



Rule 4729:5-5-02 - Comment Summary

Individual Responses

- 119 Individual Responses
 - 92 Support
 - 12 Oppose
 - 15 Interested Party

Organizational Responses

- Walgreens
- CVS Health
- Ohio Council of Retail Merchants
- CenterWell Pharmacy (Humana)
- Cleveland Clinic
- The Ohio State University College of Pharmacy



INDIVIDUAL RESPONSES

	A	B	C	D
1	Commenter Type (select one)		What is your position on the proposed rule?	Please submit your comments on the proposed rule. (NOTE: Rule comments are public record and respondents who wish to remain anonymous should avoid providing any identifying information).
2	Pharmacy Technician		Support	<p>We need rules in place that support our pharmacists. My company has meal breaks and this helps. We recently cut back on metrics but more needs to be done. Pharmacists are over worked and under appreciated. More important, they are severely distracted while performing their job. This should not be the norm. Would one expect a brain surgeon to be bothered during surgery? Same goes for a pharmacist. They are positioned in our pharmacy so they are visible to the public. I understand how this is beneficial for the patient, as the pharmacist is the easiest accessible healthcare professional. They are literally being watched all the time and from many angles. These dangerous drugs they are dispensing are also life saving medications. They can't afford errors and the pharmacist needs to be able to perform their duties free of distractions. Retail pharmacies should not be allowed to dictate how a pharmacist performs. Also, they should only have to answer to another pharmacist and not another management personnel who is less educated and unfamiliar with how the pharmacy business runs. More rules such as the ones proposed will only benefit pharmacists and their staff in their ability to deliver safe healthcare services. Another way to relieve some of the distractions is to explore a position such as a "Pharmacist's Assistant". Similar to a physicians assistant. This position could do more than a certified tech while under a pharmacist's supervision, just like most medical offices do now with their physicians assistant and doctors.</p>

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	A	B	C	D
				<p>The board needs to mandate the same lunch times throughout the retail pharmacies. Competing chains will want to stay open during times the other pharmacies are closed or close at an unusual lunch time especially on the weekends when staffing is limited. This will inundate certain pharmacies to perform the majority of the workload during those break hours. This is unsafe. There should be no penalty for staff closing at exactly the time posted for their lunch break. Patients line up at the windows and the drive thru knowing what time we open and close without any regard. This can also apply to staying closed longer if we're finishing up a transaction with patients past the start of a mandated lunch time. Doctors offices have set times for their lunch but their operation is mainly appointment based compared to the on-demand pharmacy workflow. The ratio of trainees and registered/certified techs need to also be re-evaluated. There needs to be a minimum and maximum numbers of techs per pharmacist like with interns. Even with the introduction of registered techs and trainees, the quality of hires has decreased significantly since Covid. This, unfortunately, applies to interns as well. The test to become registered for certain chains are not supervised. There are registered techs that are extremely limited in their knowledge of the medications and the law. Any medication error ultimately is on the pharmacist. Certain chains are still having goals to meet instead of metrics as a workaround for the quota mandate. There needs to be a defined (very expensive) monetary penalty for pharmacies trying to push the boundaries if reported to the BOP. Any time an infarction happens, it needs to be posted on the BOP homepage and on the e-newsletter.</p>
3	Pharmacist		Support	
4	Pharmacist		Support	At this ruling is the saving grace for all pharmacists.
5	Pharmacist		Support	
				<p>These minimum standards are insufficient to improve the safety and well-being of the patients and employees of outpatient pharmacies do to severe understaffing and overworking. While working at CVS the pharmacy is constantly understaffed and unsafe and I am told not to take my break to make up for it. CVS does not schedule or staff the pharmacy to give enough time to safety compete professional duties and responsibilities. CVS keeps requiring us to fill more prescriptions faster and by not meeting this requirement they have excluded me from any end of year bonus. CVS keeps circumventing safety and workload requirements to the detriment of patients and employees. These updates are much too nonspecific to improve the safety and workload of the pharmacy.</p>
6	Pharmacist		Support	
				<p>time to put a stop to immunization and MTM quota while not providing adequate help. Also could change the fact that pharmacies have 5 phone lines, 2 drive thru lanes, 2 counters and only 1 pharmacist and 1 tech working.</p>
7	Pharmacist		Support	
8	Pharmacist		Support	

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	A	B	C	D
9	Pharmacist		Support	
10	Pharmacy Technician		Support	As a current employee of CVS, I am incredibly proud of the Board of Pharmacy for standing against unnecessary quotas on ancillary services and standing up for the rights of employees to breaks. I completely support this rule and encourage it's immediate adoption.
11	Pharmacist		Support	There must be a more clear meaning/definition of proper staffing. Corporate chains cut staffing and add more workload and we are forced to do more with less. There also needs to be more definition of sufficient training and sufficient time to do our job. Most chains do not give enough time for training new staff. We are lucky if we get a couple weeks. This is not sufficient. Sufficient time is linked to proper staffing. If we were properly staffed we would have the time to do our job. The other issue is the 12 hour rule. I think that 12 hours is too long. Chain pharmacies only have 1 pharmacist on duty at a time. When you are working 12 hours there is more risk of fatigue and chances for errors. You never hear of a commercial pilot flying for 12 hours and only getting 30 minutes for a break. Truck drivers can only drive 11 hours in a 14 hour window. Why does the board of pharmacy think it is ok for 1 pharmacist to be on duty for this long? Especially with all of the ancillary services we are juggling with dispensing prescriptions. Our brains must be at full throttle the the entire time. This puts the general public at great risk. I am not sure why in this country we allow other professions to have limits and breaks, but we push our healthcare workers to the breaking point. You can review the stats on medical errors in this country. If you care about protecting the public then please make sure these rules are really what needs to be done and they are enforced.
12	Pharmacy Intern		Support	The proposed rule will allow pharmacists to provide enhanced patient-centered care by focusing on dispensing functions and building patient relationships. Stressful and unsafe staffing scenarios and metrics take away the attention of a pharmacist which allows more room for dispensing errors. This proposed rule will create a safer environment in all capacities.
13	Pharmacy Technician		Support	

INDIVIDUAL RESPONSES

	A	B	C	D
14	Pharmacist		Support	<p>The one component that was not addressed in this Workload rule is a nonretaliation clause for those that report staffing issues/concerns. Ensure this is applied to the pharmacy license, not the pharmacists: “Violation of these rules may result in administrative discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license” Perhaps it is implied but I think this should be very clear that any violation noted would be issued to the pharmacy and not the pharmacist (or PIC) as long as proof of reporting any workforce problems/concerns were reported/requested to corporate management. Below was a concern from another colleague at NeoMed. “There are a few things that stand out to me as potentially conflicting/concerning: re: Page 11, 11a vs. 11bii - I feel like there may be confusion and conflict regarding quotas related to 'counting services' vs. measuring quality, competence, performance etc and the potential for employers to circumvent this rule by noting that a specific metric is related to 11bii rather than 11a...”</p>
15	Pharmacist		Support	<p>1.)The one component that was not addressed in this Workload rule is a non retaliation clause for those that report staffing issues/concerns. 2.)Ensure this is applied to the pharmacy license, not the pharmacists: “Violation of these rules may result in administrative discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license” Perhaps it is implied but I think this should be very clear that any violation noted would be issued to the pharmacy and not the pharmacist (or PIC) as long as proof of reporting any workforce problems/concerns were reported/requested to corporate management. 3. “There are a few things that stand out to me as potentially conflicting/concerning: re: Page 11, 11a vs. 11bii - I feel like there may be confusion and conflict regarding quotas related to 'counting services' vs. measuring quality, competence, performance etc and the potential for employers to circumvent this rule by noting that a specific metric is related to 11bii rather than 11a...”</p>
16	Pharmacist		Support	
17	Pharmacist		Support	About time
18	Pharmacist		Support	<p>Pharmacists should have pharmacy school curriculum courses and continuing education requirements to learn about the veterinary drugs that they are marketing. Especially those involved in on line sales.</p>

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	A	B	C	D
19	Pharmacist		Support	<p>This rule has several aspects that are admirable in its proposed result. However, this will all be for naught because of several factors. Until and unless all pharmacists, especially in retail, are required to physically clock in/out to account for actual hours worked, the current practice of coming in earlier and staying later to catch up on the escalating workloads will continue unabated. This can be easily done, as is now with technicians required to be on the clock to get credentials. This practice skews the actual working conditions in the pharmacy and creates the impression that the staffing is commensurate to the workload, which we all know is unsustainable. (see OH State Board survey 2021). This is in large part due to the favorable (for employers) lax employment laws in the state of Ohio. No employer gets penalized for "voluntary" over-work and overtime does not need to be paid. Ever... Next whitewashed area is the retailers supposed lack of staff, which leads to shorter hours. The only penalized parties are, you guessed it, pharmacists who had hours cut, because that is the only way to cut their payroll and increase corporate profits. The workload did not change. The spin from the chains is that they cannot get enough pharmacists and technicians to work for them. That is partially correct, pharmacists and technicians are not willing to work for them, under the conditions that are imposed on the teams in the stores. There are other factors also contributing to the loss of personnel in pharmacies, mostly finding better paying jobs in other industries with less of the stress and guilt of working for an employer that does not care for your well-being and family. Until chain stores (especially) are legally forced by Pharmacy Boards and Labor Laws to change how they do business, and the scourge of PBM reimbursement is curtailed, I don't see that this well-meaning, but eventually pointless exercise will change anything at all. I have been a pharmacist for nearly 30 years, and I am truly worried for the future of our profession in the current climate.</p>
20	Pharmacy Technician		Support	
21	Pharmacy Technician		Support	

