<p>Has to happen. We need to protect the public health from overt capitalism as much as possible. Without measures like this, outpatient will only continue to get more and more dangerous in the pursuit of cash.</p>
<b>Proponent</b>	<p>Mandatory lunchtime closing would allow the entire staff to leave the pharmacy at the same time for a break. This would improve staffing and prevent having to work short handed while staggering lunch breaks. Most physician offices close 12-1 each day without a negative impact to their patients or business.</p>
<b>Proponent</b>	<p>While it is positive that the success of this regulation is measured by "compliance with the rules, and minimal questions" this is not the purpose. Please, if you find that any of your rules are not making pharmacy safer in Ohio eliminate them. Power and control are desirable for the BOP, but it belongs to the people of Ohio. While I believe these regulations will help they do not appear to give more power to the people of Ohio. People want choice, and transparency. They want</p>

	recourse when delays affect their health. Ohioans find value in the transparency of discount cards - we can compare price. In the future we will want to compare service. We want pharmacies to state their wait time and then stand by it. Our time is valuable. If a flight is delayed more than 2 hours the consumer has rights.
<b>Proponent</b>	Need to look at why pharmacies are not properly staffed, it's an issue of not giving pharmacies the hours needed to hire. Beyond stressful
<b>Proponent</b>	Please help save community pharmacy in the large corporate environment. There has been the "Great resignation" of Pharmacists circa 2021 because of working conditions. Have quotas on ancillary services and a reasonable Pharm/tech to volume/workload ratio. If you won't, a union will likely take the day in the end. Please be proactive and save us from both.
<b>Proponent</b>	There needs to be laws in place to protect this profession, the majority of which is burned out and has a PTSD response going into the autumn season now
<b>Proponent</b>	The pharmacists in my store routinely work alone. I would like to see minimum standards set to ensure working alone doesn't happen for longer than 1 hour.
<b>Proponent</b>	Took you long enough. Pharmacies have been operating under dangerous conditions for many years.
<b>Proponent</b>	Still having issues with "quotas" especially with giving vaccines. It's too early for flu shots according to most clinical reviews but we are being forced to get at least 6 flu shots per day!
<b>Proponent</b>	It is dangerous what the pharmacy is doing with staffing. There needs to be a minimum amount of staff. I don't feel safe
<b>Proponent</b>	I believe that the focus of pharmacy efforts should be primarily on the health and welfare of its consumers, patients and their families. This means regulatory agency standards must mandate actions which allow staff to work in relatively low-stress conditions which promote clear and thoughtful focus on the efforts which are essential to accurate preparation and delivery of pharmaceutical products. "Health care" is not a place where profit for the organization or its investors should be allowed to be pre-eminent!
<b>Proponent</b>	Biggest concern is staffing. Pharm techs are in very short supply and I worry about pharmacies needing to close if having difficulty staffing.
<b>Proponent</b>	The pharmacist must have adequate support staff in order to provide safe care. Accordingly, he or she should also have the ultimate authority to do what is necessary to ensure minimum standards, including the temporary suspension of services not directly related to the dispensing of medication.
<b>Proponent</b>	Consideration should be given to resources provided to the pharmacist that assist in work load and assure accuracy. This would include software, automation and other tools that assist in dispensing and free up time for the R.Ph. to provide clinical information to patients and care givers. Examples: automated phone system, digital counter with NDC verification, auto dispensing, validation systems.
<b>Proponent</b>	More staff is necessary at big chain pharmacies such as CVS. Pharmacists are rushed to verify prescriptions.

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

Answered: 79

Skipped: 43

Answer Choices	Responses	
Proponent	79.75%	63
Opponent	10.13%	8
Interested Party	10.13%	8
Total		79

**Please submit any comments you may have on the proposed rule. (NOTE: Comments were optional, not everyone who answered above provided a comment. Comments that included phrases such as "see attached" or "see letter" were excluded).**

Pro/Op/IP?	Comment
Proponent	I totally support the language as long as the corporation does not find another way to get around a quota by defining it as something else. I think this specific language in defining the term quota or the term "provision of ancillary services" is a good start.
Proponent	(Walgreens CPhT 15+ years) The amount of different types of quotas in our pharmacy is unbelievable. We have daily/weekly/monthly task lists, redundant calls to patients regarding picking up/refilling medications, giving a certain amount of vaccines daily/weekly/monthly amongst others. We have been asked to focus on giving patients vaccines. Occasionally they offer 1-5 dollar cash incentives on your paycheck for certain vaccines when out of season.
Proponent	1. Use of Quotas a. The problem is not quotas by itself. The problem is a growing business with growing quotas but no additional help or resources. b. With these growing quotas, I highly suggest you reach out to med safety at some of these big chain pharmacies and see how many medication and vaccine errors there have been just this year alone. Our flu shot goal this year is 1,594 flu shots. (We are considered a lower-medium volume store, doing about 3,000 scripts a week). Have we gotten any additional help? Nope. They actually are cutting our hours. If someone can explain this to me, I will sit down and listen. I have reached out to corporate asking questions to why our hours are being cut after dropping our flu shot goal of 1,594 on top of prescriptions, other vaccines, phone calls, shelf maintenance, inventory management, perpetual inventory, counseling, doctor calls, etc. How are we supposed to manage? Physically, emotionally, and mentally we can't manage. This is an impossible goal. I work 12-hour shifts by myself, have a second staff pharmacist, and a part timer where occasionally we will have enough hours for overlap. Do you realize pharmacists will start leaving the profession (including myself – seriously to the point of looking to go back to school because this is not what pharmacy was when I was an intern) if this continues to happen. You have the power to change this and you have a lot of people rooting for you. How is the workload listed above acceptable for employees but more importantly, our patients? Again, patient safety is compromised. c. "Hitting your numbers will keep you alive today. Hitting your numbers with momentum ensures you stay relevant in the future." Pharmacy has no momentum right now and people are going to start leaving the profession if things are not going to change in Ohio.

<b>Proponent</b>	Quotas only work if the staffing is adequate. If staffing lacks, some quotas will be left by the wayside. Just like triage. Some quotas are linked to Medicare standards for reimbursements, but again, lacking adequate staff, it is impossible to bring this up to the level required. Pay attention Medicare.
<b>Opponent</b>	I understand not forcing how fast or slow a pharmacist completes certain tasks and patient safety should drive all decisions, but there has to be a difference between quota and metric. In some cases, metrics alone drive the amount of staffing a location may have (i.e. 2 pharmacists for filling 300/scripts per day vs. 3 pharmacists for filling 500/scripts per day). Without having these metrics in play then business would struggle to ensure correct staffing. I believe this section needs to be more strongly worded around PUNISHMENT upon a pharmacist for missing a metric instead of removing metrics altogether.
<b>Opponent</b>	I am worried the Ohio Board of Pharmacy is overstepping their authority in issuing mandates that impact how the profession is managed.
<b>Proponent</b>	Quotas are a distraction from patient care and have a negative impact on patient safety.
<b>Proponent</b>	When being the only technician and having only 1 pharmacist, doing task based metrics can become near impossible to complete on a busy day. Yet we have to fret about them for fear of being yelled at or disciplined for not completing these tasks.
<b>Proponent</b>	The quotas for vaccines are outrageous, especially when the pharmacist is working by themselves.
<b>Proponent</b>	Retail pharmacies are already finding ways to "get around this rule". They are saying you have to commit to a some many ancillary and flu vaccines per season.
<b>Interested Party</b>	Appropriate staffing and scheduling needs to be established in conjunction with local pharmacy management. There is significant variety in the type of work seen at different pharmacies, often within the same company. The pharmacy manager should have the ability to adjust corporate staffing models accordingly based on pharmacy needs. If chain pharmacies are forced into increasing staffing to certain levels, a likely outcome is a decrease in pay to employees of the pharmacy. This cannot be allowed, or we will continue to see the decline in the profession that has been occurring.
<b>Proponent</b>	Still happening! Especially with vaccines! We are required to get at least 6 flu vaccines everyday even though a lot of info states not to start until September
<b>Proponent</b>	I work for a retail pharmacy and so much time is spent on trying to meet quotas and that are unfair and unrealistic when we should be focused on providing proper care and dispensing medication safely.
<b>Opponent</b>	Once again independent pharmacies do not push quotas on their staff. We have goals of ancillary services. And once again we independents are being punished and controlled and most likely ELIMINATED from being able to keep doors open with this regulations.
<b>Proponent</b>	quotas should be contractually bound, or used for performance bonus, but pharmacy is not, cannot be, cookie cutter. Patient interactions are not all alike, and some need more time than others, so it is subjective rather than an objective analytic tool.
<b>Proponent</b>	Patients should be first. I'm an independent pharmacy owner.
<b>Proponent</b>	Strongly believe quotas are antithetical to our mission in pharmacy.
<b>Interested Party</b>	This will not impact retail drug chains. It is unenforceable and pharmacists interested in keeping their jobs will never interfere.
<b>Proponent</b>	At a minimum a pharmacist should have a technician present during a shift. Employers should not use quota's. The maximum amount of activity (Rx's) must consider technology resources.

<b>Interested Party</b>	It seems fairly obvious that this action is being taken solely based on the failure of large chain pharmacies to practice in a way that allows their employees to feel valued. I do not think that it is necessary to legislate policy to every business in the state in order to try to fix those problems. The Board should not dictate day to day operations of individual practices. Nor should it attempt to be the advocate for a particular group by forcing daily business management decisions on the whole of Ohio pharmacies. Especially, at a time when the Board knows that pharmacies are closing daily due to reimbursement issues (that's how we got here in the first place), and when the Board admits that its solutions will cost most pharmacies more money in expenditures. If the chain pharmacies had not bought and closed pharmacies and then tried to run their own pharmacies at dangerously low staffing levels, then they would not be in this situation. It's not the Board's role to act as "Union Steward" for chain pharmacy employees.
<b>Proponent</b>	Numerous times have higher corporate leaders have pushed and threatened our job security, to me personally and to other colleagues, over not reaching certain performance based metrics. They did not care about short staffing or the mental abuse they bring by harping on us constantly. It disgusts me as a professional that this was even allowed in the first place
<b>Proponent</b>	The use of quotas in pharmacy should be prohibited. It is an unsafe practice. We work to ensure our patients are taken care of, we do not work to make sure quotas are met, especially vaccines.
Did not indicate	Quotas should NOT exist when it adversely impacts patients safety. While working at CVS there are numerous quotas to drive volume and of course profits. The rule should be clear so that chain pharmacies (especially CVS) figure out a clever way to change the wording so that it is not a "quota" but rather a component of the pharmacist's job function. For example, you as pharmacist failed to administer "x" number of vaccines to eligible patients in August therefore a less than "meets goals" is documented in a review. Not technically a quota but still a QUOTA. That same pharmacist in August may have counseled hundreds of patients, caught numerous dosing errors, stopped medication from being dispensed due to allergy, convinced someone to stop smoking, recommended numerous OTC products for various ailments, recommended patients seek medical attention by a doctor and on and on and on. Yet when CVS reviews the pharmacist they will only look at how many vaccines, how many times the phone was answered in 3 rings (which would never be a problem if there was enough staff to answer), how fast did the online order get done, how many calls to patients asking if they need refills, again I could go on and on but I think the point is made. Let me be crystal clear, I am NOT a disgruntled employee. Do not read this and think that I'm trying to get back at CVS. If my statements are framed in that manner then the individual reading this hasn't experienced what really happens in a CVS pharmacy. CVS has some amazing pharmacists that show up every day to be a great pharmacist, but corporate culture is to push as hard as they can to squeeze out as much volume and profit as possible at the expense of patient safety and the pharmacist's mental health and wellbeing. The public deserves knowing that when they pick up a prescription that the pharmacist had the time and resources to ensure it was appropriate and filled correctly "PERIOD" How is there a difference if a doctor is rushed and makes a mistake and a pharmacist is rushed and makes a mistake? The end result is usually the same patient harm or death, so why are the people in the government that are tasked to protect the public allowing this to happen in chain pharmacies (in particular CVS)? These laws need to be clear and concise so that they don't find a way to get around the rules and continue to put the public at risk. If people think they won't then they are sadly mistaken because the corporate elite cares only about profit, profit, and profit.
Did not indicate	amazing idea
Did not indicate	This would also be nice due to the fact that we lose 'hours' available for staffing every single month.



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

**Answered: 77**

**Skipped: 45**

<b>Answer Choices</b>	<b>Responses</b>	
<b>Proponent</b>	77.92%	60
<b>Opponent</b>	11.69%	9
<b>Interested Party</b>	10.39%	8
<b>Total</b>		<b>77</b>

**Please submit any comments you may have on the proposed rule. (NOTE: Comments were optional, not everyone who answered above provided a comment. Comments that included phrases such as "see attached" or "see letter" were excluded).**