INDIVIDUAL RESPONSES

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22	Pharmacist		Support	<p>I support this ruling hands down and feel as if it should have been implemented a year or two ago! The stress in the workplace has escalated immensely since covid and I am grateful that our state board is now taking steps to minimize that. It will be great to see the quotas taken away as that is drilled into us daily on how many shots are expected of us and if we don't make our quotawhy?? There are so many distractions that go on in an outpatient pharmacy between being pulled every which way; answering patients questions, giving vaccines, taking doctor calls, recommending OTCs, counseling customers, etc. besides trying to fill prescriptions, that it can be very hard to concentrate! Our staffing is based on the number of prescriptions we fill and I feel as if that is not always accurate and on the days that we may have someone call off, it is VERY challenging to try to work around that. If, in the event we make an error, we are never allowed to use distractions, illness, short staffing, etc as an excuse and we all know that we ARE human and all those should come into consideration! Way to go state board for backing up our profession and bringing pharmacy back to what it should be!</p>
23	Pharmacist		Support	<p>I have been a retail pharmacist for over 30 years. I work for a large chain. My chain does allow a 30 minute lunch break and two 15 minute breaks during my 10 to 11 hour shifts. However, due to the high volume no one ever takes the 15 minute breaks. On weekends there is only one pharmacist on duty making the 15 minute breaks virtually impossible. Stools or chairs need to be provided in the pharmacy so that the pharmacist that is standing long hours can occasionally get off of their feet. Physical fatigue and pain is a real distraction! We have had district managers remove stools from the pharmacy saying that they are not necessary. We are down to one stool for a staff of 8 people on weekdays and 4 to 5 people on weekends. Our regional manager actually asked if we really needed the last stool! I said yes as the techs place drug totes on it as they process the drug order. (They really do.) Retail pharmacy is the only healthcare setting where the healthcare professionals are unable to sit. Where did this crazy idea that retail pharmacists must stand the entire day come from? I have read that California requires stools for their pharmacists. It seems like a small request to prevent the distraction of fatigue and pain from standing long hours. I would probably pick up more shifts if I weren't so physically exhausted from standing all day! (Even the chains should support that idea)</p>

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				<p>My interpretation of this proposal is basically an attempt to give (or appear to give) the RPh working in the retail pharmacy more power or say in what goes on in that pharmacy. I'm conflicted because I really feel like the RPh should have always been in control and these companies have just gone too far in walking all over OUR profession through their interpretation of the laws. I personally have washed my hands of most responsibility in my pharmacy over the last decade because of my eroding control over operations. These companies only care about profits and shareholders and have increasingly treated the RPh's as the "body with the license". How can we be held responsible for anything while being forced to operate in situations we know are ridiculously unsafe? It created a standard where the RPh no longer prioritizes the PATIENT due to being over burdened with stats, metrics & other things which in turn don't get the time they deserve (if they ever deserved any) because there just isn't enough hours in the day (or in our case, minutes in an hour). We all have to work to feed our families. Our employers SHOULD BE falling all over themselves to remove tasks and distractions, not think up new and creative things that they can force us to do just because they've "already got us there". This proposal is a nice step in the right direction, but it's really sad that it took so many RPh's to flee retail for good and thousands of pleas for help to the board. I do understand that healthcare is a "business" and this country needs to change many things regarding its approach to health, but someone NEEDS to actually care about patients health at some point in this system (actually, several points). I'm sorry if that means less increase in profits year over year. Maybe it's time we don't see(th) dollars in peoples illnesses?</p>
24	Pharmacist		Support	
25	Pharmacist		Support	
26	Pharmacy Intern		Support	
27	Pharmacist		Support	We can no longer give vaccines all day long and safely fill prescriptions. Flu vaccines need to be done thru flu clinics like they used to be.
28	Pharmacy Technician		Support	
29	Pharmacy Technician		Support	
30	Pharmacist		Support	<p>My concern is that (C)(1)(b) will be used as a loophole. I have worked in pharmacies where there were two pharmacists working and even though company policy said that we could take 30 minute breaks with the other pharmacist covering, we couldn't realistically take those breaks and continue to keep the pharmacy running. If I stepped out for 30 minutes, I would come back to a pharmacy that was backed up with prescriptions, vaccines, patient phone calls, etc. If a high volume pharmacy doesn't have to close, the pharmacists won't actually take the breaks they need.</p>

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31	Pharmacist		Support	Reducing the use of quotas and the use of meal breaks are vital to keep pharmacy more alive during all of this mess. We have pharmacies where the pharmacist is either alone or with only one technician and that's unacceptable. Meal breaks are necessary to keep burn out down. What really needs to be done is something for pharmacy to use to legally block certain people in the population from harassing pharmacy staff and allowing pharmacists to legally tell a patient to not come back if they are being a real threat to the pharmacy team operation in an outpatient setting. Will the rule lower pharmacy profit? Most likely so the state has to account for that; we are tired of the burn out. Tired of the work shortages. Tired of the stress. And most of us are tired of the general population acting like spoiled brats. We don't go into their workplaces and yell at them; why should they do the same to us?
32	Other (please specify)	Pharmacy operations manager	Support	Post pandemic has seen a decrease in immunization appointments and an increase in prescription. Despite the growing work load, corporate continues to cut hours limiting the number of technicians that can be scheduled. This is causing further burnout with most days only having one technician opening. The environment of the pharmacy is also a struggle as during the summer we have to bring in 2 dehumidifiers to keep the humidity percentage below 80%. These are brought in by staff and not provided by the company. There are several other issues. Metrics technically aren't used for performance, yet goals for other things (such as immunizations) continue to be set and are expected to be met. We are being told filling prescriptions isn't a priority and that patients should wait so that we can make even more phone calls than in the past. The list goes on. There aren't real changes at all. It is still overworking employees with unrealistic expectations.
33	Pharmacist		Support	These rules are too vague. Any rule that allows for this much interpretation will fall on deaf ears. Our corporate overlords have no idea how much work is involved in ancillary services. Our RPhs are forced to work 10 or 12 hour shifts. While we're "given" a single 30-minute break during a 12 hour shift... our quotas basically require us to work through those breaks. Side bar: 12 hour shifts should merit TWO 30-minute breaks. Please protect our profession. Please provide specific requirements.
34	Pharmacist		Support	It appears that the rule is leaving most decisions to the pharmacist on duty, which is great. I would like to know exactly how the board will not allow "recourse" to a pharmacist that does report possible violations to the rule. Also will there be any type of template as to how many pharmacists/tech hours are required as a minimum according to the volume of scripts filled.
35	Pharmacist		Support	

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	A	B	C	D
36	Pharmacist		Support	I am very supportive of requirements for minimum staffing. The proposed rule is needed to ensure patient safety and prevent pharmacist fatigue. I would like to see a more defined metrics or more robust guidelines for justifying what will be considered adequate staffing. As worded, the proposed rule is too vague. I suggest defining volume thresholds triggering additional pharmacist and technician staffing with consideration for prescription volume limiting the duration of a shift as well.
37	Pharmacist		Support	It could be added if any RPh or techs with current license must practice biweekly to keep their license in good standing. This would help the supervisors of the organization learn and understand the daily work flow of the pharmacy.
38	Pharmacist		Support	If there are not CLEARLY DEFINED guidelines then nothing is going to change. To say that we need "sufficient personnel" means nothing, Who defines sufficient? Corporations that do NOT work in the pharmacy and May not even be pharmacist. As long as a Pharmacist in the building to open the pharmacy we will continue to run short staffed or with no staff and we will continue to jeopardize our mental well-being as well as our patients safety. Running a pharmacy with one pharmacist and one technician is NOT safe and not practical: when there is a drive through, an out window, and in window, phones ringing, and prescriptions to actually fill. That does not include any additional services or the 50 phone calls we make a day. Updating a rule with vague terms, such as "adequate time to complete tasks" and "sufficient personnel" are both decisions that will not be made by the pharmacist or even at the store level, but by a corporation who is for Profit NOT patient safety or well-being of the staff.
39	Pharmacist		Support	Whistleblower protections should be included for non-compliance reporting. Bonuses involving quotas that are "optional" should be considered by the board of pharmacy as potential abuses of the system by corporations. I can see a world where a large chain pharmacy says "these metrics are optional, the bonuses you get are optional", but then business practice involves meetings and conference calls and intimidation by district leaders insisting we meet the optional quotas.
40	Pharmacist		Support	The new rules proposed are a step in the right direction. I appreciate the boards efforts in this manner. I worry that submitting a staffing request to the board would still create repercussions from the employer despite the rule. Maybe consider Californias pharmacist staffing rules where the pharmacist is required to have a ratio of 2:1 techs per pharmacist and the pharmacist cannot work alone.
41	Pharmacist		Support	I don't think this goes far enough. There should be 2 - 15 minute breaks and a 30 minute lunch for 8 hours worked at a minimum.
42	Pharmacy Technician		Support	I hope this can help Us all however CVS has always found a way around restrictions.

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	A	B	C	D
43	Pharmacist		Support	People call off for various legitimate reasons- got sick, child got sick, baby sitter called off- that you may not be able to work around. What happens next? You can't always find a substitute. It is stressful working short staffed.
44	Pharmacist		Support	I feel that requiring so many immunizations in a specified time period has a negative impact on taking care of patients prescription needs on a daily basis. If you have the time to push them then fine....if not it is a burden and added stress.
45	Pharmacist		Support	
46	Pharmacist		Support	
47	Pharmacist		Support	I believe that what you all are attempting to do is wonderful. To make the job of being a pharmacist more enjoyable and safer. My only fear with the quota rule is how are the chains going to work around that, to continue to tighten the noose & make us feel as though we are not doing enough. Constant call lists, monster vaccination goals etc. How will they work around this rule. That is my only concern. Otherwise I feel it will improve the life of an RPh.
48	Pharmacy Technician		Support	Too little too late and not enough teeth. The industry has been gutted by your lackadaisical inability to advocate for its professional base.
49	Pharmacist		Support	WE NEED AN HOUR BREAK!!!!
50	Pharmacist		Support	
51	Pharmacist		Support	Overall support. However, a standard for the pharmacy should also include a stool or chair for the pharmacist and technicians to sit whenever standing is not necessary to perform a task. In addition, "sufficient staffing" needs to be defined. It's too vague.
52	Pharmacist		Support	As a pharmacist that gets emails and text messages regarding quotas of immunizations almost daily, I fully support this proposed rule to reduce stress and ensure safe prescription filling standards.
53	Pharmacist		Support	I would like to have it written that these rules will apply to ALL pharmacists - hourly, salary, salary-exempt.
54	Pharmacist		Support	Always feel understaffed. I work hard to take care of people.
55	Pharmacist		Support	

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				<p>I'm a huge supporter of this rule, however there are some sections that I feel could use some tightening up. 1.Paragraph B(1) says that pharmacies shall "Ensure sufficient personnel are scheduled..." How do we determine what sufficient staffing is? Alternatively, how can one show that the pharmacy's current staffing is insufficient? Staffing has probably been the #1 concern amongst outpatient pharmacy workers. The definition of sufficient staffing or who determines this definition (pharmacists who work at each particular location, perhaps?) should be clarified. 2.Section B(10) states that pharmacies shall "Provide adequate time for a pharmacist to..." (give shots, do DURs, counsel, etc). Again, what is 'adequate time'? or, who decides what 'adequate time' should be for each professional duty? Perhaps this should also be determined by the pharmacists at each individual site, adopted as policy in writing, and be subject to change only by consensus of acting pharmacists-on-duty at the individual site? 3. Section B(12) says that pharmacies shall "allow at least eight hours of off time between consecutive shifts" for employees. This isn't enough time. This requirement should be changed to at least 10 hours. Eight hours is how much sleep you need, not how much time you need to get home, eat, sleep, wake up, get ready, and get back to your worksite. C'mon. 4. Section D (1st paragraph) says that a pharmacy shall "not override the control of the pharmacist on duty regarding aspects of the practice of pharmacy..." etc. The definition of "Pharmacist on Duty" should be clarified. If District Leaders/Managers/etc. could fit this definition by legal argument, then this part of the rule could become useless, since it is often from District Leaders that these unreasonable demands come. The rest of the rule looks great, although I'm sure others will find different things that could use improvement. This will be a huge step forward to taking our profession back from Capitalist entities that have no interest in the well being of their employees or the patients they serve. Thank you for putting this in motion, sad though it is that it needs to be done at all.</p>
56	Pharmacist		Support	
57	Pharmacist		Support	
58	Pharmacy Technician		Support	<p>My pharmacists work 12hr shifts, without breaks, for 6/7 days a week; sometimes 7/7, every other week. I don't know how they do it without making mistakes, and having to be responsible for any mistakes the techs may make. I think a break during the 12hrs would help to refresh our pharmacists and relieve at least some of the stress of being so busy, while having to double check everything we do, and having peoples' lives at stake if they would miss something wrong.</p>
59	Pharmacist		Support	<p>I think you can support community pharmacists even more, but this is a good first step. I think a rule could be made for adequate staffing in terms of pharmacy technicians.</p>

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60	Pharmacist		Support	Rest breaks are necessary for pharmacists to have a mental break and for health of the employees. We deserve a chance to eat a snack/lunch and use the restroom without being interrupted multiple times. Safety issues become apparent during those interruptions. Quotas are also dangerous when numbers are the only thing important to a corporation. We are supposed to care about our patients and they are supposed to be more than just a number.
61	Pharmacist		Support	Thank you, thank you for these rule changes. I cannot tell you how many times in the past two years I would try to juggle everything corporate wanted me to do without enough staff, and spend the rest of my night just praying I had not made a medication error in all the chaos. Or alternatively I would take steps to keep the pharmacy more manageable (take less vaccines or close drive through, etc) and spend the night praying I would not be fired. These rules I feel will be very beneficial for patient safety and the mental health of pharmacy staff. The only concern I have is for the situation where, at a chain pharmacy "with twelve or more" Ohio pharmacists, there are normally two pharmacists working overlapping shifts and for whatever reason (sickness most often), one pharmacist works alone their entire shift or even the entire day. This is a situation that does happen every now and then, and it is unclear how the pharmacist/ pharmacy would take their break in that situation since it was not planned or originally scheduled. Based on the rules as written, the pharmacy would have to close for the break I believe, but it is a bit unclear.
62	Pharmacy Technician		Support	It is better for patient safety, if we are less fatigued, and re-energized.
63	Pharmacist		Support	
64	Pharmacist		Support	It is not clear if these rules apply to pharmacists or other licensed staff at a medical marijuana dispensary. I think that they should.
65	Pharmacist		Support	We are overworked and patient safety is definitely affected. We waste more time on soliciting immunizations, dealing with phone calls and emails about immunizations, even conference calls if we don't do enough (quota). It's overwhelming and frustrating. I don't mind doing immunizations and I'm glad I can help keep the community safe from disease, but it's too much of a focus, especially when the majority of us are trying to run on either a short staff or a young staff that has yet to complete their tech training. And more and more keeps being thrown at us...more paperwork, more surveys, more people to call (because we are supposed to call or message to get them in for shots too). It's all about profit, not care. Please help us, I used to enjoy this job. It's all about money and nothing about service.

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66	Pharmacy Technician		Support	our companies main focus is shots currently. instead of focusing on pts and their meds being filled efficiently, we have to field calls from corporate about how many shots and what kinds because 'not all types count'? so protection is not the main goal like they claim :) unfair to the workers and our customers
67	Pharmacist		Support	
68	Pharmacist		Support	
69	Pharmacist		Support	Regarding page 9 paragraph b 1,2: the use of the word sufficient is far too vague to benefit anyone with the possible exception of the employer. Who is to decide what is a sufficient amount of help or sufficient tech hours to protect the pharmacist and the clients from mistakes or overwork? If the employer is to decide what is sufficient, they will surely base the decision on money and not real world situation. This will be the exact opposite of what would be helpful to the pharmacy environment. Realistic guidelines must be set out to define the use of the word sufficient in order to curtail the employer taking advantage of their right to define the word 'sufficient' in any way they see fit
70	Pharmacist		Support	
71	Pharmacist		Support	Regarding the 12 hr maximum shift: can an outpatient pharmacy require a pharmacist to work more than 12 hrs using the 1/2 hour meal break as a reasoning that the pharmacist is not working 12 consecutive hours? I've heard some managers made that claim. The text should state explicitly the maximum shift is 12 hours including the meal break. Also with regards to staffing: the pharmacist on duty should have more flexibility in determining staffing rather than an outpatient pharmacy fixing the amount of tech hours they can use.
72	Pharmacist		Support	Overall I am support of the proposed rule, but I have many reservations about rules that call out differences based on the number of outpatient pharmacy locations. Why can't all of these pharmacists be treated the same? What is special about 11 locations (section C2)? I will also be interested to see how some of these judgement rules can be enforced as pharmacists have different levels of performance and comfort - how will the board decide if there is an infraction?
73	Pharmacy Technician		Support	Proper staffing at pharmacies is absolutely critical to prioritize patient safety, deliver exceptional quality of service, and manage therapy and medication effectively. Insufficient staffing can lead to errors, delays, and negative patient outcomes. By investing in adequate staffing levels, pharmacies can not only improve patient safety and outcomes, but also enhance their reputation as a trusted and reliable healthcare provider. So, let us prioritize proper staffing to ensure the best possible care for patients.