<b>Pro/Op/IP?</b>	<b>Comment</b>
<b>Interested Party</b>	Several pharmacies in Indiana have attempted this over the years. Unfortunately, this practice often creates more stress and fatigue for the employees due to having to turn away patients during the set up and closure for a break.
<b>Interested Party</b>	This is a basic worker's right. Did you even review the context in which Illinois (Walgreens, WalMart, Etc) agreed to provide rest breaks? Rather than focusing on the needs of the patient, Illinois chose to once again punish patients by closing the pharmacy. A win-win for chains ...
<b>Opponent</b>	The minimum hours worked to get a lunch are too low. should be over 8 hours mandatory break.
<b>Opponent</b>	Ohio labor laws govern breaks for hourly personnel. If you're the manager and you're not getting proper rest breaks, then do not be the manager.
<b>Proponent</b>	I especially support the language for mandating breaks for those that work more than six hours ( this can happen in a chain pharmacy where the second pharmacist make work the evening shift such as 2pm- 10pm without overlap with another pharmacist to be able to take a lunch break. In this instance this evening pharmacist should be allowed to have an uninterrupted meal break in the evening. The pharmacy most likely can not close for a second meal break for the evening pharmacist so I would support allowing them to have an uninterrupted meal if they can stay in the pharmacy to eat, but tell any patients that drop of new prescriptions that these scripts will not be ready until the pharmacist is done with their meal break. 24 hour night shift pharmacists also should be able to have an uninterrupted meal break during the night, although most do not have any technicians or staff working with them after 11pm or midnight. They should be able to close the pharmacy for half hour in the middle of the night.
<b>Proponent</b>	Walgreens CPhT 15 years experience. The only break we take in the pharmacy is a lunch break and that is a pretty new development. We can still choose to work through our lunches, which we do when we are significantly behind on work. I have never taken any 15 minute breaks nor does anyone in our pharmacy. For many many years we didn't take any breaks at all in the pharmacy.
<b>Proponent</b>	1. Meal Breaks a. We are still fighting for UNINTERUPPTED meal breaks. b. The chain I work for finally decided to give us a 30-minute lunch break. HOWEVER, all of our conference calls and manager meetings are scheduled during that break time. If you decide to mandate these breaks, can you please throw in the word "uninterrupted"? c. "Under Federal law and Ohio law, an employer is required to pay its employees for all time spent performing "compensable" work. However,

	employers do not have to compensate employees during "bona fide meal periods." A bona fide meal period, aka a lunch break or dinner break, is an uninterrupted break where the employee is relieved from all job duties for the purpose of eating meals. In other words, whether a lunch break should be paid depends on whether you actually stop working." – Mansell Law That being said, if we have a scheduled lunch break, doesn't that mean it should be "free of work"? You would think this would be common sense but for my employer it is not. This will have to come from you. Please fight for uninterrupted breaks. d. Working 12 hours without any uninterrupted meal breaks is not only a concern for employees, but should be a major concern to public safety. They deserve 100% of our knowledge and concentration when checking prescriptions. Working a 12-hour day with no "real" break is exhausting and compromises patient safety. If you don't do it for us, do it for the patient.
<b>Proponent</b>	Rest periods should be mandatory to take a breather and to recover somewhat from the stress of a very challenging job. In Ohio, however, there are no protections given by Labor Laws, and given the utter disregard of the wellbeing of pharmacy staff by the large chains, this will not change unless specific changes are mandated by Board of Pharmacy. This will surely be challenged in court, but if the Governor, legislature and Board are serious about this, it can be done. As an example, in CA, due to labor rules, a pharmacist can only get credentials to log in once they are clocked in. This means that lunch breaks will be off the the clock, hence no work can be done. Ohio Board can perhaps make this a rule?
<b>Proponent</b>	While I do not disagree with the need for breaks for pharmacists, I am not sure the State of Ohio has regulations around mandatory breaks for any profession. Also, why to the regulations only apply to pharmacists where 12 or more locations are needed? If these are important patient safety regulations, shouldn't the rules be equally applied to all pharmacists in that practice setting?
<b>Proponent</b>	Mandatory closing for a lunch break would improve working conditions for all pharmacies. Having everyone leave at the same time would guarantee an actual break and improve workflow by not having to work short handed while lunch breaks are staggered throughout the afternoon. Most physician offices close from 12-1 without a negative impact to patient care or the business. Why should pharmacy be any different?
<b>Proponent</b>	Fortunately the chain I work for has mandated 30min meal periods. I believe it greatly improved our ability to focus when we have a guaranteed break, so this will be great for independents
<b>Proponent</b>	We only get a 30 minute lunch no other breaks due to understaffing
<b>Proponent</b>	We need the board to step in and help!
<b>Proponent</b>	As a type 1 diabetic who needs to administer insulin and eat at the same time everyday, I fully agree. Food should not be eaten while working, especially in view of patients, whose medications we are handling, or worse skipping eating all together. The employees health is just as important, we need to be healthy to continue our jobs efficiently. I need to be healthy to help the patients stay healthy.
<b>Proponent</b>	Most retail pharmacies have already implemented this and it is GREATLY appreciated.
<b>Proponent</b>	While working 14 hour days with no break, judgement becomes a factor along with focus.
<b>Proponent</b>	A Pharmacist should never work more than 10 hours per shift.
<b>Proponent</b>	Propose not just mandatory break periods but penalties for not using said mandatory periods for breaks.
<b>Proponent</b>	16+ years of not being able to take a break or being told I need to "make time" but having no ability to actually do so has increased my mental stress and anxiety.
<b>Proponent</b>	Closing for lunch helps but public isn't too understanding yet
<b>Proponent</b>	We already do this with our staff in the independent world!!!!

<b>Proponent</b>	Breaks allow for mental "reset" and "refocus" to ensure patient safety.
<b>Proponent</b>	Honestly, the break should be longer. An hour would do. The public can wait if they expect long lunch breaks for their careers. How are we any different?

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

**Answered: 78**

**Skipped: 44**

<b>Answer Choices</b>	<b>Responses</b>	
<b>Proponent</b>	75.64%	59
<b>Opponent</b>	8.97%	7
<b>Interested Party</b>	15.38%	12
<b>Total</b>		<b>78</b>

**Please submit any comments you may have on the proposed rule. (NOTE: Comments were optional, not everyone who answered above provided a comment. Comments that included phrases such as "see attached" or "see letter" were excluded).**

<b>Pro/Op/IP?</b>	<b>Comment</b>
<b>Interested Party</b>	Appropriate staffing and scheduling needs to be established in conjunction with local pharmacy management. There is significant variety in the type of work seen at different pharmacies, often within the same company. The pharmacy manager should have the ability to adjust corporate staffing models accordingly based on pharmacy needs. If chain pharmacies are forced into increasing staffing to certain levels, a likely outcome is a decrease in pay to employees of the pharmacy. This cannot be allowed, or we will continue to see the decline in the profession that has been occurring.
<b>Interested Party</b>	All I can say is ... get serious. Loss prevention and employee relations processes at chains are not to protect the employee, but for the company to identify 'risk'. This self-policing never works.
<b>Interested Party</b>	100%. I already know what needs to be done. Corporations shouldn't be allowed to cap hours on a pharmacy. Some Corporations use a matrix that thinks store A can run on this amount of hours and store B can run on this amount of hours. Because of this cap on hours I have worked in stores where we only have 1 technician at a time! Some stores I work at could use another 300 to 400 tech hours a week to properly run the pharmacy and take care of our patients how we should be able too.
<b>Opponent</b>	Any Pharmacy personnel should be allowed to communicate a staffing concern without fear of retaliation. But the answer should be allowed to be "no" without fear of an employee revolution. This rule doesn't seem necessary, but I feel there are more stores than ever that just ignore the concerns of their employees.
<b>Opponent</b>	If your boss or company isn't listening to your concerns-- go work someplace else.
<b>Proponent</b>	I support the rule as stated in previous comments as long as there is transparency and follow through by the immediate and district supervisors ( especially when these supervisors are most likely non pharmacists) Pharmacists have no power to hire additional pharmacist or technician staff since their pharmacy hour budgets are controlled by corporate. These rules must have teeth to hold these supervisors accountable and to protect the pharmacist and technician staff from retaliation. Corporations can always find an ambiguous reason to fire a pharmacist who complains about unsafe workplace conditions since Ohio is not a right to work state. They just find a way to label the pharmacist as a low performer by defining their reason for getting rid of the pharmacist as something else other than complaints about unsafe workplace concerns. I would hope that the BOP staff who reviews these complaints by pharmacists will back them up instead of cow towing to the corporation.

<b>Proponent</b>	Unfortunately large chain reputations have been ruined by poor staffing concerns that go to a deaf ear.
<b>Proponent</b>	(Walgreens CPhT 15 years experience)
<b>Proponent</b>	See attached letter
<b>Proponent</b>	Staffing concerns regularly fall on deaf ears, as if it has not been uttered. Unfortunately staff have no clout to make decisions re the amount of hours allotted for budgeted work. Any ancillary functions simply get added, with no regard as to who is actually there to do it. This will not change, since the corp deems it proprietary. Unless there is a system whereby the immediate supervisor is bypassed for concerns that are not addressed in a reasonable time, or with a reasonable explanation, what recourse is there but to quit. This would become a free-for-all since the authority of any manager is then undermined. Getting the board involved adds layers of complexity, which is not actually in the purview of the board. Safety issues as defined by the Board and/or OSHA are different, and have to be addressed by management anyway.
<b>Proponent</b>	No concerns except for the additional paperwork and record keeping that appears to be required.
<b>Proponent</b>	I would argue that this needs to even go further and have harsh monetary punishments for businesses that ignore the rule, and they will do their best to side step this rule.
<b>Proponent</b>	should be addressed
<b>Proponent</b>	As a life-long resident of the state of Ohio, and a practicing pharmacist in a variety of settings since 1999, I applaud the proposed rules from the Board. I personally support suggested revisions that have been submitted by the Ohio Pharmacists Association as follows: "The OPA provides additional suggestions for revisions to the following items in the rule: 4729:5-5-02.3 (Staffing Concerns): The ability to balance public safety with workload, staffing, and workflow most certainly rests with staffing authority, the pharmacist. While OPA is hesitant to see a regulatory board enter an employee/employer relationship, clear communication on staffing expectations and mechanisms for addressing concerns between pharmacists and their employers is paramount. The OPA appreciates the Board's effort to open these lines of communication; however, the OPA challenges the likelihood that these internal staffing plans will be sought out by pharmacists due to concern for retribution and suggest staffing plan documentation be required in the instance of an inspection that demonstrates workplace safety violations to directly preserve public health and address pharmacist concerns. Specifically, the OPA suggests the wording, "(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)." be changed to, "(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) following a State Board of Pharmacy inspection identifying a violation of safe workplace conditions". 4729:5-5-02.4 (Significant Delays): Similar to the above concerns on 4729:5-5-02.3, this section of the rule also may be more effective if targeted after a report has been made or a violation has been documented in a pharmacy. There are various factors that can cause a prescription to be delayed beyond 72 hours. It would be impossible to capture all these legitimate reasons in the rule. While we applaud the Board's attempt to exclude certain circumstances, the most important factor is the desire of the patient to have the prescription filled and/or the patient to accept the delay. As such, OPA suggests a shift in the wording from, "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy." To "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy and explicitly requested to be filled by the patient." OPA fully supports and seeks to partner with the Board of Pharmacy in their work to address identified pharmacist workplace issues. Representing pharmacists in the state of Ohio, we believe there is no greater value than a pharmacist's professional judgment in caring for patients in community pharmacies. Public safety is best protected when the deliverer

	of care, the pharmacist, is empowered to preserve the standard of care in Ohio and the Board provides guidance to support a safe and effective workplace environment for pharmacy personnel. As the Board progresses on these rules, the OPA supports tying existing law regarding the practice of pharmacy (Sec 4729.01(B)) to safe and effective workplaces provided by a TDDD (4729.55(D)) to enhance public safety. " I am appreciate of the opportunity to provide comment, and of the Board's work in this important matter. Respectfully, Debra L Parker, PharmD Licensed Ohio Pharmacist 1999-Present Dean, University of Findlay
<b>Proponent</b>	The chain pharmacies are all the same on this one. "Understaffed and underpaid". No one wants to be a technician that gets screamed at for their whole shift for things they can't control for \$12, \$15 or even \$18/hr in this economy. It's just not realistic to most people. Being mandatory emotional punching bags to people gets exhausting day in and day out. I understand these people are sick and might be having a bad day, but I am too and I don't deserve to be called inappropriate names for something I don't choose (like prices). Pay people more and more people will want to work for you, in turn making our patients safer.
<b>Proponent</b>	Chain pharmacies are not giving hours needed to bring on new hires
<b>Proponent</b>	We know why we have staffing concerns. Our company doesn't allow adequate staffing.
<b>Proponent</b>	Pharmacies should never pull colleagues from the front store to wait on customers due to staffing. This puts the rest of the store at jeopardy for theft, colleagues being left alone which is also not safe.
<b>Proponent</b>	Staffing needs need to be addressed minimally by the metrics of daily script count and access points per pharmacy. Access points should be off limits if staffing is not minimally sufficient.
<b>Proponent</b>	We get told "everyone is in same boat" but no information on what is being done to address the issue of short staffing.
<b>Proponent</b>	We already do this in the independent world. It is called hiring staff and training them and treating fairly and paying appropriately and having an invested owner.
<b>Proponent</b>	Developing a process is not helpful enough. They need to actually follow that process
<b>Proponent</b>	Dark hours and restricting pharmacy hours are very vital to this dilemma outpatient pharmacies face. Staffing issues are everywhere and we cannot stand to say that the issue will go away on its own. It will not. Would this cause financial harm to large pharmacy retailers? Most likely. However, does the public expect the work to be done fast or done correctly? In this day and age we cannot expect both any longer.

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

**Answered: 77**

**Skipped: 45**

<b>Answer Choices</b>	<b>Responses</b>	
<b>Proponent</b>	71.43%	55
<b>Opponent</b>	11.69%	9
<b>Interested Party</b>	16.88%	13
<b>Total</b>		<b>77</b>

**Please submit any comments you may have on the proposed rule. (NOTE: Comments were optional, not everyone who answered above provided a comment. Comments that included phrases such as "see attached" or "see letter" were excluded).**