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	A	B	C	D
74	Pharmacist		Support	While this rule is long overdue, it is such a huge win for our profession. This is placing professional judgement back into the hands of those working on the front lines and is the first rule of this kind I have seen in my 20+ year pharmacy career. Big chain organizations have literally destroyed so many pharmacists, to a point that many discourage the next generation from entering the profession. I'm so proud of all of those that have put the time in to develop this rule. Maybe pharmacists will become the most trusted professionals again.
75	Pharmacist		Support	The "sufficient staffing" is ambiguous. As former Ohio BOP Inspector George Pavlich told me back in 2009, what 1 person finds sufficient someone else may find insufficient and your company can fire you for not keeping up with what the company fees is enough help, not the individual pharmacist. This vague language changes nothing. Large chains will argue they provide enough payroll for everything even when I feel they don't. This rule doesn't provide any good support for staffing levels. We need direct laws that are direct on tech ratios and rxs per hour.
76	Pharmacist		Support	It should be unlawful for a pharmacist to work an entire shift alone without at least one technician to support the volume of prescriptions and distractions. It should be the pharmacist's responsibility to close the pharmacy provided there is another location within the same chain open or other pharmacies open to serve patients.
77	Pharmacy Technician		Support	
78	Pharmacist		Support	I do not think this law is specific enough. I am happy that the BOP is finally stepping in to do some preservation for the field of pharmacy, but fear this is not going to be enough. This law specifies 'outpatient pharmacy/distributer of drugs' when many pharmacist work behind the scenes for these major retail chain pharmacies and aren't considered 'outpatient/distributors of drugs,' but rather central pharmacies or remote off site locations designed to off load much of the burden these customer facing 'outpatient pharmacies' have endured for years. We all know that the field is changing and retail/outpatient pharmacies have cut hours and stores are closing because technology and the field are shifting to mail order/remote work. While not discrediting what this law will do for outpatient pharmacies, let's not forget where much of the workload is being designed to go. These central pharmacies are the ones being pushed to do well over 800 prescriptions in a single shift and this law will do nothing to ensure they are receiving mandatory breaks, lunches, or putting patient safety first. There are often no 'ancillary' job functions for these employees, but their sole job is one giant quota of how many prescriptions can you do in SECONDS. This law feels like a bandaid to a shifting problem to temporarily keep peace.
79	Pharmacist		Support	

INDIVIDUAL RESPONSES

	A	B	C	D
80	Pharmacy Technician		Support	This does nothing to help independent pharmacies. We don't get breaks either. We are told that we aren't allowed to take breaks and to eat on the job which isn't sanitary.
81	Pharmacy Technician		Support	"Scheduling conflicts" is too vague of language. Pharmacies will need clear language on minimum staffing requirements in order to remain compliant. Hours are currently being cut on how long pharmacies are open, as well as from available technician support. Stores are being closed, leading to increased demand at remaining pharmacies.
82	Pharmacy Technician		Support	Mandatory breaks are a good start but there is no reason to be open a full 12 hours. The 30 minute lunch break isn't really enough time to fully eat and rest. Upon opening back up we usually get bombarded with angry people. Pick up counter and drive through typically have several people waiting, while the phone lines are ringing off the hook. Retail pharmacy is causing people to quit with all the demands placed on staff.
83	Pharmacist		Support	Maybe address unhealthy working conditions. For example, many stores require standing only for work. No sitting. It's bad for your body and also for morale to work in pain. There is no reason we shouldn't be able to rest our body as long as the work doesn't suffer (and it doesn't) Aldi cashiers get to sit and they are also paid more than most techs in this state. I've never heard a complaint about it. So why aren't we, professionals, allowed to be comfortable and human?
84	Pharmacy Technician		Support	
85	Pharmacist		Support	
86	Pharmacy Technician		Support	
87	Pharmacist		Support	Quotas take away from being able to properly perform the standard functions of a pharmacist by forcing the pharmacists to rush through the filling process in order to make cold calls to meet said quotas
88	Pharmacist		Support	
89	Pharmacist		Support	This is way overdue. Thank you
90	Pharmacist		Support	
91	Pharmacist		Support	I fully support this rule and appreciate the long overdue help from the BOP to help us make sure we are practicing safely.

INDIVIDUAL RESPONSES

	A	B	C	D
92	Pharmacist		Support	<p>I am a licensed pharmacist in the State of Ohio, license 02322517. Overall, the new rule changes are a very welcome action by the Board; please do not allow large chain retailers to soften the impact of these new changes.</p> <p>Specifically related to rule 11 "Not establish any productivity or production quotas relating to the provision of ancillary services..." there needs to be specific language preventing such quotas or ancillary services from being used to affect pharmacy staff compensation, whether base pay, yearly performance raises, or bonus/incentive calculation. This strikes at the heart of what the board is trying to do to prevent these kinds of ancillary services from directly affecting patient access to medication and preventing staff fatigue/reducing medication errors.</p>
93	Pharmacy Technician		Support	
94	Pharmacist		Oppose	<p>This rule is weak sauce and does not go far enough. there should be limits to the number of prescriptions a pharmacist can fill in a day and also the number of technicians provided should be regulated as well. Many pharmacists work without enough staff and are expected to verify 50 or more prescriptions an hour. This is unsafe</p>
95	Pharmacist		Oppose	<p>The ambiguity of these rules is further proof of how toothless the board of pharmacy truly is. This benefits neither pharmacist nor patients and shows the priorities of the board lie with keeping the cooperations happy.</p>

INDIVIDUAL RESPONSES

	A	B	C	D
96	Pharmacist		Oppose	<p>I would move to strike section 11. It is not reasonable for the state board of pharmacy to incorporate into the administrative code the inability for the employer to establish productivity metrics for staff. "Ancillary services" are those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs as set forth in this chapter of the Revised Code. Examples of such services include, but are not limited to, immunizations, medication therapy management, disease state management, and refill reminders. There are some pharmacy staff members whose sole job is ancillary task work. By reading the rule, any productivity metrics for these caregivers would be forbidden. (11) Not establish any productivity or production quotas relating to the provision of ancillary services; (a) 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. (b) For purposes of this rule, "quota" does not mean any of the following: (i) 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. (ii) 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. (iii) Any performance metric required by state or federal regulators. William Kupka, PharmD</p>
97	Pharmacist		Oppose	<p>The threshold for Rule 13 C should be raised from 12. We have low enough volume to have lunch breaks already while supervising technicians but would not be able to due to being above the threshold of being owned by a company with 12 or more stores. This arbitrary number should be increased or allow both 13-C-1 and 13-C-2 the option to not close but to allow pharmacy personnel to continue to perform tasks while the pharmacist is in the pharmacy. Closing for 30 minutes would have an unnecessary and negative impact on our business.</p>
98	Pharmacist		Oppose	<p>"The Board did not include a prohibition on quotas related to the volume of prescriptions dispensed" By not doing so, the Board is allowing detrimental activities to continue as chain pharmacies abuse staffing levels and require herculean volume metrics out of their pharmacists. Most chains have designed their systems to make cuts to staffing to "become more efficient" when those cuts simply become unfeasible. The boards lack of ruling undermines the entire effort.</p>
99	Pharmacist		Oppose	<p>I oppose the portion of the proposed rule that limits a pharmacist to only working a twelve-hour shift. Many of us are accustomed to working a thirteen-hour shift and see no need to implement this change. It should be left up to the pharmacist to decide if they are comfortable working a long shift or not. Putting a cap on working hours will further restrict public access to pharmacies.</p>

INDIVIDUAL RESPONSES

	A	B	C	D
100	Pharmacist		Oppose	<p>If this rule is to establish the minimum standards for both occupational and public safety, can you clarify why number of sites has bearing on the standards? An outpatient pharmacy is an outpatient pharmacy to the pharmacist working within and especially to the patient obtaining care from the pharmacy. What evidence shows that an independent outpatient pharmacy is inherently safe and thus should be exempt from certain standards? Minimum standards, if necessary to preserve occupational and public safety, should be equitable. Please clarify in the rule language that data and discussions of data are not quotas. Businesses of all types and medical practices of all types rely on data to ensure quality patient care and drive continual quality improvement. The rule is not clear that data regarding immunizations and other clinical services are able to be discussed without being at risk for perception as a quota. Lastly, if such prohibition on quotas is deemed necessary, may the board share what evidence was used that shows both occupational and public safety benefit?</p>
101	Pharmacist		Oppose	<p>All the proposed rules must also be applied to inpatient/hospital pharmacies as well.</p>
102	Pharmacist		Oppose	<p>-This is a step in the right direction but the wording needs updated. Why is the focus on outpatient only? Strike that word and change to "pharmacies" in general. Idk what lobbying the institutions did but that's odd considering the safety and burnout was high for that setting too. -Why is the definition of independent pharmacies 11 or less owned stores? That's a lot of businesses. Independent pharmacies should be 1 max. Any more and you should NOT be exempt from this rule as described in the rule. Also what's to stop the big chains from creating shell corporations of 10 pharmacies each to avoid being labeled as a "chain"? -Define what "adequate staffing" means. Otherwise it will be left much up to interpretation and too subjective. The more subjectivity, the higher likelihood that the big chains and big hospital systems will use legal loopholes to skirt the rules. -I am disappointed that this doesn't prohibit the use of quotas on prescription volume. Without addressing this issue, I'm sorry to say that this bill and countless hours of a multi-year task force funded by taxpayers will have been wasted on a half measure. We aren't asking that you limit how many prescriptions a pharmacy can dispense but rather prohibit them from enacting quotas for that task. That is one of the largest sources of abuse in retail pharmacy; management will continue to set unrealistic quotas for prescription volume for techs and pharmacists. There shouldn't be a quota on safety related items. The aspects of quotas and safety cannot coexist without explicit measurable definitions on their meanings and restrictions. The survey is a scathing report on the status of pharmacy work environments and this bill largely falls short of fixing the real problems. Have you noticed Walgreens not being able to hire pharmacists even with a 75k sign on bonus lol? That says a lot. There isn't a shortage of pharmacists. There's a shortage of pharmacists willing to work in bad work environments.</p>

INDIVIDUAL RESPONSES

	A	B	C	D
103	Pharmacy Technician		Oppose	<p>I believe that ancillary pharmacy service quotas are unnecessary and do not contribute to better patient care. However, I do not believe that regulating ancillary pharmacy service quotas is the answer. Instead, the Board should consider delegating responsibilities to Certified Pharmacy Technicians (CPhTs), who are capable of providing a wide range of services. CPhTs have proven themselves to be invaluable members of the healthcare team, particularly during the COVID-19 pandemic, where they played a critical role in administering vaccines. With additional training, CPhTs could perform tech-check-tech on non-controlled refills, freeing up pharmacists to spend more time on data review and patient care. This would help to alleviate the workload of pharmacists, reducing the likelihood of burnout and turnover and ultimately improving patient care. Unfortunately, I believe that the Ohio Pharmacists Association's negative view of pharmacy technicians is preventing pharmacists from receiving the relief they need. The Association's demeaning attitude towards pharmacy technicians has led to a lack of investment in technician training and development, preventing them from performing more advanced tasks and contributing more fully to patient care. This lack of investment has also contributed to high turnover rates among technicians, further exacerbating pharmacist workload.</p>
104	Pharmacy Technician		Oppose	<p>As a pharmacy technician, I strongly believe that decisions regarding my lunch breaks should be made between me and my employer, rather than being mandated by the State Board of Pharmacy. While I appreciate the Board's concern for the wellbeing of pharmacy personnel, I feel that this regulation is an unnecessary intrusion into the daily operations of pharmacies. As a professional in the field, I am well aware of the importance of taking breaks and staying properly nourished and hydrated during a long workday. However, I also understand that every pharmacy operates differently, and what may work for one may not work for another. It is crucial that the decision on when and how long to take lunch breaks is made on a case-by-case basis between the employer and the employee. Additionally, I believe that imposing such regulations on lunch breaks will only create additional administrative burdens for both the Board and the pharmacies. Compliance with this regulation may require additional paperwork and tracking of break times, which could ultimately take away from the time that could be spent on patient care.</p>
105	Pharmacist		Oppose	<p>Rule #5: Maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered by the pharmacy It is nearly impossible with the current manufacture's shortages. How am I to maintain an adequate stock of medications that are on national back-order?</p>

INDIVIDUAL RESPONSES

	A	B	C	D
				<p>As a pharmacist who has had experience with scheduling technician help according to a company algorithm that calculates payroll demand, a situation that concerns me the most that is not adequately addressed by the proposed rule is when a chain pharmacy deems that a single pharmacist on duty is sufficient to maintain pharmacy operations during certain times of the workday. Not only is it important to ensure enough staff is scheduled to ensure a high level of patient safety while the pharmacist performs their clinical duties, but it is also important to consider the safety of the employees themselves. Over the past 6 years working as a technician, then intern, then pharmacist, I have witnessed pharmacies being targets of drug diversion as well as violent crime. Thankfully, no such incident ever happened to me while I was alone, however, there have been plenty of instances where I or another pharmacist had to be scheduled to work by themselves at night due to payroll hours needing allotted during the busiest times of the day to ensure operational standards are being met. The majority of the pharmacies that I have worked in require me to turn my back from the pharmacy counter to, for example, tend to the drive-thru. Every time that I needed to tend to the drive-thru window while working by myself was an opportunity for a potential armed robber to jump the counter and steal controlled substances from the shelves. Furthermore, I was unable to walk customers toward certain OTC products or take a quick bathroom break unless an employee from a different department was willing to guard the counter while I was gone. To ensure that both patient and pharmacy personnel safety standards are met, I would be willing to change my position on the proposed rule from "interested" to "support" if a provision is added that ensured that an outpatient pharmacist would not be required to work alone. There has been a precedent established for such a provision. In 2018, the California state legislature and governor approved SB 1442, which ensures that except for certain stipulations a community pharmacy "shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times." A provision such as this would further enable pharmacists to provide a higher level of customer service and care while mitigating certain safety risks to pharmacies and the personnel staffing them.</p>
106	Pharmacist		Interested Party	
107	Pharmacist		Interested Party	<p>It's a great initiative! This would definitely add respect and dignity to the profession and make it a safer work environment for the pharmacy worker as well as patient. However I wish this break was paid for... that is it should be a paid break.</p>
108	Pharmacist		Interested Party	<p>It still seems that companies will be able to say you must do x number of vaccines (or whatever) to receive a positive designation on a yearly review.</p>

INDIVIDUAL RESPONSES

	A	B	C	D
109	Pharmacy Technician		Interested Party	
110	Pharmacist		Interested Party	This comment is related to improving the pharmacist's workflow in a retail setting: Refills should be able to be checked and approved by 2 Certified Pharmacy Technicians. The benefits to this would be many. Thank you for your consideration.
111	Pharmacist		Interested Party	My question would be how would immunizations then be handled? Currently pharmacists are running in and out of pharmacy at the demand of all types of immunizations that can be scheduled or walk in appointments. Pulling pharmacist from their main role of dispensing. Would there be designated immunization times with dedicated staff to only immunize?
112	Pharmacist		Interested Party	The one part I don't like is limiting the hours to 12 . I like the 13 hours as that gives time to catch up early in the morning from 8 to 9 am before patients starts to pick up more at 9 am. The last couple hours in the evening gives the team time to finish what is due and restock and clean. Plus do all the outdated and other inventory management. Some chains lowered their opening hours but the team still have to do everything in shorter amount of time so it's more stressful.
113	Pharmacist		Interested Party	
114	Pharmacist		Interested Party	Max days in a row that are required to be worked with the option of volunteering for additional days
115	Pharmacist		Interested Party	The use of the word "sufficient" in both B(1) and (2) is too vague in my opinion. Leaves too much room for the chains to make their own definition of "sufficient" which they have proven incapable of doing. More clarity/spelled out minimums/etc is needed in these areas or the whole issue of staffing might as well not be addressed at all.
116	Pharmacist		Interested Party	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 staff during working hours. How will the BOARD ensure a reporting pharmacist concerns are addressed and penalties for employer retaliation for reporting a violation?
117	Other (please specify)	Sr Vice President of Pharmacy with RPh credentials	Interested Party	This looks great, however, letting a pharmacist volunteer for more than 12hours seems like a poor idea. Unless this can just be left out and assumed, it will be taken advantage of by employers and the pharmacist will continue to be placed in a position of danger.