<b>Pro/Op/IP?</b>	<b>Comment</b>
<b>Interested Party</b>	See attached. We are requesting an exemption from the significant delay language for online, nonpublic facing pharmacies and/or pharmacies serving only animal patients. Thanks.
<b>Interested Party</b>	In general I don't mind this rule. But we use Med Sync and compliance packaging, and need to process prescriptions in order to trigger pharmacy ordering points. Sometimes, the doctor has not authorized one or more of the needed medications within that 72 hour window, which would put us out of compliance. Maybe this rule should refer to new prescriptions only (i.e leaving an e script queue overflowing).
<b>Interested Party</b>	72 hours IS the problem from the perspective of patients. Chains can easily provide prescriptions quicker than they do. But, they choose not to for profits sake. And, with all the exceptions provided in the rule, chains have nothing to fear.
<b>Interested Party</b>	Until we can properly staff our pharmacies there will always be huge delays. Corporations can't be allowed to cap pharmacy technician hours. Pharmacies are understaffed because of hour restrictions.
<b>Opponent</b>	How is the pharmacy supposed to control the staff at the office to get a prior auth done, or the staff in the prior auth department at the insurance company, or even the wholesaler or the manufacturer. Why is the pharmacy being held to standards when they are so many other people and groups involved in getting the product to the patient.
<b>Opponent</b>	Take CVS TDL licenses if they can't handle the business they have stolen from their competitors through creating a monopolistic business environment. Let me have the business with fair payment and nobody will wait 72 hours to get there medicine. This is ridiculous.
<b>Opponent</b>	Our pharmacy only fills Rx's as they are requested by the patient. All incoming Rx's are put on the patient file. We still spend about 2 hours/week returning unpicked up Rx's to stock. It cost money to fill them (employee time and adjudication fees and labels and bottles and bags) and it takes an equal amount of time to put them back employee time and adjudication fees and labels and bottles and bags). If we fill every Rx that comes in we will spend five times that time and money putting things back in stock.
<b>Proponent</b>	I especially like this rule. So often times pharmacists have not been able to meet "promise times" because of short staff, yet they have no power to close the pharmacy or the drive thru, or to be able to mandate the supervisor to be able to send additional support staff to get a pharmacy caught up or to be able to finish other non dispensing tasks such

	as inventory management ( putting an order away, pulling expired drugs, controlled substance audits or other administrative tasks).
<b>Proponent</b>	Staffing concerns at chain locations have lead to patients experiencing delays in getting their medications. Nearby locations have taken the brunt of this effect.
<b>Proponent</b>	Office of the Dean College of Pharmacy at The Ohio State University 217 Parks Hall☐☐ 614-292-2266 September 12, 2023 Steven Schierholt, Esq. Executive Director Ohio Board of Pharmacy 77 S. High Street Columbus, Ohio 43215 Re: New Rule 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. Dear Director Schierholt, On behalf of The Ohio State University College of Pharmacy (OSUCOP), we appreciate the opportunity to provide our support of your recent rule: 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy. We would like to express gratitude to the Board of Pharmacy for seeking feedback and addressing the many workplace concerns that are creating negative implications for Ohio pharmacists and pharmacy personnel. OSUCOP has submitted comments on initial drafts released related to workplace rule changes, and we appreciate that many of our previous comments have been considered and addressed in the newly published rule 4729:5-5-02. We are supportive of these new rules. Once implemented, we encourage the Board to evaluate the implementation of the new rules to ensure they are having the anticipated impact and that the Board take further regulatory action as necessary. We suggest one consideration with 4729:5-5-02.4 addressing prescription delays. Due to the common situation involving a prescription being submitted to a pharmacy before a patient is ready for the medication to be filled, we suggest adjusting wording in this rule to define the 72-hour timeline based upon the request to fill by the patient. Thank you again for the opportunity for OSUCOP to provide our feedback on this rule. If there is anything we can do to further support the advancement of this rule, or if you have any questions about our recommendations, please contact me at kroetz.3@osu.edu. Sincerely, Deanna Kroetz, BS Pharm, PhD Dean and Professor
<b>Proponent</b>	Very tough rule to implement, and will have to be specific. Enforcement will also be hard to implement, as there will always be the excuse of "nobody wants to work", "we are actively working on it" etc. Proper documentation of steps being taken will have to be provided.
<b>Proponent</b>	No concerns except that language should be added to detail an expectation that the patient needs or wants the medication. Too often the pharmacy is overwhelmed with prescriptions that are not yet due for filling/refilling for a patient. Having staff focus on these types of medications would be a waste of resources. If the patient needs/wants the medication, then filling within 72-hours seems like a reasonable request.
<b>Proponent</b>	Power failure or circumstances related to weather or natural disaster should be an included exemption to delay.
<b>Proponent</b>	This would be great because then pharmacies can actually air out their grievances with the board instead of an invested party (such as a DM going for a bonus). Being able to tell the board, "we are understaffed, underpaid, mandated to complete thousands (literal thousands) of flu shots, complete all metrics based tasked, and not having a break is causing us to burn out and lose technicians. Leading to a vicious cycle. We would be heard by the board better than our management!
<b>Proponent</b>	No customer should have to wait a week or more for their medication. 48 hours is long enough.
<b>Proponent</b>	I waited 3 days for my prescription my doctor sent in because there wasn't enough staff



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

**Answered: 72**

**Skipped: 50**

<b>Answer Choices</b>	<b>Responses</b>	
<b>Proponent</b>	70.83%	51
<b>Opponent</b>	12.50%	9
<b>Interested Party</b>	16.67%	12
<b>Total</b>		<b>72</b>

**Please submit any comments you may have on the proposed rule. (NOTE: Comments were optional, not everyone who answered above provided a comment. Comments that included phrases such as "see attached" or "see letter" were excluded).**

<b>Pro/Op/IP?</b>	<b>Comment</b>
<b>Interested Party</b>	define access points please
<b>Interested Party</b>	Self-policing will not impact chains. The only way for chains to continue posting profit increases is to increase paid access to pharmacists.
<b>Opponent</b>	I agree that the pharmacists should have full control of the outpatient pharmacy. We don't need additional rules for this. WE need a free market place and let the pharmacies that are best run survive and the ones that aren't close. Fair payment for all services --- including dispensing medicine.
<b>Proponent</b>	another really good rule- pharmacists should be able to manage the vaccine appointment scheduler software to block certain scheduling times for vaccines, tests, etc if we don't have the pharmacist/ tech staff to support it. We should also be able to close a drive thru lane if there are not enough technicians to manage the front register as well as drive thru, such as when the pharmacist is working by themselves during really busy time frames because the corporate leaders will not allow them to bring in extra technicians during call offs, or will consistently only budget one tech or zero techs when the pharmacy volume warrants more than one tech. Only exception should be for disabled patients that are not mobile to be able to come inside to pick up a prescription. BOP staff should insist on these high volume stores have software or processes to siphon non patient phone calls to call centers or other means, to free up the pharmacists and techs from constant ringing phones. Pharmacists should only have to worry about responding to patient care calls ( drug or healthcare questions, counseling questions, calling prescribers to discuss concerns on a prescription, or doctor calls.) Patient refills, drug inventory questions, copay or insurance questions should be able to be sent to a call center or voice mail system if the pharmacy does not have enough staff to constantly answer these calls. Chains have the resources to develop call centers or other processes to support these higher volume pharmacies or create the process where pharmacy personnel can turn on the call center function during emergencies or other unusual circumstances(unusually high volume, computer failure, electricity goes out etc). I thank you for your efforts in creating some serious teeth to these new rules as long as they can be enforced by the BOP staff.
<b>Proponent</b>	No concerns in this section except to ensure section C would allow for electronic storage and does not require printed paper and record keeping.

<b>Proponent</b>	currently should be able to do
<b>Proponent</b>	<p>As a life-long resident of the state of Ohio, and a practicing pharmacist in a variety of settings since 1999, I applaud the proposed rules from the Board. I personally support suggested revisions that have been submitted by the Ohio Pharmacists Association as follows: "The OPA provides additional suggestions for revisions to the following items in the rule: 4729:5-5-02.3 (Staffing Concerns): The ability to balance public safety with workload, staffing, and workflow most certainly rests with staffing authority, the pharmacist. While OPA is hesitant to see a regulatory board enter an employee/employer relationship, clear communication on staffing expectations and mechanisms for addressing concerns between pharmacists and their employers is paramount. The OPA appreciates the Board's effort to open these lines of communication; however, the OPA challenges the likelihood that these internal staffing plans will be sought out by pharmacists due to concern for retribution and suggest staffing plan documentation be required in the instance of an inspection that demonstrates workplace safety violations to directly preserve public health and address pharmacist concerns. Specifically, the OPA suggests the wording, "(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)." be changed to, "(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) following a State Board of Pharmacy inspection identifying a violation of safe workplace conditions". 4729:5-5-02.4 (Significant Delays): Similar to the above concerns on 4729:5-5-02.3, this section of the rule also may be more effective if targeted after a report has been made or a violation has been documented in a pharmacy. There are various factors that can cause a prescription to be delayed beyond 72 hours. It would be impossible to capture all these legitimate reasons in the rule. While we applaud the Board's attempt to exclude certain circumstances, the most important factor is the desire of the patient to have the prescription filled and/or the patient to accept the delay. As such, OPA suggests a shift in the wording from, "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy." To "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy and explicitly requested to be filled by the patient." OPA fully supports and seeks to partner with the Board of Pharmacy in their work to address identified pharmacist workplace issues. Representing pharmacists in the state of Ohio, we believe there is no greater value than a pharmacist's professional judgment in caring for patients in community pharmacies. Public safety is best protected when the deliverer of care, the pharmacist, is empowered to preserve the standard of care in Ohio and the Board provides guidance to support a safe and effective workplace environment for pharmacy personnel. As the Board progresses on these rules, the OPA supports tying existing law regarding the practice of pharmacy (Sec 4729.01(B)) to safe and effective workplaces provided by a TDDD (4729.55(D)) to enhance public safety. " I am appreciate of the opportunity to provide comment, and of the Board's work in this important matter. Respectfully, Debra L Parker, PharmD Licensed Ohio Pharmacist 1999-Present Dean, University of Findlay</p>
<b>Proponent</b>	<p>Our chain requires us to counsel every new prescription. (Even if the patient has been on the medication for the last ten years. The unnecessary interruptions are an overwhelming distraction at our high volume BIG box store. The patients are annoyed that they are being sent to counseling when no changes were made to their maintenance medications and they don't have any questions. They should have the right to decline counseling with their signature. Our BIG box chain requires that all of these people have face time with the pharmacist.</p>
<b>Proponent</b>	<p>Pharmacists should always have the ability to focus on one task. But those services are important to, so coming up with a way to still provide them would be a good idea. appointment based models are becoming the standard</p>

**Proponent**

It would be nice to know that I will not be fired when I cannot handle drop off, pick up, drive though, phones, and deliveries all by myself (on top of filling prescriptions and giving vaccines).



September 11, 2023

Ohio Board of Pharmacy  
77 S. High Street  
Columbus, Ohio 43215

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

Ohio Board of Pharmacy,

We appreciate the opportunity to comment on the proposed language defining a significant delay in pharmacy services and a process to address such delays (4729:5-5-02.4).

Animal Policy Group (APG) represents online pharmacies dedicated to serving our animal community and the veterinary profession. We recognize that states are addressing pharmacy work environments in a variety of ways. Most of these measures are intended for traditional pharmacies serving human patients. Animal pharmacies are often unintentionally overlooked, much like veterinarians are in regards to prescriber requirements.

In most cases, animal pharmacies process prescriptions within 72 hours, but there are situations where they are not dispensed within that timeframe. Online and/or animal pharmacies operate quite differently from traditional, public-facing pharmacies. Patients/clients are not typically using online pharmacies for time-sensitive medication, especially for animal drugs. Animal pharmacies may have additional delays in serving nontraditional species or providing uncommon medications.

We encourage the board to include an additional exemption for nonpublic-facing, online pharmacies and/or pharmacies serving animal patients. We do not feel the proposed requirements are appropriate for these pharmacies or that these pharmacies are the focus of these types of requirements.

Please let me know if you have any questions. Thank you very much.

Scott Young

Animal Policy Group  
Vice President, Legislative and Regulatory Affairs



**THE OHIO STATE UNIVERSITY**

College of Pharmacy

Office of the Dean  
217 Parks Hall  
500 West 12<sup>th</sup> Avenue  
Columbus, OH 43210

614-292-2266 Phone

September 12, 2023

Steven Schierholt, Esq.  
Executive Director  
Ohio Board of Pharmacy  
77 S. High Street  
Columbus, Ohio 43215

**Re: New Rule 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy.**

Dear Director Schierholt,

On behalf of The Ohio State University College of Pharmacy (OSUCOP), we appreciate the opportunity to provide our support of your recent rule: 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy.

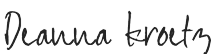
We would like to express gratitude to the Board of Pharmacy for seeking feedback and addressing the many workplace concerns that are creating negative implications for Ohio pharmacists and pharmacy personnel. OSUCOP has submitted comments on initial drafts released related to workplace rule changes, and we appreciate that many of our previous comments have been considered and addressed in the newly published rule 4729:5-5-02.

We are supportive of these new rules. Once implemented, we encourage the Board to evaluate the implementation of the new rules to ensure they are having the anticipated impact and that the Board take further regulatory action as necessary.

We suggest one consideration with 4729:5-5-02.4 addressing prescription delays. Due to the common situation involving a prescription being submitted to a pharmacy before a patient is ready for the medication to be filled, we suggest adjusting wording in this rule to define the 72-hour timeline based upon the request to fill by the patient.

Thank you again for the opportunity for OSUCOP to provide our feedback on this rule. If there is anything we can do to further support the advancement of this rule, or if you have any questions about our recommendations, please contact me at [kroetz.3@osu.edu](mailto:kroetz.3@osu.edu).

Sincerely,

DocuSigned by:  


E8D673BE19F8435...  
Deanna Kroetz, BS Pharm, PhD  
Dean and Professor



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2674 Federated Blvd., Columbus, OH 43235 • Phone: (614) 389-3236 • Fax: (614) 389-4582

September 12, 2023

Executive Director Steven W. Schierholt, Esq.

State of Ohio Board of Pharmacy

77 S High Street, 17<sup>th</sup> Floor

Columbus, Ohio 43215-6126

RE: Proposed 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

Dear Executive Director Schierholt:

This letter is in response to the solicitation for stakeholder comment on the proposed rule(s) issued under the Common Sense Initiative dated August 11, 2023.

The Ohio Pharmacists Association (OPA) was formed September 2, 1879 in Columbus, Ohio under the name Ohio State Pharmaceutical Association (OSPA). The purpose of the Association was to elevate the character of the pharmaceutical profession, by uniting the reputable druggists of the state, in order to foster the education of those learning the art, and thereby stimulate the talent of those engaged in pharmacy. In cooperation with its members and leaders, the present-day OPA continues to function by this purpose and act to positively impact the profession as these past extraordinary individuals did.

The Ohio Pharmacists Association appreciates the opportunity to provide comments on the proposed rule set related to establishing minimum standards in an outpatient pharmacy. Anytime OPA can improve both public safety and the pharmacy work environment, we will partner towards that improvement. We submit the following comments for your consideration.

Under existing Chapter 4729 of the Ohio Revised Code (ORC), the State of Ohio Board of Pharmacy has standing to regulate the practice of pharmacy through an authorized business entity (Sec 4729.161). Specifically, Terminal Distributor of Dangerous Drugs License (TDDD) holders are required to utilize the services of a pharmacist, and provide the ability of the pharmacist to practice in a safe and effective manner (Sec 4729.55). Within this framework, the pharmacist is required to be in full and actual charge of the pharmacy (Sec 4729.27). All prior cited entities are compelled to cooperate in investigations (Sec 4729.19) and are subject to enforcement (Sec 4729.25) and disciplinary actions (Sec 4729.57). This includes suspension or revocation of a license or other actions provided under rule(s).

Recently, the Board cited multiple TDDD license locations across Ohio with various risks related to public safety and the pharmacist(s) ability to practice in a safe and effective manner. This also raised the question of whether the pharmacist was in full and actual charge of the pharmacy. When a pharmacist is engaged in an environment where they unwillingly place public safety at risk, the question of single, multiple, or systemic cause should be asked. Because pharmacy is an art of practice, it is subjective, to some degree, on what a pharmacist can safely perform in a certain period of time. Their scope is wide (4729.01(B)) and weighted equally in terms of safety (4729.55(D)).

Given this, it is not unreasonable for an experienced Board Inspector to enter a pharmacy (TDDD) and quickly sense if the workload is reasonable for the pharmacist and staff to practice safely. The Board relies on experienced inspectors rather than law enforcement for this very reason.