INDIVIDUAL RESPONSES

	A	B	C	D
118	Pharmacist		Interested Party	<p>This rule has several aspects that are admirable in its proposed result. However, this will all be for naught because of several factors.</p> <p>Until and unless all pharmacists, especially in retail, are required to physically clock in/out to account for actual hours worked, the current practice of coming in earlier and staying later to catch up on the escalating workloads will continue unabated. This can be easily done, as is now with technicians required to be on the clock to get credentials. This practice skews the actual working conditions in the pharmacy and creates the impression that the staffing is commensurate to the workload, which we all know is unsustainable. (see OH State Board survey 2021).</p> <p>This is in large part due to the favorable (for employers) lax employment laws in the state of Ohio. No employer gets penalized for "voluntary" over-work and overtime does not need to be paid. Ever... Next whitewashed area is the retailers supposed lack of staff, which leads to shorter hours. The only penalized parties are, you guessed it, pharmacists who had hours cut, because that is the only way to cut their payroll and increase corporate profits. The workload did not change. The spin from the chains is that they cannot get enough pharmacists and technicians to work for them. That is partially correct, pharmacists and technicians are not willing to work for them, under the conditions that are imposed on the teams in the stores.</p> <p>There are other factors also contributing to the loss of personnel in pharmacies, mostly finding better paying jobs in other industries with less of the stress and guilt of working for an employer that does not care for your well-being and family.</p> <p>Until chain stores (especially) are legally forced by Pharmacy Boards and Labor Laws to change how they do business, and the scourge of PBM reimbursement is curtailed, I don't see that this well-meaning, but eventually pointless exercise will change anything at all.</p> <p>I have been a pharmacist for nearly 30 years, and I am truly worried for the future of our profession in the current climate.</p>

INDIVIDUAL RESPONSES

	A	B	C	D
119	Pharmacist		Interested Party	<p>This rule has several aspects that are admirable in its proposed result. However, this will all be for naught because of several factors. Until and unless all pharmacists, especially in retail, are required to physically clock in/out to account for actual hours worked, the current practice of coming in earlier and staying later to catch up on the escalating workloads will continue unabated. This can be easily done, as is now with technicians required to be on the clock to get credentials. This practice skews the actual working conditions in the pharmacy and creates the impression that the staffing is commensurate to the workload, which we all know is unsustainable. (see OH State Board survey 2021).</p> <p>This is in large part due to the favorable (for employers) lax employment laws in the state of Ohio. No employer gets penalized for "voluntary" over-work and overtime does not need to be paid. Ever... Next whitewashed area is the retailers supposed lack of staff, which leads to shorter hours. The only penalized parties are, you guessed it, pharmacists who had hours cut, because that is the only way to cut their payroll and increase corporate profits. The workload did not change. The spin from the chains is that they cannot get enough pharmacists and technicians to work for them. That is partially correct, pharmacists and technicians are not willing to work for them, under the conditions that are imposed on the teams in the stores.</p> <p>There are other factors also contributing to the loss of personnel in pharmacies, mostly finding better paying jobs in other industries with less of the stress and guilt of working for an employer that does not care for your well-being and family.</p> <p>Until chain stores (especially) are legally forced by Pharmacy Boards and Labor Laws to change how they do business, and the scourge of PBM reimbursement is curtailed, I don't see that this well-meaning, but eventually pointless exercise will change anything at all.</p> <p>I have been a pharmacist for nearly 30 years, and I am truly worried for the future of our profession in the current climate.</p>

INDIVIDUAL RESPONSES

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

(A) As used in this rule,

(1) “Pharmacy personnel” means any of the following who are licensed or registered in accordance with Chapter 4729, of the Revised Code:

(a) Pharmacist;

(b) Pharmacy intern;

(c) Certified pharmacy technician;

(d) Registered pharmacy technician;

(e) Pharmacy technician trainee.

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

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

(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 staff during working hours. An employee of a pharmacy shall be identified by a name tag that includes the employee's job title.

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

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

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

(i) The board's website (www.pharmacy.ohio.gov);

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

Commented [DK1]: Are these individuals licensed or registered?

Commented [DK2]: There are a number of these subjective terms used - will be interesting to see how various companies decide to interpret them.

Commented [DK3]: This really doesn't fit here - suggest eliminating or creating a separate section.

Commented [DK4]: These are 2 distinct issues - need to be separated with each having their own description. Most of this info here pertains to the tools and equipment issue.

Commented [DK5]: See above comment re this term

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

(iv) The code of federal regulations.

(b) References necessary to conduct a pharmacy in a manner that is in the best interests of the patients served; and to comply with all state and federal laws, this shall include hard copy or internet access to appropriate pharmacy reference materials.

(c) The telephone number of a poison control center.

(4) Ensure staff are sufficiently trained to safely and adequately perform their assigned duties.

(5) Maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered by the pharmacy.

(6) Maintain a stock of prescription containers necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.

(7) Ensure all areas where drugs and devices are stored and prepared are dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(8) For outpatient pharmacies open to the public, publicly post the operating hours of the pharmacy department.

(9) 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.

(10) Provide adequate time for a pharmacist to complete professional duties and responsibilities, including:

(a) Drug utilization review;

(b) Immunization;

(c) Patient counseling;

(d) Dispensing of prescriptions;

(e) Patient testing; and

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

Commented [DK6]: Another very subjective term that, I assume, each organization will interpret differently

Commented [DK7]: ??? Is this supposed to be Chapter 4729?

Commented [DK8]: Another subjective term; various interpretations of this could be VERY significant

Commented [DK9]: I haven't verified, but I am assuming someone has verified the proper referencing of Chapter 4729 of the Revised Code and 4729 of the Administrative Code - this needs to be accurate, obviously.

INDIVIDUAL RESPONSES

(11) Not establish any productivity or production quotas relating to the provision of ancillary services;

(a) 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.

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

(i) 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.

(ii) 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.

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

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

(13) Provide for rest periods and meal breaks in accordance with paragraph (C) of this rule.

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

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

(a) The outpatient pharmacy shall close for the required thirty-minute break. The pharmacy shall implement a regular break schedule and communicate the break schedule to customers wherever pharmacy hours are publicly posted or communicated.

(b) The outpatient pharmacy shall not be required to close for rest periods and meal breaks in accordance with paragraph (C)(1)(a) of this rule if there is more than one pharmacist working at the pharmacy that can provide coverage.

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

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

(b) If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking their break within the pharmacy or on the premises. The pharmacist on duty

Commented [DK10]: This is VERY confusing - what are they trying to say here?

Commented [DK11]: Do we provide 'competence of care' to patients? Or 'performance of care'? Suggest rewording, or just eliminating everything but 'quality of care'.

Commented [DK12]: Wording in this section is very inconsistent and confusing - there's this general wording, then below there is 'uninterrupted rest periods and meal breaks', and 'thirty minute uninterrupted rest period and meal break', 'thirty-minute break', then what's in C. Need to have consistent terminology throughout.

Commented [DK13]: Uninterrupted? What's the difference between a 'break' and a 'rest period' and a 'meal break'? See earlier comment - inconsistent wording is an issue.

Commented [DK14]: Where did this number come from? Seems random, and unnecessary.

Commented [DK15]: See above regarding terminology

Commented [DK16]: Is it 'customers' or 'patients' or 'persons'? Seems like these terms are used interchangeably - should they?

Commented [DK17]: See above

Commented [DK18]: It's possible that the other pharmacist CAN provide coverage, but what if both pharmacists want to take their uninterrupted break, or whatever it's going to be called, at the same time? Will the pharmacists be able to convince their manager that this needs to happen, to prevent keeping the pharmacy open the entire 12-14 hours? Doubt it...

Commented [DK19]: Again, very curious where these numbers came from (11, 12). Seems random

INDIVIDUAL RESPONSES

must determine if pharmacy personnel may continue to perform duties and if the pharmacist is able to provide adequate supervision.

(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 picking up a prescription shall be made, 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 returning from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling.

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

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

(D) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not override the control of the pharmacist on duty regarding aspects of the practice of pharmacy and duties of pharmacy personnel.

(1) Except as provided for in paragraph (D)(2) of this rule, a pharmacy shall develop and implement an organizational policy that permits a pharmacist to do all the following:

(a) 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

(b) 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.

(2) In the absence of an organizational policy in paragraph (D)(1), 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.

Commented [DK20]: If you have the 'and' need to make (b) and (c) all one section.

Deleted: ; and

Commented [DK21]: Is this the correct term? Should it be 'only prescriptions that have been verified by the pharmacist and are ready for dispensing, pursuant to this chapter of...'?

Deleted: filling

Deleted: offered

Commented [DK22]: This seems unreasonable; I'd think the following makes more sense, considering there may be other urgent issues to address when returning from break: "...from break shall, within a reasonable amount of time, attempt to contact persons who requested counseling."

Commented [DK23]: See earlier comments

Commented [DK24]: See earlier comments about terminology

Commented [DK25]: How can a 'pharmacy' 'override'? This doesn't make any sense? Management can override, but no object can override.

Commented [DK26]: Is this really the 'pharmacist on duty', as described earlier? Seems like the core of this policy is designed to better empower the pharmacist who's working, or the one 'on duty' - again suggest consistent terminology throughout this document, wherever possible.

Commented [DK27]: See previous comment

Commented [DK28]: See earlier comment

INDIVIDUAL RESPONSES

(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.

(3) Organizational policies developed in accordance with paragraph (D)(1) of this rule shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

(E) Staffing requests or concerns shall be communicated by the responsible person or pharmacist on duty to the terminal distributor using a form or reporting system developed by the board and accessible via the board's website (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.

(F) 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.

(G) Under no circumstances shall a good faith report of staffing concerns by the responsible person or pharmacist on duty, notification of such issues by pharmacy personnel to the responsible person or pharmacist on duty, or any other pharmacy personnel compliance with this rule, result in workplace discipline against the reporting staff member.

Commented [DK29]: Aren't these distinctly different? Shouldn't they be addressed separately?

Commented [DK30]: See earlier comment re consistent terminology

Commented [DK31]: Is this the appropriate 'chain of command'?

Commented [DK32]: Why is the State Board dictating this? The latter half fine, but this? Ridiculous

Commented [DK33]: I'm sorry, but as I mentioned above, THINGS like pharmacies can't do this, people have to.

Commented [DK34]: I'm having a difficult time with the Board getting into the weeds with all these staffing issues. When concerns have the potential to affect pt care and safety, yes. But to dictate and require staffing request info seems ridiculous.

CLEVELAND CLINIC



Sam Calabrese
Chief Pharmacy Officer

May 2, 2023

Cameron McNamee
State of Ohio Board of Pharmacy
77 South High Street, 17th Floor
Columbus, OH 43215

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

Submitted via: Cameron.mcnamee@pbarmacy.ohio.gov, RuleComments@pbarmacy.ohio.gov, CSIPublicComments@governor.ohio.gov

Dear Cameron:

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. With a footprint in Northeast Ohio, Florida and Nevada, Cleveland Clinic Health System operates 19 hospitals with more than 6,400 staffed beds, 21 outpatient Family Health Centers, 11 outpatient surgery locations and numerous physician offices. Cleveland Clinic employs over 5,000 physicians and scientists. Last year, our system cared for 2.9 million unique patients, including 10.2 million outpatient visits and 304,000 hospital admissions and observations. The following are the comments of Cleveland Clinic in response to the above-captioned proposed rule.

Proposed Language 4729:5-02(B)(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 staff during working hours. An employee of a pharmacy shall be identified by a name tag that includes the employee's job title.

Cleveland Clinic Comments

We are concerned with the inclusion of the “fatigue and distraction.” Adequate staffing should not be based on preventing fatigue or distraction but rather providing the highest quality care to patients. Both fatigue and distraction can exist even with adequate staffing. In addition, fatigue and distraction can be very subjective.

Consistent with these comments, we suggest the Pharmacy Board adopt the following language. “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.”

Proposed Language 4729:5-02(B)(12)

Except in an 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

CLEVELAND CLINIC

longer than twelve continuous hours in any workday and shall allow at least eight hours of off time between consecutive shifts. A pharmacist may, however, volunteer to work longer than twelve continuous hours.

Cleveland Clinic Comments

In the beginning of this rule, it states that a terminal distributor of dangerous drugs shall not require pharmacy personnel to work longer than 12 hours. Later in the rule it allows for a pharmacist to volunteer to work longer hours. Thus, we believe that if a pharmacy technician would like to volunteer to work longer than 12 hours, they should be afforded the same consideration. If this is not changed, in the event of call-off, or other emergent situation, pharmacy technicians would not be allowed to volunteer to cover a shift that may exceed 12 hours.

Consistent with these comments, we suggest the agency instead adopt the following language: Except in an emergency that would endanger the health and safety of patients, an outpatient pharmacy licensed as a terminal distributor of dangerous drugs shall not require pharmacy personnel to work longer than twelve continuous hours in any workday and shall allow at least eight hours of off time between consecutive shifts. ~~A pharmacist~~ Pharmacy personnel may, however, volunteer to work longer than twelve continuous hours.

Proposed Language 4729:5-02(E)(2)(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.

Cleveland Clinic Comments

We believe that it should be left up to the pharmacist to determine which access points should be closed to maintain safety. Additionally, similar to the comment above in (B)(1), we believe the terms "fatigue and distraction" should be deleted from this section.

Consistent with these comments, we suggest the agency instead adopt the following language: 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.~~

Thank you for conducting a thoughtful process that allows us to provide input on such important issues. Should you need any further information, please don't hesitate to contact me.

Sincerely,



Sam Calabrese, RPh, MBA, FASHP
Chief Pharmacy Officer



CVS HEALTH

John Long

Director Regulatory Affairs, CVS Health

One CVS Drive
Woonsocket, RI 02895

p 614-572-9008
f 614-766-6957

john.long@cvshealth.com

VIA ELECTRONIC MAIL

April 30, 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

Re: Comment proposed rule 4729:5-5-02 – Establishes minimum standards in an outpatient pharmacy

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 the country. CVS Health appreciates the opportunity to submit comments on the State of Ohio Board of Pharmacy (“Board”) proposed rule 4729:5-5-02, which establishes minimum standards in an outpatient pharmacy, and would like to thank the Board for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in Ohio.

While CVS Health fully supports the creation of a professional work environment for all pharmacy personnel in our pharmacy practice settings throughout Ohio, we do not agree with the amendment of this new State of Ohio Board of Pharmacy rule. Metrics are a tool that helps measure the impact on patient care and the healthy operations of a business. Rest breaks should be used based on the needs of the personnel and operation and not dictated by the number of pharmacies owned by an organization. In addition, the Responsible Pharmacist should work with the pharmacy management in deciding how to best handle a pharmacy workflow.

In today’s healthcare market, pharmacy has established a stronghold as a center to patient care. This can be seen throughout Ohio pharmacies in the increasing number of immunizations administered, prescriptions dispensed, patient counseling sessions provided, and patient tests performed. The way

patients interact and engage with pharmacy businesses has changed dramatically in recent years to meet patient expectations. Local pharmacies are a cornerstone of the community. Currently 90% of Americans live within five miles of a retail pharmacy.

CVS Health requests that the Board repeal this proposal and continue dialogue with industry stakeholders because 1) the proposed rule exceeds the scope of the Ohio Board of Pharmacy's statutory authority, 2) the Ohio Board of Pharmacy has failed to prepare a complete and accurate fiscal analysis of the proposed rule, and 3) the Ohio Board of Pharmacy has failed to demonstrate through the business impact analysis that the regulatory intent of the proposed rule justifies its adverse impact on businesses in this state.

The Ohio State Board of Pharmacy does not have the statutory authority to promulgate these rules. R.C. § 119.01(C) clearly defines a "Rule" to mean any rule, regulation, or standard, having a general and uniform operation, adopted, promulgated, and enforced by any agency **under the authority of the laws governing such agency**. The laws governing the Ohio State Board of Pharmacy are found in Chapter 4729 of the Ohio Revised Code, which unequivocally states under R.C. § 4729.26 that the state board of pharmacy may adopt rules in accordance with Chapter 119. of the Revised Code, not inconsistent with the law, as may be necessary to carry out the purposes of and to **enforce the provisions of this chapter**. Nowhere in Chapter 4729 does the Ohio Legislature contemplate the Ohio State Board of Pharmacy having the authority to **regulate the business practices** of entities engaged in the practice of pharmacy, which effect how said businesses optimize the delivery of pharmaceutical care.

In fact, the various sections of Chapter 4729 have a consistent theme...to protect the public and to promote the public health. The proposed regulations do not purport to do either. Specifically, the Board is relying on surveys, with no statistical significance and filled with opinion, as a basis for rulemaking. The Board has failed to show the public true data and evidence to support the necessity of these regulations in fulfilling the Board's mandate under Chapter 4729. As stated in the Common Sense Initiative Business Impact Analysis Section Development of the Regulation "Scientific data was not used to develop or review this rule. However, surveys were used to gauge pharmacist working conditions." Utilizing this survey methodology to reach the conclusion that onerous overregulation, which will impact pharmacy businesses, was required is by its very nature a failure to demonstrate that the regulatory intent of the proposed rule justifies its adverse impact on businesses in this state. The body of this letter will further demonstrate the negative impacts to pharmacy licensees.

The proposed rule is deceiving to the public in its representation and redefining of an objective business measure, which every business in the State of Ohio utilizes, as a quota. The Merriam-Webster Dictionary defines a quota to mean a proportional part or share, especially the share or proportion assigned to each in a division or to each member of a body. CVS Health pharmacies do not establish quotas. We do not require individuals to fill a certain number of prescriptions or provide a certain number of immunizations. CVS Health does however have business goals based on historical

utilization and demand from the public. What the Board proposes to do is put blinders on all pharmacy personnel by not providing any visibility into key business measures that would fully inform them as to whether the public is provided the full spectrum of pharmacy services within that pharmacy's capability. This provides a disservice to both the public and to the pharmacy personnel that deserve to know how well pharmaceutical care is being provided or what areas of opportunity are needed. Furthermore, this vague proposed language places licensees in a position whereby Board of Pharmacy inspectors interpret, apply and enforce the regulatory language in a subjective, ambiguous, arbitrary and uneven manner.

Phrases in the rule such as “minimize excessive distractions”, “provide adequate time”, and “ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue” are subjective and will not be applied equally amongst those persons being regulated. Two pharmacies, each with the same prescription volume, services and staff, may have two different perceptions on the level of staffing required to perform those services. Therefore, what may be viewed as insufficient personnel, excessive distractions and inadequate time for one pharmacy may be sufficient for the other pharmacies. The business impact analysis states that the proposed regulation is “written in plain language” that would have “minimal questions from licensees regarding the provisions of the rules”. This is false on its face. The subjective nature of the proposed regulations would lead a licensee to question what is considered legal or illegal and the application of the same regulation would look different in every pharmacy.