The OPA stands with the Board of Pharmacy in improving the workplace environment, particularly the community setting. As such, **the OPA supports the following:**

**Regarding 4729:5-5-02 (*Minimum Standards*):** OPA applauds the Board in better defining *Minimum Standards for the Operation of an Outpatient Pharmacy*. Sec 4729.55(D) is clear in that a TDDD must give pharmacists the ability “to practice in a safe and effective manner.” 4729:5-5-02(11) proposes sufficient time and personnel for a pharmacist to complete professional duties and responsibilities. OPA believes this rule to be in harmony with public health and Sec 4729.

**Regarding 4729:5-5-02.1 (*Ancillary Services*):** OPA supports the Board in the elimination of quotas. Demanding a practice outcome based solely on its quantitative parameters rather than quality of service or needs of the patient for care is detrimental to public health. Broad performance metrics, rather than target functions (quotas), are a standard in the workplace. That said, any broad metrics should be safety- and patient-centered. Upon inspection by the Board, an agent should be able to quickly differentiate the two propositions and consider pharmacist input around how such are implemented by the employer.

**Regarding 4729:5-5-02.2 (*Rest Breaks*):** Countless studies demonstrate mental acuity deteriorates as someone grows physically and mentally exhausted. In Pharmacy, that corresponds to errors that could negatively impact public health. From the outside, it’s hard to evaluate an individual’s mental acuity. For this reason, OPA would support the ability of a pharmacist to have the discretion to take a meaningful break after a certain period of work and at their discretion. While no standard currently exists, the law is clear that the TDDD must provide a safe and effective manner for the practice of pharmacy to the pharmacist.

**Regarding 4729:5-5-02.3 (*Staffing Concerns*):** The ability to balance public safety with staffing, workload, and workflow most certainly rests with staffing authority. The Board has already demonstrated its ability to determine this fine line through recent reports, citations, and investigations. As mentioned prior, an experienced inspector can quickly determine staffing and its relationship to workflow and public safety through observation and dialog.

Specifically, the OPA suggests the wording, “(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)).” be changed to, “(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)) **following a State Board of Pharmacy inspection identifying a violation of safe workplace conditions.**”

**Regarding 4729:5-5-02.4 (*Significant Delays*):** Similar to above concerns on 4729:5-5-02.3, this rule also seems remedial and could be targeted. There are various factors that can cause a prescription to be delayed beyond 72 hours. It would be impossible to capture all these legitimate reasons in the rule. While we applaud the Board’s attempt to exclude certain circumstances, the most important factor is the desire of the patient to have the prescription filled and/or the patient to accept the delay.

As such, OPA suggests a shift in the wording from, "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy." To "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy and ***explicitly requested to be filled by the patient.***"

**Regarding 4729:5-5-02.5 (Outpatient Access):** OPA supports a pharmacist being in control and in charge of the pharmacy (Sec 4729.27), and places the professional judgement of the pharmacist in the middle of the equation with regard to public health. OPA would suggest the addition of the same retaliation/discipline provisions regarding this rule.

The Ohio Pharmacists Association fully supports and partners with the Board of Pharmacy's identification of pharmacist workload issues. Representing the profession, we believe there is no greater value in these matters than professional judgment of which only a pharmacist can truly use to gauge such issues as the above. Public safety is best protected when the pharmacist is empowered to preserve this standard of care, and the Board provides guidance to support a safe and effective workplace environment for pharmacy personnel. As the Board progresses on these rules, the OPA supports tying existing law regarding the practice of pharmacy (Sec 4729.01(B)) to safe and effective workplaces provided by a TDDD (4729.55(D)) to enhance public safety. A standard of care model for pharmacy could be that solution. OPA would rise to that challenge with the Board in building this framework in a collaborative manner.

OPA is thankful for the Ohio State Board of Pharmacy's provision of this open period of comment and the Board's focus on public health through pharmacist workplace safety. We trust our thoughts add value to this process. We would request the Board of Pharmacy continues to engage OPA as an active partner in implementation of these rules.

Most Respectfully,



David E Burke, RPh, MBA  
Executive Director  
Ohio Pharmacists Association



To Whom It May Concern:

Let me start by coping the Pharmacists Oath we all took on graduation day. I still remember that day as if it were yesterday. I have never been prouder for graduating with a Doctor of Pharmacy degree. My dream had finally come true and it truly was the best of times.

*"I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:*

- *I will consider the welfare of humanity and relief of suffering my primary concerns.*
- *I will promote inclusion, embrace diversity, and advocate for justice to advance health equity.*
- *I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for all patients.*
- *I will respect and protect all personal and health information entrusted to me.*
- *I will accept the responsibility to improve my professional knowledge, expertise, and self-awareness.*
- *I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.*
- *I will embrace and advocate changes that improve patient care.*
- *I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.*

*I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."*

Fast forward 4 years. 4 years was all it took for me to burn out. I write this letter to not complain but in hopes to see some type of positive change in outpatient pharmacy. I am ashamed it has taken the Ohio State Board this long to propose changes that will not only help grow the profession, but keep our patients safe. The data we now have is essential to uphold the **dignity** of our profession.

We have our data from the survey results. I can sit here and type out all of the data you have already posted and talk about the numbers. I'm not going to do that and please, if you haven't seen the data, visit [www.pharmacy.ohio.gov/PWAC](http://www.pharmacy.ohio.gov/PWAC) and skim the survey results. **It is astonishing, but not surprising.** There is one statistic that stood out to me more than others.

*18% of respondents strongly agree to the statement "I feel safe voicing any workload concerns to my employer".*

**Do we realize that means 82% do NOT feel safe discussing concerns to an employer? 82%!!!!**

As a pharmacy manager, if I had to deal with this issue at the store level with my staff, I would consider myself to have failed. If you do not feel safe bringing up workload environment and conditions to your employer, then I would say the safe bet would to be to find a new employer,

right? Wrong. Look at the data. Look at the survey results. It's everywhere. You have the power to make change in our profession. Please help us. This is my last cry for help.

I'm going to touch on two topics. Meal breaks and use of Quotas.

## 1. Meal Breaks

- a. We are still fighting for UNINTERUPPTED meal breaks.
- b. The chain I work for finally decided to give us a 30-minute lunch break. HOWEVER, all of our conference calls and manager meetings are scheduled during that break time. If you decide to mandate these breaks, can you please throw in the word "uninterrupted"?
- c. "Under Federal law and Ohio law, an employer is required to pay its employees for all time spent performing "compensable" work. However, employers do not have to compensate employees during "bona fide meal periods." A bona fide meal period, aka a lunch break or dinner break, is an uninterrupted break where the employee is relieved from all job duties for the purpose of eating meals. In other words, whether a lunch break should be paid depends on whether you actually stop working." – Mansell Law
  - i. That being said, if we have a scheduled lunch break, doesn't that mean it should be "free of work"? **You would think this would be common sense but for my employer it is not. This will have to come from you. Please fight for uninterrupted breaks.**
- d. Working 12 hours without any uninterrupted meal breaks is not only a concern for employees, but should be a major concern to public safety. They deserve 100% of our knowledge and concentration when checking prescriptions. Working a 12-hour day with no "real" break is exhausting and **compromises patient safety.** If you don't do it for us, do it for the patient.

## 2. Use of Quotas

- a. The problem is not quotas by itself. **The problem is a growing business with growing quotas but no additional help or resources.**
- b. With these growing quotas, I highly suggest you reach out to med safety at some of these big chain pharmacies and see how many medication and vaccine errors there have been just this year alone. **Our flu shot goal this year is 1,594 flu shots.** (We are considered a lower-medium volume store, doing about 3,000 scripts a week). **Have we gotten any additional help? Nope. They actually are cutting our hours.** If someone can explain this to me, I will sit down and listen. I have reached out to corporate asking questions to why our hours are being cut after dropping our flu shot goal of 1,594 on top of prescriptions, other vaccines, phone calls, shelf maintenance, inventory management, perpetual inventory, counseling, doctor calls, etc. How are we supposed to manage? **Physically, emotionally, and mentally we can't manage.** This is an impossible goal. I work 12-hour shifts by myself, have a second staff pharmacist, and a part timer where

occasionally we will have enough hours for overlap. Do you realize pharmacists will start leaving the profession (including myself – seriously to the point of looking to go back to school because this is not what pharmacy was when I was an intern) if this continues to happen. You have the power to change this and you have a lot of people rooting for you. How is the workload listed above acceptable for employees but more importantly, our patients? **Again, patient safety is compromised.**

- c. “Hitting your numbers will keep you alive today. Hitting your numbers with momentum ensures you stay relevant in the future.” Pharmacy has no momentum right now and people are going to start leaving the profession if things are not going to change in Ohio.

If you have made it this far, I appreciate you reading this in its entirety and I really hope you take some of my words into consideration. I’ll leave you with the very last line of our oath. *“I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.”* **If you don’t do it for us, do it for the safety of the patients.**

Sincerely,

A very sad pharmacy manager looking for a new profession



September 12, 2023

By Electronic submission

Executive Director Steven W. Schierholt, Esq.  
State of Ohio Board of Pharmacy  
77 S High Street, 17<sup>th</sup> Floor  
Columbus, Ohio 43215-6126

RE: Proposed 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

Dear Executive Director Schierholt:

This letter is in response to the solicitation for stakeholder comment on the proposed rule(s) issued under the Common Sense Initiative dated August 11, 2023.

The Independent Pharmacy Cooperative (IPC) is a national trade group representing the interest of nearly 2500 independent pharmacy store owners in all 50 states and the District of Columbia, including over 100 stores in Ohio. Many of our member pharmacies reside in rural, underserved and economically disadvantaged parts of the country. These pharmacies continue to accept the responsibility of being the first point and often only source for delivering health care in their local communities. As a part of our services to members we engage in Government Relations to actively participate in public policy advocacy for our members on both the federal and state level. It is in this capacity that we are submitting our comments on the draft rule noted above.

IPC appreciates that the Ohio Board of Pharmacy's role in protecting the public in Ohio by assuring that pharmacies and all pharmacy personnel have professional responsibilities and rules to ensure that the public served by these health care centers are done in a safe and professional manner. IPC also understands that the Board, in response to much press attention and several investigations into the operations of Ohio pharmacies - focused on major chain pharmacies - has proposed these rules related to establishing minimum standards in an outpatient pharmacy. IPC does agree that pharmacies in Ohio and all other jurisdictions need to operate in ways that ensure public safety and have appropriate work conditions provided the regulations are crafted in a way that is not a "one size fits all" approach that treats small community based independent pharmacies, often the only health care provider in underserved Ohio communities the same as multi-billion dollar large, national and international corporate owned chain and mass retailer pharmacies. We submit the following comments for your consideration.

Under existing Chapter 4729 of the Ohio Revised Code (ORC), the State of Ohio Board of Pharmacy has standing to regulate the practice of pharmacy through an authorized business entity (Sec 4729.161). Specifically, Terminal Distributor of Dangerous Drugs License (TDDD) holders are required to utilize the services of a pharmacist and provide the ability of the pharmacist to practice in a safe and effective manner (Sec 4729.55). Within this framework, the pharmacist is required to be in

full and actual charge of the pharmacy (Sec 4729.27). All prior cited entities are compelled to cooperate in investigations (Sec 4729.19) and are subject to enforcement (Sec 4729.25) and disciplinary actions (Sec 4729.57). This includes suspension or revocation of a license or other actions provided under rule(s).

IPC concurs with the Ohio Pharmacists Association in looking to work with the Ohio Board of Pharmacy to ensure all Ohio pharmacies ensure a good workplace environment.

The Ohio Pharmacists Association stands with the Board of Pharmacy in improving the workplace environment, particularly the retail setting. Turning to page 12 and question 7 of the Common Sense Initiative (CSI) we find:

**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.*

IPC is concerned that the survey process will become burdensome to our members and their staffs and some may feel a sense of coercion to complete the surveys. IPC asks that for such staff at independent owned pharmacies – defined as a common ownership of 10 or less OH based pharmacies – this survey process be voluntary.

4729:5-5-02 (Minimum Standards): IPC concurs with OPA in supporting the Board’s better defining *Minimum Standards for the Operation of an Outpatient Pharmacy*. Sec 4729.55(D) is clear in that a TDDD must give pharmacists the ability “to practice in a safe and effective manner.” 4729:5-5-02(11) proposes a length of time for a pharmacist to complete professional duties and responsibilities. OPA believes this rule to be in harmony with public health and Sec 4729. While not defining a specific length of time, the Board seems to indicate that the time be based on an individual’s efficiency.

4729:5-5-02.1 (Ancillary Services): IPC understands the Board’s interest in eliminating quotas for large scale corporate owned Ohio pharmacies. We believe that such a quota system isn’t applicable for independent pharmacies since many of the pharmacy payer entities do own the chain pharmacies that are at the heart of the problem and have been the focus of investigations in Ohio. Further, there is a difference between quantitative parameters and broad performance metrics. These regulations need to ensure that such payer-based performance metrics are not classified as target functions (quotas).

Regarding 4729:5-5-02.2 (Rest Breaks): IPC understands the importance of pharmacy staff needing work breaks when they believe they are necessary for them as an individual. We do not support an arbitrary regulatorily mandated timeframe for such break when these individuals will know when a rest or a break will work best for them. IPC does appreciate some flexibility in these proposed regulations that does allow pharmacy professional staff in an independent pharmacy with the right to choose to work through a shift without a break. Still IPC believe a broader exemption is needed for Ohio independently owned pharmacies.

4729:5-5-02.3 (Staffing Concerns): IPC agrees with OPA that the Board has sufficient regulatory authority to determine pharmacy staffing needs through recent reports, citations, and investigations. Rule 4729:5-5-02.3 appears to be more remedial to these reports than standing policy. An experienced BOD inspector can quickly determine staffing and its relationship to workflow and public safety through observation and dialog. A pharmacist, staff member or patient/customer can also file a report with the Board itself. Historically, this would trigger an inspection focused on the concern. To that and upon such finding, only then does 4729:5-5-02.3 seem to make sense than the proposed regulation. Also, for independent pharmacy owners, especially in underserved areas, having limited staff can be a function of finding personnel, prescription volume and the economic conditions for that particular pharmacy location. Independently owned pharmacies are not cutting staff or staff hours to increase corporate profit. They are making staffing needs to fit their individual, unique pharmacy operations. IPC requests this rule provide that it only applies to independent owned pharmacies based on a written filed, compliant with the Ohio Board of Pharmacy.

4729:5-5-02.4 (Significant Delays): Like the above concerns on 4729:5-5-02.3, this rule also seems remedial and could be targeted. There are various factors that can cause a prescription to be delayed beyond 72 hours especially when it could be securing the drug from wholesaler sources or payer actions (i.e., prior authorizations, concurrent reviews, review of PBM approval denial appeals). That is a big difference from circumstances where a pharmacy hasn't taken the time to complete the prescription dispensing process within this 72-hour timeframe. Exemptions should be clear that this proposal would not apply during times of Government declared states of emergencies for that pharmacy's location, FDA declared drug shortages for that particular drug or during long 3-day holiday periods and should only defined as 72 hours when a pharmacy is open, not calendar days.

4729:5-5-02.5 (Outpatient Access): IPC agrees with OPA in supporting a pharmacist being in control and in charge of the pharmacy (Sec 4729.27) and places the professional judgement of the pharmacist in the middle of the equation with regard to public health.

Need for Exceptions for Independently Owned Pharmacies: As stated at the beginning of this comment on these proposed rules, and in accordance with the Ohio regulatory CSI, the Ohio Board of Pharmacy should not take a "one size fits all" approach to these rules apply equally to a large, corporate owned pharmacy as to a small, community based independent pharmacy that may be the only health care provider in a county or for more than 10 miles. Many Ohio independent pharmacies are a sole pharmacist owned and operated facilities with a limited number of staff because they serve a limited number of patients given the population of their communities. These proposed rules could prove very burdensome for them to comply with. For these reasons, either in each proposed regulation or as a new subparagraph section at the end 4729:5-5-02, IPC respectfully requests that the Board provide language for exemptions from these sections for Ohio independently owned TDDD, defined as a common ownership of 10 or less Ohio based TDDD locations, from these provisions if any of the following conditions are met:

- 1) The TDDD has only one pharmacist in-charge who also owns and operates the pharmacy location;

- 2) The TDDD is located in a federal designated medically underserved area (MUA) or medically underserved population (MUP);
- 3) The TDDD has on one registered Pharmacy Technician or only one registered Pharmacy Technician on site during a specific work period; and
- 4) the TDDD is located in an Ohio community where the nearest TDDD is located 10 or more travel distance miles or 15 minutes of travel time from that TDDD location.

In addition to these exception and exemptions, the final rule should provide a mechanism for any Ohio independently owned pharmacy TDDD to seek a written hardship waiver from the Board for these regulations and that waiver should be considered by the Board with a written decision no later than 30 days from the date of the written submission, unless it is mutually agreed upon by the applicant and the Ohio BOP to extend the Board’s consideration of the waiver request for a mutually agreed upon time frame.

IPC believes these changes will make these final rules compliant with the Ohio CSI requirements.

IPC appreciates the opportunity to provide this written comment on Ohio BOP Proposed Rules regarding pharmacy workplace standards. We look forward to working with Ohio Board of Pharmacy to adopt reasonable rules that protect the public, reflects the need for professional pharmacy working standards while also recognizing the need for flexibility to not have a “one size fits all” approach in these rules – consistent with Ohio’s Common Sense Initiative regulation development requirements - that require the Board to include in its final regulations appropriate regulatory flexibilities for Ohio’s independent pharmacies and their staff.

If you have any questions or need any additional information, please feel free to contact me by either by email ([john.covello@ipcrx.com](mailto:john.covello@ipcrx.com)) or by phone (609-915-4888).

Respectfully submitted,



John Covello  
Director of Government Relations  
Independent Pharmacy Cooperative



The Kroger Co.  
Kroger Health  
www.krogerhealth.com

555 Race St.  
5<sup>th</sup> Floor  
Cincinnati, Ohio 45202

September 12, 2023

Executive Director Steven W. Schierholt, Esq.  
State of Ohio Board of Pharmacy  
77 S High Street, 17<sup>th</sup> Floor  
Columbus, Ohio 43215-6126

Re: Proposed Rules on Minimum Standards and Working Conditions

Dear Mr. Schierholt:

The Kroger Co. appreciates the opportunity to submit comments in reference to the Ohio Board of Pharmacy's proposed new and amended rule changes to **4729:5-5-02.1/5 – Minimum Standards and Working Conditions**. The Board's efforts to establish new rules governing quotas and workforce standards based on prior pharmacist surveys is commendable. Upon review of these proposed rules and the surveys they are based on, however, we have identified several issues that would exacerbate the concerns the Board is attempting to address in some ways and overstep its authority in others.

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

Kroger does not utilize metrics to evaluate the performance of our pharmacy teams. However, metrics remain an important tool for determining the healthcare needs of community. Vaccines are more than an "ancillary service." They are a life-saving resource that can be overlooked by patients without their pharmacist's urging or intervention. Metrics help pharmacies organize and better prepare pharmacy teams serve patients. The Board's revised rule defining "quotas" still discounts that important function.

Public health is only effective through quantitative repetitiveness – administering services such as vaccines, testing, etc. for highly communicable diseases to patients. As the most accessible healthcare providers in America, pharmacists fill that need every day. Measuring a pharmacy's impact vis-à-vis the vaccine rates in the community it serves, for example, is a necessary component to meeting that need. Since Ohio is an at-will employment state, the usage of metrics is an unnecessary benchmark on which to hinge a pharmacist's employment. Instead, the elimination of metrics for non-prescription services will only mask the potential shortcomings of that pharmacy – including potential shortfalls in staffing – which would negate the intent of the proposed rule 4729:5-5-02.3 on staffing levels and result in an underserved community.

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

Kroger provides break time for our pharmacy staff, closing each afternoon for 30 minutes for





The Kroger Co.  
Kroger Health  
www.krogerhealth.com

555 Race St.  
5<sup>th</sup> Floor  
Cincinnati, Ohio 45202

lunch. In instances where staff shifts overlap, the pharmacy team can choose to stay open during that time. This break is above and beyond what is required by state or federal law. Currently, Ohio does not have any laws requiring employers to provide employees with meal or rest breaks, nor does the federal Fair Labor Standards Act. We do not believe the Board has the authority to establish or enforce such regulations in the pharmacy setting. It is currently, and should remain, the responsibility of the employer to set workplace standards for its staff in a way that balances the needs of employees as well as the healthcare needs of the community the pharmacy serves. Government-imposed breaks may not align with the workload of the pharmacy and lead to backlogs in workload and safety lapses.

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

Kroger supports the spirit of the proposed rule to trust a pharmacist’s professional judgement and have a plan in place for handling pharmacist concerns that arise. However, in many instances, such situations can be corrected when, or even before, they become a problem if the pharmacist-in-charge communicates the issue to their supervisor or other leadership position. The employer is in the best position to shift resources as needed to address the concerns without limiting patient access to vaccines, testing and other necessary services.

#### **Rulemaking Origin and Methodology**

We believe the premise from which these new rules are derived is a flawed standard of measurement. Just 20% of Ohio pharmacists were concerned enough to respond to the 2021 Pharmacy Survey in some way and just two-thirds of those respondents answered questions on how the proposed rules would impact them. The survey was also conducted at the height of the COVID-19 pandemic when working conditions were uniquely stressful and not indicative of today’s work environment, nor reflective of the improvements pharmacies have made to the workplace since. At Kroger, these improvements in workflow include a 25% increase in the use of automation to fill prescriptions – reducing both workload and error rates. We also:

- Significantly invested in the expanded use of automated fill technology to ease the workload burden on pharmacists.
- Designated specific hours to vaccines only to limit calls and other workplace distractions.

Further, the repeated issuance of citations to companies for workforce violations demonstrates that a mechanism is already in place for the Board to address its concerns. Additional rules would be duplicative and run counter to the goals of Ohio’s Common Sense Initiative which include, “eliminate excessive and duplicative rules and regulations...” The citations issued by the Board and the articles cited<sup>1</sup> by the Board in the Board’s Business Impact Analysis on the

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<sup>1</sup> “These issues are further reinforced through inspections detailing significant staffing issues at outpatient



The Kroger Co.  
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Proposed Rules reflect ongoing issues with a specific chain. We believe the Board should use its existing authority to address these concerns and can adequately remedy them with an application of the penalties sufficient to dissuade further recurrence.

Finally, the suggestion that companies operating pharmacies can simply hire more pharmacists runs contrary to the existing realities of current workforce conditions. America is facing a significant and well-documented<sup>2</sup> shortage of pharmacists, making this hiring mandate nearly impossible to meet. The estimates shown by the Board on the cost of fulfilling this mandate (\$13,717,248 in the case of Kroger) are much lower than the actual costs associated with recruiting and employing 96 additional pharmacists and would represent a significant financial burden imposed on businesses by the government.

In conclusion, The Kroger Co. has significant concerns about the Proposed Rule as drafted and its potential adverse impact on patient access and the practice of pharmacy. We stand ready to work with the Board to address its concerns on these or other issues in a way that works best for pharmacies, pharmacies, and the patients they serve. Please do not hesitate to contact Jeff Steckman at [jeff.steckman@kroger.com](mailto:jeff.steckman@kroger.com) if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Colleen Lindholz".

Colleen Lindholz  
President, Kroger Health

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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-dispenseprescriptions-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-understaffedcvs-pharmacies-are-said-to-be-widespread-the-ohio-ag-is-taking-a-look/>" Pg. 5, CSI - BIA - Minimum Standards and Working Conditions, [https://www.pharmacy.ohio.gov/documents/lawsrules/proposedrules/commonsense/csi%20-%20bia%20-%20minimum%20standards%20and%20working%20conditions%20\(comments%20due%209.12.2023\).pdf](https://www.pharmacy.ohio.gov/documents/lawsrules/proposedrules/commonsense/csi%20-%20bia%20-%20minimum%20standards%20and%20working%20conditions%20(comments%20due%209.12.2023).pdf)

<sup>2</sup> <https://www.bls.gov/ooh/healthcare/pharmacists.htm#tab-1>

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# Unite For Safe Medications

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PO Box 513  
Park Hills, MO 63601

9/12/2023

Ohio Board of Pharmacy  
77 S High St  
Columbus, OH 43215

Dear Board of Pharmacy Members:

Our organization supports the proposed guidelines to ensure safer staffing of pharmacies in Ohio. Staff staffing and safe working conditions are basic needs to ensure safe medication access, and I'm thankful to see a Board of Pharmacy begin to truly protect patients by acknowledging that the current failure to meet these basic needs is causing patient harm and harm to the profession overall.

Pharmacists and patients must be protected from corporate chain pharmacies' purposeful, abusive, and chronic understaffing. When purposeful understaffing is directly tied to errors, pharmacists should not be held as accountable as the executives and corporations demanding understaffing.

Understaffing is not only a risk for all patients in America who need medications, but the future of pharmacy and medication access is impacted as pharmacists leave the profession and students refuse to enter.

Thank you for taking the lead in our nation to protect not only patients but pharmacists and the future of the pharmacy profession.

Sincerely,

Loretta Boesing

Founder of Unite For Safe Medications

OHIO  
NORTHERN  
UNIVERSITY

THE RAABE COLLEGE OF PHARMACY  
OFFICE OF THE DEAN

September 12, 2023

Steven W. Schierholt, Esq.  
Executive Director  
Ohio State Board of Pharmacy  
77 S High Street, 17<sup>th</sup> Floor  
Columbus, Ohio 43215-6126

RE: New Rule 4729:5-5-02 - Establishes minimum standards in an outpatient pharmacy

Dear Director Schierholt:

This letter is in response to the solicitation for stakeholder comment on the proposed rule(s) issued under the Common Sense Initiative dated August 11, 2023.

Founded in 1884, the Ohio Northern University Raabe College of Pharmacy (ONU) is one of seven colleges of pharmacy in the state of Ohio. With more than half of our more than 7,000 living alumni licensed in the state of Ohio, the practice of pharmacy in the state is of the utmost importance to our faculty and administration. Additionally, our mission is to provide a transformative education to prepare student pharmacists to enter the pharmacy workforce and care for the members of their community. For these reasons, ONU commends the Ohio State Board of Pharmacy in working to improve the community pharmacy workplace.

Specifically, ONU **supports** the following:

4729:5-5-02 (Minimum Standards): We applaud the Board in better defining *Minimum Standards for the Operation of an Outpatient Pharmacy*. Sec 4729.55(D) is clear in that a TDDD must give pharmacists the ability “to practice in a safe and effective manner.” 4729:5-5-02(11) proposes sufficient time and personnel to complete professional duties and responsibilities by a pharmacist.

4729:5-5-02.1 (Ancillary Services): We support the Board in the elimination of quotas. Demanding a practice outcome on quantity instead of quality of service or patient needs potentially detrimental to public health. Broad performance metrics, rather than target functions (quotas), may be an important part of job performance and evaluation, but any metric utilized by an employer needs to be safety- and patient-centered.

4729:5-5-02.2 (Rest Breaks): ONU supports the ability of a pharmacist to have the discretion to take a meaningful break after a certain period of work and at their discretion as well as the provisions in 4729:5-5-02.2 (A) (2). While no standard currently exists, the law is clear that the TDDD must provide a safe and effective manner for the practice of pharmacy to the pharmacist.

4729:5-5-02.3 (Staffing Concerns): ONU feels the public safety with workload, staffing, and workflow most certainly rests with staffing authority, the pharmacist. Consistent with 'just culture' the pharmacist should have the authority to raise concerns with staffing concerns directly with the Ohio State Board of Pharmacy. To the degree possible, the Ohio State Board of Pharmacy should also ensure no retribution against a pharmacist raising concerns by his/her employer.

4729:5-5-02.5 (Outpatient Access): ONU strongly supports that a pharmacist be in control and in charge of the pharmacy (Sec 4729.27).

ONU suggests the following **revision**:

4729:5-5-02.4 (Significant Delays): There are various factors that can cause a prescription to be delayed beyond 72 hours and while the intent of the rule is noted, it would be impossible to capture all these legitimate reasons in the rule. To ensure the patient is part of the prescription process, ONU suggests an addition to the working to "Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy and **explicitly requested to be filled by the patient.**"

On behalf of the administration, faculty, and students, ONU fully supports the Ohio State Board of Pharmacy and their work to improve community pharmacy workplace issues. Pharmacists have long been a trusted and accessible healthcare provider that promotes public health. Ensuring a safe working environment for pharmacists in Ohio is also an important part of the educational environment for the student pharmacists in Ohio. As a long-established College of Pharmacy in the state of Ohio, ONU looks to continue to advance the profession of pharmacy and patient safety. We would request that the State Board of Pharmacy continue to engage with the pharmacy community and Colleges of Pharmacy in the state of Ohio on implementation of the rules.

Sincerely,

A handwritten signature in black ink that reads "Stuart J Beatty". The signature is written in a cursive style with a long horizontal flourish extending to the right.

Stuart J Beatty, PharmD, BCACP, FAPhA  
Dean and Professor  
Ohio Northern University Raabe College of Pharmacy



Nichole Cover, R.Ph.  
Director, Pharmacy Affairs  
Walgreen Co.  
p: 224-507-9405  
nichole.cover@walgreens.com

September 11, 2023

Via <https://www.surveymonkey.com/r/DTRrules>

State of Ohio Board of Pharmacy  
Attention: Steven Schierholt, Esq.  
Executive Director  
77 S. High St., 17<sup>th</sup> Floor  
Columbus, OH 43215

Re: Proposed Rules: Minimum Standards and Working Conditions

Dear Executive Director Schierholt,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the state of Ohio, we thank the Board for the opportunity to provide comments on your draft Minimum Standards and Working Conditions rules. Walgreens appreciates the Board's time and effort related to reviewing these regulations and considering public comments for improving patient safety and healthcare services provided by pharmacies.

#### **4729:5-5-02 Minimum Standards for the Operation of an Outpatient Pharmacy**

Walgreens supports the Board's role of protecting patient health and safety in the State of Ohio. Incorporating subjective terms such as "sufficient" into a number of sections here creates a regulatory framework that is nearly impossible for drug outlet owners to anticipate all outcomes that could potentially impact compliance. How would the board determine what is considered sufficient, and maintain a consistent approach to enforcement, across a very diverse group of drug outlets that utilize vastly different workflow models and levels of technology. Therefore, we ask that the board strike the following language:

~~4729:5-5-02 (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.~~

~~(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; 23~~
- ~~(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**

Walgreens appreciates that the Board did not include prohibition on quotas related to volume of prescriptions dispensed as there are several different workflow models utilized to fulfill the dispensing portion of the prescription process. It is important to enforce consistent standards across all segments of pharmacy. While Walgreens agrees with the concept of a prohibition on the use of quotas for performance evaluations, there is a significant concern with the utilization of metrics in pharmacy and how an inspector or the Board may decide to interpret this utilization. Walgreens recently announced the removal of the use of metrics from performance evaluations and believes that the onus should be on individual pharmacy owners to manage the utilization of metrics effectively and responsibly. Many current reimbursement models and Specialty Accreditation (i.e., URAC (Utilization Review Accreditation Commission) Standards rely on the use of metrics to assist in measuring adherence, utilization, patient impact, quality measures, etc. As this information is captured and shared back to pharmacy teams, the concern is the perception that these are seen as quotas, when in fact they are simply providing updates.

In summary, The Board is attempting to solve, through rulemaking, an issue that involves human behavior. Human behavior regardless of if the licensee acts in the best interest of the patient, is not limited to how many stores you own or if you are independent, chain, or a health system. The world of pharmacy utilizes many other metrics to assist in gauging customer service, patient care services, and quality. Leaders within the pharmacy may decide to set internal goals to improve quality or customer service or help change patients' lives through an improvement in services offered. The concern is: how does an inspector or the Board differentiate between a goal and a quota for ancillary pharmacy services? We believe one key component of quotas, that the Board has not addressed, is the punitive nature associated with quotas. As a pharmacy owner, if I offer my pharmacy staff incentives for reaching certain milestones – is that a quota? We do not believe it is since there are no punitive actions associated with not reaching these milestones. However, as these rules are currently proposed, an inspector or the Board may interpret this as a quota.

Walgreens therefore recommends instead of banning quotas that the Board issue guidance surrounding the proper use of metrics and improper utilization of quotas. These proposed rules may then serve as notice to all pharmacies that continued utilization of quotas may result in future rulemaking. As mentioned, the utilization of metrics can be open to individual interpretation, therefore Walgreens recommends that the Board strike the proposed rule language prohibiting quotas:

- ~~(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.~~

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

Walgreens supports the Board's proposed rules regarding rest breaks and currently has policies and procedures in place that support this process. However, we ask that the Board does not create rules that differentiate between independently owned small businesses and "chain" pharmacies when creating rules and instead create uniform practice standards across all community pharmacies caring for patients across Ohio. Therefore, we ask that the board strike any language which creates this division including the following language:

##### *4729:5-5-02.2(B)(2)*

*(B)(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.*

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

Walgreens asks that the Board strike the requirement to report staffing concerns on a predetermined form. Walgreens agrees that pharmacy personnel should share concerns and as an Ohio Licensed pharmacy permit holder, would encourage and support being compliant. However, Walgreens believes that the responsibility should be on individual pharmacy owners to address these concerns effectively and responsibly. Therefore, we recommend striking the following language:

##### *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.~~

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

Walgreens has for over a century been a steadfast believer and deliverer of safe and effective access to pharmacy and health services within the communities of Ohio and across the nation. When a patient decides to have their pharmacy and health services delivered at a Walgreen location, our organization considers an “informal contract” has been executed with that patient, and it is Walgreens responsibility to live up to the “terms” by meeting the patient’s healthcare needs in a consistent and reasonable manner. The patient always holds the ultimate right to have their healthcare needs fulfilled by another provider. The creation of a state regulatory scheme that interjects itself between the patient and the pharmacy provider is an unparalleled level of intrusion into business practices and customer service. Walgreens continues to be open to dialogue and collaboration with the board on any specific instances where limited patient access to services could cause patient harm. We ask that the board strike the following language:

##### ~~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.~~

~~— 30 — (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**

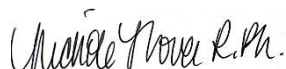
Walgreens has and continues to openly engage with pharmacy staff and leadership to ensure that our pharmacists are appropriately supported to provide safe and effective pharmacy and health services to those in Ohio communities. Each of the sections below reference “in the pharmacist’s professional judgment.” This term of phrase is inherently subjective in nature and could lead to disruptions in patient care delivery if a pharmacist, by

means of these proposed regulations, discontinues pharmacy access points without first engaging and looking for solutions with their organization. Walgreens stands ready to engage with the board on any specific instances where patient safety is a concern. It is for these reasons that Walgreens feels this section should be removed from these proposed rules:

~~(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.~~

Walgreens appreciates the work of the Pharmacy Workload Advisory Committee (PWAC) and thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,



Nichole Cover, RPh

September 12, 2023

Steven W. Schierholt, Esq.  
Executive Director  
Ohio Board of Pharmacy  
77 S. High St., 17<sup>th</sup> Floor  
Columbus, OH 43215

Re: OHA Comments on Proposed Rule 4729:5-5-02 – 02.5 (Minimum Standards/Quotas/Rest Breaks/Staffing);  
Submitted via: <https://www.surveymonkey.com/r/MINSTAND>

Dear Executive Director Schierholt:

On behalf of our 248 member hospitals and 15 health systems, the Ohio Hospital Association appreciates the opportunity to comment on the Pharmacy Board's proposed rules regarding Minimum Standards, Quotas, Rest Breaks, Staffing and other issues regarding outpatient pharmacies. Our members value the Board's willingness to receive our feedback and the collaborative relationship we have with the Board. In response to the publication of these proposed rules, OHA convened a representative group of hospital pharmacy leaders to provide their perspective on the rules.

Our feedback regarding the proposed rules follows:

It appears the Pharmacy Board has attempted to be responsive to some of OHA's comments shared on the quota and rest breaks rules that were circulated for comment last fall and winter, and on which OHA commented in November 2022 (regarding the quota rule) and January 2023 (regarding the rest break rule). One thing the Board did was make the new proposed rules applicable to "outpatient pharmacies." The limitation to outpatient pharmacies may have been an effort to address some of our concerns about operationalizing these rules in a hospital setting. However, we are concerned that the newly proposed rules remain very difficult to operationalize in a hospital outpatient pharmacy without seriously impacting patient care and hospital operations.

OHA is concerned that the Board is attempting to regulate the minutiae of pharmacy practice and operations in a way that broadly impacts hospital operations and patient care, even though we believe the real target of the regulation is the large pharmacy chains. The large pharmacy chains have been the subject of intense media scrutiny for how they run their operations, and they were the target of the overwhelming majority of negative responses to the Pharmacist Workload Advisory Committee's survey of pharmacists. OHA's concern is that the Board's efforts to regulate bad actors will sweep up hospital outpatient pharmacies which do not operate in the same way as the large pharmacy chains.

We believe that if the Pharmacy Board is concerned about the operations in large pharmacy chains, the regulations should be directed at those actors. **We urge the Pharmacy Board to exempt outpatient pharmacies that are owned or operated by hospitals or health systems from these regulations.**

Examples of how these proposed rules will adversely impact hospital pharmacy operations include:

- Proposed rule -02.1 prohibits the use of quotas related to the provision of “ancillary services.” However, in some hospitals, there are dedicated hospital outpatient pharmacy professionals whose job is solely or predominately to provide “ancillary services” as that term is defined in the rule. Accordingly, the provision of ancillary services by those individuals does not interfere with other roles as pharmacy personnel. But the rule would forbid quotas related to those individuals’ work.
- Proposed rule -02.2 defines circumstances in which a pharmacy must close to allow for a 30-minute break, with some exceptions. We recognize that there are exceptions to the rule for those pharmacies operated by a company with fewer than 12 pharmacies. However, if a large health system owns hospital outpatient pharmacies at 12 locations, this rule would apply to them and is simply unworkable in a hospital setting. It would be cleaner, and still achieve what we believe to be the Board’s objectives (regulation of large chain pharmacies), to just exempt hospital- or health system-owned pharmacies from this rule. For the reasons stated in our January 20, 2023 comment letter, closing a hospital outpatient pharmacy to accommodate a mandatory break is not practical from a patient care perspective.
- Mandatory breaks for hospital outpatient pharmacists are not practical and will delay care. Hospital outpatient pharmacists are routinely consulted by physicians and other clinicians regarding patient care issues. Mandatory breaks will result in delays in patient care, not just for the patient whose clinician is trying to contact the pharmacist who is on a break, but all other patients whose care will be delayed as the hospital outpatient pharmacist returns from the break to a stack of messages and orders that the pharmacist is now behind on and has to work through. As noted in our January 20, 2023 comment letter, hospital pharmacies are required to meet federal requirements under the Medicare Conditions of Participation, including requirements to dispense drugs in a safe and timely manner and in accordance with acceptable standards of practice. In many cases involving hospital outpatients, delays in care resulting from mandatory breaks would not meet these federal requirements.
- For example, many health systems have community family health centers with a variety of different primary care providers and an outpatient pharmacy attached. A mother who has received care for a child in the pediatrician’s office at the family health center, and who is sent downstairs to the pharmacy to pick up a prescription on her way out would potentially face at least a 30-minute delay in receiving the prescription (the break time plus time spent dealing with a backlog that resulted during the break). Some parents will be forced to leave to go back to work, rather than wait, and may not make it back to the pharmacy. Delays in care often result in no care at all, as families attend to other priorities.
- The delays detailed in proposed rule -02.4 simply do not occur frequently in hospital outpatient pharmacies, so this provision seems like a regulatory overreach as it relates to hospital pharmacies. When unexpected delays occur, hospitals have processes in place to remedy those delays to minimize any adverse impact on patients.

Closing access points as proposed in rule -02.5 does not accurately reflect the integrated nature of a hospital and hospital outpatient pharmacy. Most hospital outpatient pharmacies only have a single access point – a single pickup window or medication delivery to the bedside. Furthermore, many hospital outpatient pharmacies may have dedicated personnel performing the ancillary functions complementary to the medication dispensation process. Since this work is being completed in parallel to and with separate personnel to the medication dispensing it would not make sense to close the ancillary services. Doing so would negatively impact patient access to medications which is contrary to the intention of this rule.

There are many other instances of these proposed rules simply not being operational in a hospital. Furthermore, the breadth and vagueness of some of the rules would make compliance very difficult, as it is impossible to know how the Board would interpret certain requirements. For example, how will the Board survey (under proposed -02(B) for whether a pharmacy has “excessive distractions” or takes adequate steps to “prevent fatigue?” Is a tired employee who works a second job outside of the pharmacy a reflection of how the pharmacy has scheduled or choices the employee makes outside of employment by the pharmacy? How will the Board survey for whether the pharmacy resolved staffing issues “in a timely manner to ensure a safe working environment (-02.3(B)(2)? How will the Board determine whether a pharmacy retaliated against someone who reported staffing concerns? How will the Board determine that an individual did not receive a promotion they “otherwise would have received” or did not receive a salary increase to which they are “otherwise entitled?” Is the Board really equipped to make these complicated human resources determinations?

OHA appreciates the problem the Pharmacy Board is trying to solve, and we support efforts to ensure safe and effective pharmacy services. However, the operations of hospital outpatient pharmacies are fundamentally different than retail pharmacy chains, and we urge the Board to recognize that distinction and regulate them differently (in this case, by carving out hospital- or health system-owned pharmacies from the rules). These rules will impair hospital outpatient pharmacies’ ability to provide safe patient care and will unnecessarily impair access to care.

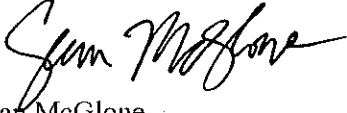
Finally, we have heard from several hospital pharmacists who would be insulted to be required to take a mandatory break. They view these proposed rules as a degradation of their professionalism and their necessary and valuable role in the direct care of hospital patients. They do not want to have to ignore a cardiologist’s call regarding a patient care issue because they are on a mandatory break – doing so is a slight against their important role in the care of hospital patients.

Thank you again for the opportunity to provide feedback from the hospital pharmacy leader perspective. OHA’s representative group of hospital pharmacists would welcome the opportunity to discuss this feedback with you as the Board continues to process these rules. Please feel free to contact me with questions or to schedule a call with our group of hospital pharmacists.

[signature on next page]

Executive Director Schierholt  
September 12, 2023  
Page 4

Sincerely,

A handwritten signature in black ink, appearing to read "Sean McGlone". The signature is written in a cursive style with a large initial "S".

Sean McGlone  
Sr. V.P. & General Counsel

cc: Cameron McNamee, Ohio Board of Pharmacy



September 12, 2023

Executive Director Steven W. Schierholt, Esq.  
State of Ohio Board of Pharmacy  
77 S High Street, 17th Floor  
Columbus, OH 43215-6126

Submitted electronically via [surveymonkey.com](https://www.surveymonkey.com)

RE: Proposed Rule 4729:5-5-02.4 – Significant delays in the provision of pharmacy services

Dear Executive Director Schierholt:

This letter is in response to the solicitation for stakeholder feedback on proposed rule 4729:5-5-02.4 issued by the Common Sense Initiative on August 11, 2023. CenterWell Pharmacy appreciates the opportunity to provide comments on this proposed rule.

CenterWell Pharmacy, Inc. (CenterWell Pharmacy) is a full-service home delivery pharmacy serving patients across all 50 states. CenterWell Pharmacy provides holistic care that is personalized and coordinated with easy-to-use options so our patients can receive the care and prescriptions they need exactly when they need them. This includes home delivery services, as well as retail and specialty pharmacy services. Our pharmacies employ many pharmacists and pharmacy technicians who are critical to ensuring that patients across the country have access to the medication that they need. CenterWell Pharmacy's largest dispensing facility, which opened in 2008, is located in West Chester Township, Ohio.

For many months, the Board has been working on rulemaking related to quotas. CenterWell Pharmacy and other interested parties submitted feedback along the way. Overall, we appreciate the Board's recognition of the public comments on its previous proposals and the changes that were made as a result. While we applaud these efforts, we have concerns on the new language relating to significant delays.

- ***The Board's proposal still does not fully consider the differing pharmacy models within the State, including closed-door pharmacies.***

It appears the proposed language on significant delays is intended to focus on community and retail settings. The proposal sets a 72-hour deadline for prescriptions to be dispensed, but the expectation of what steps need to occur within that timeframe is unclear. While the language includes some exceptions, there are other reasons why a prescription may not be dispensed in 72 hours. For example, this could include additional time needed for a patient to pick up a prescription at their convenience or for a prescription to be delivered to a patient.

CenterWell Pharmacy proactively educates its patients about our standard turn-around times for prescriptions to be received, filled, and delivered to the patient's home. In the event our stated timeframe cannot be met due to circumstances outside of our control, we contact patients to discuss alternative ways to access the medications they need.

Additionally, many specialty medications require careful coordination of delivery with

500 West Main St., Louisville, KY 40202

[CenterWellPharmacy.com](https://www.CenterWellPharmacy.com)



patients, and those agreed upon delivery dates may exceed 72 hours based on patient availability and when they need the medication.

**Recommendation**

While we appreciate the changes in comparison to the previous versions of the proposed rules on quotas, the current proposal on significant delays does not completely distinguish between the varying pharmacy models in Ohio. Given these factors, ***CenterWell Pharmacy strongly recommends that the Board reconsider the draft rule's language on significant delays and its applicability to closed-door pharmacies.***

In other proposed rules, there are clear delineations that exempt outpatient pharmacies that are not open to the public. We would appreciate a similar distinction as it relates to significant delays and suggest the following:

*(E) The requirements 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 deliver medication by a date agreed upon and/or provided to the patient. If the timeframe cannot be met, the pharmacy shall discuss with the patient how to obtain his or her medication through alternative means.*

Thank you for the opportunity to provide feedback to the Board on this proposed rule. Please feel free to contact me if you have any questions related to the comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Travis Garrison", with a stylized flourish at the end.

Travis Garrison  
Associate Vice President, State Affairs  
tgarrison2@humana.com





September 12, 2023

Steven Schierholt, Executive Director  
Ohio Board of Pharmacy  
77 South High Street, 17<sup>th</sup> Floor  
Columbus, OH 43215

Mr. Schierholt,

On behalf of the chain drug members of the Ohio Council of Retail Merchants, I write to share that we are very disappointed that the latest rule package proposing a completely new 4729:5-5-02 and creating five new subsections has been submitted for consideration. The first version of a new 4729:5-5-02 proposed back in April of 2023 was onerous and unnecessary. This new package is even more so with the addition of 4729:5-5-02.4, Significant Delays in the Provision of Pharmacy Services.

As I stated in May, it is very important to note at the onset that the Board is basing the proposed new rules on survey results from a minority of Ohio pharmacists during a historic pandemic that severely impacted healthcare in many settings with high stress and fatigue, but particularly retail settings. In 2020 and 2021 during the pandemic, there were increased demands for COVID-19-related services, as well as challenges with staffing due to medical leaves and attrition of healthcare workers. Based on the 2021 survey responses reported by the Board, only 26.41% of pharmacists in Ohio responded to the survey and of those, 71% did indicate they did not have adequate time to complete their jobs in a safe and effective manner. This is not at all surprising based on the state of healthcare during the pandemic. Many companies that operate pharmacies in Ohio have made changes since 2021 to improve work-life balance due to the strains placed on their employees during the pandemic. As the Board reported, all but two large chains are now closed for lunch breaks. In order to be attractive to new employees and retain current employees, companies will continue to listen to feedback from their employees and make changes to how they operate, without the need for Board of Pharmacy rules pertaining to this.

We also contend that this rule package is unnecessary as the Board already has the authority to act on unsafe conditions reported by a pharmacist. These new regulations would cause unintended consequences that would negatively impact patient access to care and pharmacist work-life balance and would result in significantly increased costs to the businesses being regulated, as noted in the CSI Business Impact Analysis. With the current workforce shortage pharmacies and other health care employers are struggling with, the proposed rule changes would only exacerbate the conditions the Board contends it is trying to improve.

This new rule package is still reliant upon subjective terms such as “sufficient personnel,” “excessive distractions,” “sufficiently trained,” and “sufficient time.” In 4729:5-5-02(B)(11), the proposed rule states, “Provide sufficient time for a pharmacist to complete professional duties and responsibilities, including...” To properly engineer to be compliant, metrics would need to be reviewed and would potentially violate other sections of the proposed rule. A utopian labor budget would potentially need to be created. Infinite resources, including time, are not possible to provide.

The profession of pharmacy continues to advance its scope of practice, and the Board of Pharmacy has worked very hard on rules and regulations that expand the care that pharmacists can provide Ohioans. Proposed 4729:5-5-02.1 focuses on quotas on “ancillary services” not directly involved in the dispensation of dangerous drugs, which includes “immunizations, medication therapy management... and refill reminders.” This language infers it is fine to have quotas on the number of prescriptions being dispensed but not to have meaningful goals to advance care for Ohioans that prevent disease or reduce hospital admissions. Also, the definition of “quota” has a detrimental side effect. The number of tasks and services performed by pharmacy personnel are used to determine labor needs, so not being able to evaluate tasks and services to determine how much labor is needed to operate safely is counter intuitive.

Proposed 4729:5-5-02.2 would not be universal for community pharmacy as it makes exceptions for small chains and independent pharmacies when it should apply to all pharmacies equally. If safety really is a concern for the Board, why would there be a difference? If this is to protect the public health, is the Board indicating that the risk is higher at an independent pharmacy? There should not be two standards as there is not a material difference in the burden as it relates to the practice of pharmacy and public safety. This inequality is anti-competitive and would punish successful companies by saddling them with an additional burden.

The new 4729:5-5-02.4 addressing significant delays in the provision of pharmacy services requires that a prescription be dispensed within 72 hours of receiving a prescription and allows for only five exceptions. Some pharmacy systems allow patients to submit a refill request and select their pick-up date and time further out than 72 hours. The proposed language does not take this scenario into consideration.

In proposed 4729:5-5-02.5, without truly defining what is or is not an unsafe condition, the language limiting access points leaves a lot to interpretation by the pharmacist, the Board and the employer. Any interpretation that is unrealistically conservative will negatively impact patient care. For example, there are patients who are unable to come into a building and rely on alternate access points such as drive-thru windows. Those patients would be negatively impacted by frequent restrictions that would result in that access point being unavailable to them. Even without the proposed rule, if a pharmacist discusses with his or her supervisor about a closed access point, and if that pharmacist truly believes the employer is creating an unsafe condition by forcing them to keep it open, the pharmacist can currently report this to the Board and the Board has the authority to act on it.

I close by reiterating that we find the proposed rule package to be unnecessary, subjective, burdensome and costly and would result in many unintended consequences. We respectfully request that the rule package be withdrawn in its entirety.

Please let me know if you have any questions or wish to discuss any of the points made in this letter.

Sincerely,



Lora Miller  
Director of Governmental Affairs & Public Relations  
Ohio Council of Retail Merchants  
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Columbus, OH 43215  
614-271-8262  
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cc: [CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)  
[joseph.baker@governor.ohio.gov](mailto:joseph.baker@governor.ohio.gov)  
[stephanie.mccloud@governor.ohio.gov](mailto:stephanie.mccloud@governor.ohio.gov)  
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Ohio Chain Drug Committee

September 12, 2023

Steven W. Scheirholt, Esq.  
Executive Director  
The State of Ohio Board of Pharmacy  
77 S High Street  
Columbus, OH 43215

**RE: RULES 4729:5-5-02; 4729:5-5-02.1; 4729:5-5-02.2; 4729:5-5-02.3; 4729:5-5-02.2 4729:5-5-02.4; 4729:5-5-02.5**

Dear Mr. Scheirholt,

I am writing to you on behalf of the National Community Pharmacists Association regarding proposed amendments to **4729:5-5-02; 4729:5-5-02.1; 4729:5-5-02.2; 4729:5-5-02.3; 4729:5-5-02.2 4729:5-5-02.4; 4729:5-5-02.5**. NCPA commends the State of Ohio Board of Pharmacy in addressing the issues of pharmacy staffing and workflow that have resulted in documented public safety concerns. Rule 4729:5-5-02 establishes minimum standards for Ohio outpatient pharmacies such as ensuring sufficient time and personnel to compete professional duties and responsibilities. These standards include requiring access to tools and equipment to allow pharmacies to operate efficiently and to better serve patients. We applaud the language in Rule 4729:5-5-02.2 that grants exceptions to owners of 11 or fewer pharmacies to have the pharmacist in charge determine whether the pharmacy needs to be closed when a pharmacist is on break.

NCPA represents the interest of America's community pharmacists, including the owners of more than 19,400 independent community pharmacies across the United States and 398 independent community pharmacies in Ohio Virginia that employ over 4,000 full-time employees who filled over 25.1 million prescriptions last year. Our members are small business owners who are among America's most accessible health care providers in many communities.

Increased workload and reports of burnout, even before the COVID-19 pandemic, have been associated with medication and dispensing errors. Regulators auditing pharmacies in Oklahoma found understaffed facilities, employees working around unopened delivery boxes and discovered that a specific pharmacy was up to two weeks behind on filling prescriptions because of inadequate staffing.<sup>1</sup> The state's Board of Pharmacy recommended increased training for technicians and removing some required metrics along with other tasks that could over burden the staff. Missouri's Board of Pharmacy formed a taskforce on workplace conditions, including staffing, prescription volumes, this being a response to reports of pharmacists and staff feeling pressured to meet metrics and not having adequate time to complete tasks.<sup>2</sup> Ohio is no different from Oklahoma and Missouri, which is why it is incumbent on this Board to approved these proposed rules. Many of these issues are less prevalent in independent settings, which is why we support the exception for 11 pharmacies or fewer which, includes

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<sup>1</sup> Ellen Gabler *CVS Fined for Prescription Errors and Poor Staffing at Pharmacies* New York Times, July 16, 2020, available at <https://www.nytimes.com/2020/07/16/business/cvs-pharmacies-oklahoma.html>

<sup>2</sup> Annika Merrilees *Missouri board to investigate working conditions at pharmacies after hundreds complain* St. Louis Post-Dispatch, July 3, 2020, available at [https://www.stltoday.com/business/local/missouri-board-to-investigate-working-conditions-at-pharmacies-after-hundreds-complain/article\\_7a872c83-93a6-58d3-bd26-097ffefdbfa5.html](https://www.stltoday.com/business/local/missouri-board-to-investigate-working-conditions-at-pharmacies-after-hundreds-complain/article_7a872c83-93a6-58d3-bd26-097ffefdbfa5.html)

the vast majority of independent pharmacies in the state, and grants them the flexibility to manage their staff and care for their patients.

Since the COVID-19 pandemic, pharmacists in Ohio and across the country have had to respond to a greater workload and have risen to the occasion by delivering quality services that may not have been accessed by the public due to capacity limits and spacing restrictions. As the demand has increased for pharmacy services and care, it is imperative that pharmacy staff are protected so they can deliver the highest quality of care possible. As we enter flu season, the demand of pharmacy services will continue to increase and it is critical that safeguards are put in place to assist pharmacists and pharmacies to practice and operate to the best of their ability.

NCPA appreciates the opportunity to provide comments supportive of the proposed rules that promote quality patient care by defining minimum standards of outpatient pharmacies. The proposed rules maintain accountability within the practice of pharmacy and better protect patients when providing care and other services. If you have any questions, please do not hesitate to contact me at [belawoe.akwakoku@ncpa.org](mailto:belawoe.akwakoku@ncpa.org).

Sincerely,



Belawoe Akwakoku  
Associate Director, State Government Affairs  
National Community Pharmacists Association

Cc: The State of Ohio Board of Pharmacy

September 12, 2023

Steven Schierholt, Esq.  
Executive Director  
Ohio State Board of Pharmacy 77  
S High Street  
Columbus, OH 43215

Re: Request for comments – Re: OHA Comments on Proposed Rule 4729:5-5-02 – 02.5 (Minimum Standards/Quotas/Rest Breaks/Staffing); Submitted via: [www.pharmacy.ohio.gov/comments](http://www.pharmacy.ohio.gov/comments)

Dear Director Schierholt,

On behalf of The Ohio State University Wexner Medical Center (OSUWMC), we appreciate the opportunity to provide feedback on your recent request for public comments on “4729:5-5-02: Minimum Standards/Quotas/Rest Breaks/Staffing. We would first like to express gratitude to the Board of Pharmacy for working to seek feedback and addressing the many workplace concerns that are creating negative implications for Ohio pharmacists and pharmacy personnel. Many of the concerns shared by pharmacy personnel in Ohio have identified fear that patient safety and well-being are being compromised due to workplace issues. Additionally, it appears the Board has attempted to be responsive to some of our comments shared last fall and winter related to the quota rule and rest break rule. **However, the newly proposed rules remain very difficult to operationalize in a hospital outpatient pharmacy without impacting patient care.**

OSUWMC is an academic medical center that provides over 1.9 million outpatient visits, over 60,000 patient admissions, and over 130,000 emergency department visits each year. OSUWMC recognizes the importance of the pharmacist as a member of the healthcare team and utilizes the expertise of the pharmacist in a variety of patient care settings across OSUWMC, including, but not limited to, hospital outpatient (community) pharmacies, inpatient generalists, inpatient specialists, ambulatory care generalists, and ambulatory care specialists. With multiple licensed hospital outpatient pharmacies across Central Ohio, these rules are relevant to the workplace practices of our pharmacies.

As written, **these rules seem to be directed toward a traditional large chain community pharmacies** and we urge the Board to direct changes towards the those organizations and **exempt outpatient pharmacies that are owned and operated by hospitals and health systems, in the same way the proposed rules exempt closed door pharmacies.**

Pharmacists who work in traditional large chain community pharmacies need support which is evident from their feedback. In reviewing the Ohio Survey Results from 2020 and 2021, there is a stark difference in the response from pharmacists who work in large chain pharmacies compared to pharmacists who work in any other setting. We support efforts to improve the working conditions in traditional large chain community pharmacies. Enrollment in pharmacy school continues to drop across the country and we need to do everything we can support the practice of pharmacy in this setting. Alternatively, the Board could consider a separate TDDD type for outpatient pharmacies

owned and operated by hospitals and health systems. Hospital outpatient pharmacies operate within the same electronic medical record as the institution and pharmacists who practice in these locations function more like their peer institutional pharmacists. Additionally, as health systems continue to grow, they may soon operate more than 12 hospital outpatient pharmacies across their enterprise.


Examples of how these rules will negatively impact hospital outpatient pharmacies are outlined below and we would strongly request the Board to differentiate hospital outpatient pharmacies.

- Proposed rule 4729:5-5-02.1 prohibits the use of quotas related to the provision of “ancillary services.” However, in many hospitals, there are dedicated hospital outpatient pharmacy professionals whose job is solely or predominately to provide “ancillary services” as that term is defined in the rule. Accordingly, the provision of ancillary services by those individuals does not interfere with other roles as pharmacy personnel. But the rule would forbid quotas related to those individuals’ work. **We would request that hospital outpatient pharmacies be exempt from 4729:5-5-02.1 in the same manner as closed door pharmacies.**
- Proposed rule 4729:5-5-02.2 defines circumstances in which a pharmacy must close to allow for a 30-minute break, with some exceptions. It is not practice to close a hospital outpatient pharmacy from a patient care perspective. We appreciate the Board’s attempt to exclude companies with fewer than 12 pharmacies which likely exempts all or most hospital outpatient pharmacies. However, as health systems continue to grow they could reach the 12 location limit in the near future. **For this reason we would request that hospital outpatient pharmacies be exempt from 02-2 in the same manner as closed door pharmacies.** This would be cleaner and allow the Board to support pharmacists practicing in traditional large chain community pharmacies.
  - Mandatory breaks for hospital outpatient pharmacists are not practical and will delay care. Hospital outpatient pharmacists are routinely consulted by physicians and other clinicians regarding patient care issues. Mandatory breaks will result in delays in patient care, not just for the patient whose clinician is trying to contact the pharmacist who is on a break, but all other patients whose care will be delayed as the hospital outpatient pharmacist returns from the break to a stack of messages and orders that the pharmacist is now behind on and has to work through. Hospital pharmacies are required to meet federal requirements under the Medicare Conditions of Participation, including requirements to dispense drugs in a safe and timely manner and in accordance with acceptable standards of practice. In many cases involving hospital outpatients, delays in care resulting from mandatory breaks would not meet these federal requirements.
  - Given the relationship with the medical teams many of our staff stated they would be insulted to be required to take a break. They view the proposed rule as a degradation of their professionalism and their necessary and valuable role in the direct care of patients. They do not want to be treated differently than their institutional peers and be required to ignore a cardiologist’s call regarding a patient care issue because they are on a mandatory break.

- In addition, there may be situations when an employee may decide to work through their uninterrupted lunch period – to complete other tasks, potentially leave early at the end of the day, etc. As a department we always recommend that the staff take their lunch break but do allow flexibility for the employee to make this decision if needed.
- Proposed rule 4729:5-5-02.4 outlines a process when significant delays in the provision of pharmacy services occur. **The rules as outlined, simply do not apply to hospital outpatient pharmacies and therefore we request exemption.** If a delay were to occur, the hospital has processes in place to remedy and avoid any delay in care as we would for any patient seeking care within the institution.
- Proposed rule 4729:5-5-02.5 address closing access points. These proposed rules do not accurately reflect the nature of health system or hospital outpatient pharmacies operations. Most or nearly all hospital outpatient pharmacies are within the institution or ambulatory medical building and have a single point of access. Hospital outpatient pharmacies have dedicated staff performing ancillary duties such as discharge medication delivery, prior authorization, and medication assistance in conjunction with traditional dispensing. This workflow is completed in parallel and therefore it does not make sense to close ancillary services. Closing ancillary services will have a negative impact on patient care and will dramatically impact the discharge process. **The rules as outlined in -02.5, simply do not apply to hospital outpatient pharmacies and therefore we request exemption.**

OSUWMC supports the Board of Pharmacy's steps to address workplace environments putting patients and pharmacy personnel at risk, **and strongly recommend that terminal distributors of hospital outpatient pharmacies be excluded due to the patient acuity experienced in these settings as well as existing practices and policies in place that already support the general intent of this rule.** We also encourage the Board to bring together hospital pharmacy leaders to develop rules that work for the hospital outpatient pharmacy setting and do not put patient safety at risk. I would be happy to discuss these recommendations further at the e-mail listed below.

Sincerely,



Trisha A. Jordan, PharmD, MS  
Chief Pharmacy Officer  
Assistant Dean for Medical Center Affairs  
The Ohio State University Wexner Medical Center  
[Trisha.jordan@osumc.edu](mailto:Trisha.jordan@osumc.edu)





**John Long**  
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VIA ELECTRONIC MAIL

DRAFT 7

September 10, 2023

Cameron McNamee  
Director Policy and Communications  
The State of Ohio Board of Pharmacy  
77 South High Street  
Columbus, OH 43215  
[Cameron.McNamee@pharmacy.ohio.gov](mailto:Cameron.McNamee@pharmacy.ohio.gov)

**Re: Comment proposed rule 4729:5-5-02 –Minimum Standards for the Operation of an Outpatient Pharmacy FILE NEW RULE**

Mr. McNamee,

I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across Ohio. CVS Health (“CVS”) appreciates the opportunity to submit comments on the State of Ohio Board of Pharmacy (“Board”) proposed new updated rule 4729:5-5-02, which provides the minimum standards for the operation of an outpatient pharmacy.

**Section 4729:5-5-02 - Minimum Standards for the Operation of an Outpatient Pharmacy**

CVS agrees that today’s retail pharmacy operation is a complex, dynamic healthcare work environment employing highly skilled professionals. For this reason, CVS has developed a sophisticated and robust scheduling program that uses the resources of experienced industrial engineers, statisticians, analysts, and pharmacists to ensure that sufficient pharmacy personnel are scheduled to work in our retail pharmacies to support the needs of our patients and communities. As part of this proprietary program, several metrics are used to forecast the needs for the pharmacy workday schedule. These metrics are used by CVS pharmacist managers to schedule the appropriate amount of personnel during the week. A few of these

key metrics include drug utilization review, patient counseling, immunization administration, patient testing, and prescription volume. Proper scheduling of employees is vital to ensure the healthcare needs of the communities that CVS serves is met.

A successful part of CVS's nationwide approach to assist pharmacist workload and increase dispensing quality is the expanded use of pharmacy technology and automation. Technology and automation have been embraced by the majority of the state boards of pharmacy to help reduce pharmacist workload and improve working conditions. CVS does not believe that the proposed regulation, likely to be enforced with a high degree of subjectivity and variability, offers a true solution to perceived issues in a complex working environment. Rather, CVS requests that the Board work with industry stakeholders to draft regulations that promote innovation, reduce regulatory barriers and allow for the same technology and automations to be used in Ohio as it is used across the United States. Specifically, the ability to freely share work amongst pharmacies and allow for automated technology that minimizes pharmacy distractions and improves dispensing quality. CVS has experienced a reluctance by the Board, through several regulatory barriers imposed by the Board, to allow pharmacies to utilize proven technology and workflow solutions, which reduces pharmacist distraction and workload, further exacerbating the current employment challenges that many pharmacies are facing in Ohio.

An important reason to focus on enhancements to pharmacy automation and technology is the forecasted decrease in pharmacists. American Association of Colleges of Pharmacy (AACCP) data has shown significant decreases in the number of students interested in pursuing pharmacy careers. In fall 2011, AACCP found that there were 106,815 applicants to pharmacy school, a figure that dropped to 76,525 by fall 2015 and 40,552 by fall 2021. In less than a decade, pharmacy school applications had decreased by more than 60%.<sup>1</sup>

#### **Section 4729:5-5-02.1 – Provision of ancillary Services in an Outpatient Pharmacy**

CVS supports the idea of not allowing individual quotas in the provision of ancillary services. CVS also supports the Board's allowance of pharmacies using metrics to support the overall business planning and for the use of metrics in the proper scheduling and staffing to help serve the patients and communities that CVS proudly serves.

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

CVS was the first national drug store chain to require a daily mandatory pharmacy closure for 30 minutes to allow for pharmacy personnel rest breaks. We are encouraged that several other organizations have followed, providing their pharmacist, interns, and pharmacy technicians this needed break time. CVS also supports non-retaliation for all of its employees when they voice their opinions or concerns. However, the Board's attempt to define and regulate the definition of discipline and retaliation doesn't account for the various justified scenarios that may present, whereby the proposed broad definition of retaliation may be applied inappropriately. For example, if a pharmacist decides that they do not want to work a certain shift,

it may mean that they see a decrease in hours with a corresponding decrease in pay. It also follows that a pharmacy may want to transfer the pharmacist to a store that could meet the desired hours of the pharmacist. CVS is concerned that the Board is engaging in rulemaking that has not received the proper statutory authority to regulate pharmacy business practices and therefore, is considered a statutory overreach.

To ensure clarity in this section of the proposed rule, CVS proposes the following language in the first paragraph of 4729:5-5-02.2:

(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 scheduled off time between consecutive shifts.

(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's in pay or position.~~

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

A critical component of pharmacy practice is to ensure prescriptions are dispensed to patients in a timely and safe basis. CVS generally supports 4729:5-5-02.4, however, CVS offers the below amendment to account for a situation where a community-based pharmacy is closed every weekend and a national or religious holiday falls on a Monday.

(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 business hours of receiving the prescription. Receipt of the prescription is said to occur when it is transmitted or submitted to the pharmacy.

While the proposed rule provides five examples that will not be defined as a “significant delay”, several other scenarios are not included in the Board approved list, which will surely be proven to be incomplete

over time. For example, all pharmacies do not have contractual access to all medications, such as specialty medications; a pharmacy may be out of stock and unable to receive the wholesaled medication over a weekend or holiday; or a pharmacy may choose not to carry a slow moving/high cost medication in which there may be a delay in obtaining the medication. CVS suggests the following changes that will allow pharmacists to utilize professional discretion for reasons not included in this list.

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

(2) For purposes of this rule, “significant delay” does not mean any of the following, which includes but is not limited to:

(f) The pharmacist shall always use professional judgment in the dispensing of prescriptions that will not be included a significant delay.

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

The Board has offered no scientific or clinical analysis that multiple patient access points have any relevance to the pharmacist’s workload or fatigue. To the contrary, multiple access points help improve patient continuity of care. The disabled and elderly quite often use the drive through window portion of the pharmacy, while other patients prefer to walk to the pharmacy counter. In a typical pharmacy workflow, ancillary pharmacy personnel, not pharmacists, are the first contact for patients through all access points. Also, 4729:5-5-02.5(B)(b) places the pharmacist in an impossible position. The closing of any pharmacy access point clearly means that a patient’s choice on where to drop off or pick up a prescription will be interfered with. By allowing the pharmacist to close access points to pharmacy care, the Board is unnecessarily creating a patient safety and continuity of care issue. CVS believes 4729:5-5-02.5 of this proposed rule will directly affect the ability of the most vulnerable population from properly receiving the pharmacy care that they deserve and need. CVS requests this section to be stricken or drafted in a manner to account for patient continuity of care and ease of compliance.

We appreciate the opportunity to provide feedback to the Board and as always thank you for your consideration. Please contact me directly at **XXX-XXX-XXXX** if you have any questions.

Best regards,

<sup>1</sup> Antrim,Aislinn. “Despite Rapid Growth of Institutions, Pharmacy School Applications Decline”, Pharmacy Times, April 5,2023

## Mcnamee, Cameron

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**From:** [REDACTED]  
**Sent:** Wednesday, September 13, 2023 11:38 AM  
**To:** Mcnamee, Cameron  
**Subject:** FW: CVS Consumer Injury Tip  
**Attachments:** KathrynFletcher- CVS-PharmacyTimeline.pdf; HHS-ResponseLetter.pdf; BOP-Investigation-Status.jpg; Signature-Comparison-Documents.pdf; Signature-Comparison-Documents.pdf; HealthPartners Itemization and Subro Lien Info.pdf.pdf; CVS-Facebook-Messages.pdf

Kathryn Fletcher's comment for the *Minimum Standards in an Outpatient Pharmacy* rule package.

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**From:** Kathryn Fletcher [REDACTED]  
**Sent:** Wednesday, August 16, 2023 6:26 PM  
**To:** Mcnamee, Cameron <Cameron.McNamee@pharmacy.ohio.gov>  
**Cc:** CSIPublicComments <CSIPublicComments@governor.ohio.gov>  
**Subject:** CVS Consumer Injury Tip

Hello,

I'm a consumer who was harmed by an understaffed CVS Pharmacy in Minnesota. I'm currently working with my Minnesota State Senator (Heather Gustafson) to propose similar legislation to the newly proposed Ohio rules that came from the AG's investigation of CVS. The Minnesota Board of Pharmacy has an open & active investigation of CVS into my case since last year. For background, I was administered the wrong vaccine (a duplicate), hospitalized and given an initial diagnosis of Interstitial Lung Disease (which can be terminal) and is a rare condition associated with the flu vaccine. Not only did CVS ignore me when I caught the error in my medical records, their headquarters implied I was somehow at fault. I have retained an attorney, but CVS will not cover my bills, and even withheld my medical records and consent forms until investigators at HHS Headquarters threatened sanctions. I have a video of the pharmacists admitting I never signed the consent forms and that they turned all documents over to the CVS Headquarters in 2021. Despite having CVS on camera admitting I never signed the forms, CVS miraculously produced "signed" documents with a squiggle on them. Here is a link to the [video of the admission](#):

I have submitted my complaint to the Minnesota Attorney General but I wanted to make your office aware of my situation and I'm happy to provide any documentation to the Ohio BOP and the AG's office as evidence that this is a widespread issue and not isolated.

Thank you for standing up for consumers and the working conditions of pharmacy staff.

Regards,  
Kathryn Fletcher

[REDACTED]

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sent from my iPhone

**CAUTION:** This is an external email and may not be safe. If the email looks suspicious, please do not click links or open