When an agency may enforce a rule arbitrarily because of imprecise or subjective language, the rule may violate due process. Due process requires that a law or rule be sufficiently precise and definite to give fair warning to those who are subject to it what is allowed, prohibited and what is expected of them by the state. CVS Health does not believe that this proposed regulation meets this standard.

Furthermore, these proposed regulations create a scenario where a pharmacist may restrict services for **any** reason they see fit, which may create a scenario where services are restricted for unjustified reasons. This will inevitably impact patient access to pharmaceutical care and serve as a detriment to the public rather than a public safety measure, which is the primary charge of the Board of Pharmacy.

The proposed regulations provide different regulatory standards and treatment for Independent Pharmacies versus Chain Pharmacies, which is not just and is not supported by the Ohio Pharmacy Practice Act. The pharmacy law does not differentiate between a large chain or an independent pharmacy. CVS Health is in favor of providing meal breaks to pharmacy personnel. However, this

standard should be applied equally to all pharmacy licensee's rather than the Board of Pharmacy clearly demonstrating favoritism towards Independent Pharmacies.

The business impact analysis does not adequately provide the detailed analysis of the adverse impact to business that this new rule would have on the outpatient pharmacies located in Ohio or an adequate fiscal analysis. The adverse effect as described is an update to procedures, which may incur an administrative cost to pharmacies. This is not a complete and thorough fiscal analysis. The practical reality will be that pharmacists will utilize payroll in an inappropriate and unjustified manner. This could lead to impacts to pharmacy profitability that may inevitably close a pharmacy. Pharmacists may close access to certain services, which not only negatively impacts patients, but restricts sales to the pharmacy business. Furthermore, the Board of Pharmacy will enforce based on a vague and subjective standard, incurring administrative fines and discipline, which is unjustified. Lastly, the regulatory climate in Ohio may lead pharmacies to not want to do business in the state. All of these factors must be represented in the fiscal analysis and were not.

The proposed rules are contradictory in their meaning. On the one hand, the Board of Pharmacy purports to give the pharmacist on duty full control in all aspects of the practice of pharmacy. If the Board is defining the practice of pharmacy as the business of pharmacy, which is an improper application, then the pharmacist in charge is required to ensure that the appropriate number of staff is hired, onboarded, trained, and retained as pharmacy employees. Yet, the Ohio Board of pharmacy puts the onus on the permit holder to provide "adequate staffing". This application is confusing and demonstrates the fundamental flaws in the proposed regulation.

This proposed rule set forth by the Board creates a regulatory environment that is "anti-business" and creates a framework throughout Ohio that is unfriendly to the practice of pharmacy and not required in today's healthcare setting. CVS Health is concerned with the impact this will have to patient care and the message this will send to pharmacy personnel in all practice settings throughout the state. CVS Health pharmacies will continue to provide the highest quality of patient care in all our Ohio based pharmacy settings. As such, CVS Health requests that the Board repeal this proposal and continue dialogue with industry stakeholders as how to best address concerns by pharmacy personnel without the need for overregulation that will inevitably lead to unintended barriers in the execution of the business of pharmacy. The Board should stay focused on the regulation of the practice of pharmacy rather than the business of pharmacy, which was not intended by the Ohio Legislature.

We appreciate the opportunity to provide feedback to the State of Ohio Board of Pharmacy and as always thank you for your support. Please contact me directly at 614-572-9008 if you have any questions.

Best regards,



John Long RPh, MBA

May 5, 2023

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

Submitted via email to RuleComments@pharmacy.ohio.gov

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

Dear Executive Director Schierholt:

This letter is in response to the solicitation for stakeholder feedback on proposed rule 4729:5-5-02 issued by the Common Sense Initiative.

CenterWell Pharmacy, Inc. (CenterWell Pharmacy) is a full-service home delivery pharmacy serving 2.5 million patients across all 50 states and dispensing nearly 50 million prescriptions annually. CenterWell Pharmacy provides holistic care that is personalized and coordinated with easy-to-use options so our customers and members can receive the care and prescriptions they need exactly when they need them. This includes home delivery services, as well as retail and specialty pharmacies and over the counter (OTC) fulfillment. CenterWell Pharmacy's largest dispensing facility, which opened in 2008, is located in West Chester Township, Ohio. There are over 240 registered pharmacists and 580 pharmacy technicians working for CenterWell Pharmacy in Ohio who are critical to ensuring that patients across the country have access to the medication that they need.

CenterWell Pharmacy appreciates the opportunity to provide comments on the proposed rule related to establishing minimum standards in an outpatient pharmacy.

Several months ago, the Board considered a more comprehensive proposed rule to prohibit quotas. CenterWell Pharmacy and other interested parties submitted feedback at the time. Overall, we appreciate the Board's recognition of the public comments on its previous proposal and the changes that were made as a result. While we applaud these efforts, we have concerns on one portion of the latest proposed rule.

- ***The Board's proposal does not fully consider the differing pharmacy models and work environments within the State, including closed-door pharmacies, and the ways pharmacists support patient care by providing ancillary services.***

The proposed rule prohibits the use of quotas for ancillary services. "Ancillary services" are defined as "those services performed by pharmacy personnel that are not directly involved in the dispensation of dangerous drugs as set forth in this chapter of the Revised Code. Examples of such services include, but are not limited to, immunizations, medication therapy management, disease state management, and refill reminders."

Closed-door pharmacies, like CenterWell Pharmacy's home delivery facility in Ohio, have different fulfillment and dispensing processes than traditional retail or community pharmacies. In a traditional community pharmacy setting, an individual pharmacist may be asked to manage the complete process of a prescription fulfillment and dispensing while also interacting with patients directly, managing other external factors, and providing ancillary services. Unlike this traditional

model, CenterWell Pharmacy's pharmacists are assigned specific tasks within the overall process and have limited external distractions. This approach allows our employees to work efficiently and at the top of their license.

Some of our Registered Pharmacists perform functions that would be considered ancillary services, such as medication therapy management (MTM), late-to-refill outreach, disease state management, and medication synchronization. They may also place refills for patients who ask for them as part of their interactions. However, the pharmacists only perform these duties and are not simultaneously involved in the dispensing of drugs. This approach allows pharmacists to focus on their primary function without having to manage competing priorities.

Establishing rates and goals is an important way to measure our delivery of these services. Additionally, it allows our management teams to monitor employee performance trends, staffing levels, and patient service. The proposed rules would not allow us to utilize quotas for ancillary services, and that prohibition could impact our ability to effectively manage our staffing levels and address patient needs promptly and at the highest quality levels.

Recommendation

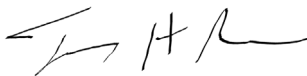
While we appreciate the changes in comparison to the previous proposed rule on quotas, the current proposal does not completely distinguish between the varying pharmacy models and pharmacist employment in Ohio. Given these factors, ***CenterWell Pharmacy strongly recommends that the Board reconsider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

In the section of the proposed rule relating to rest periods and meal breaks, there is a clear delineation for how those requirements would apply to outpatient pharmacies that are not open to the public. We would appreciate a similar distinction as it relates to the prohibition on quotas for ancillary services:

(11) Not establish any productivity or production quotas relating to the provisions of ancillary services. This requirement does not apply to outpatient pharmacies that are not open to the public.

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,



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

cc: CSIPublicComments@governor.ohio.gov

RETAIL MERCHANTS



OHIO COUNCIL OF
RETAIL
MERCHANTS

May 5, 2023

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

Mr. Schierholt,

On behalf of all the chain drug members and two independent members of the Ohio Council of Retail Merchants, I write to oppose 4729:5-5-02 in its entirety. While we believe it is questionable whether the Board has the authority to enforce this rule and as such, it should be discarded entirely, I will offer detailed commentary on its lack of practicality.

It is very important to note at the onset that the Board is basing the proposed new rule 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 vaccines, as well as challenges with staffing due to medical leaves and attrition of healthcare workers. Based on the 2021 survey responses noted 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 at that time of the pandemic. If hospital nurses were similarly surveyed at the same time pharmacists were, that percentage would likely be even higher than 71%. 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 a Board of Pharmacy rule pertaining to this.

In regard to the rule itself, we contend that it is completely 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 negatively impact patient access to care and pharmacist work-life balance and would result in increased costs to the businesses being regulated.

Moving on to specifics, the rule is fraught with subjective terms such as “sufficient personnel,” “excessive distractions,” “sufficiently trained,” and “adequate time.” In (B)(10), the proposed rule states, “Provide adequate 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

RETAIL MERCHANTS

budget would potentially need to be created. Infinite resources, including time, are not possible to provide.

The term “quota” is still very vague and does not clearly define what it is, which will have negative consequences for access to care. 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. The proposed rule infers that pharmacists, as the most accessible healthcare professionals, should take a significant step back on providing care to patients beyond just dispensing dangerous drugs. The language focuses on “ancillary services” not directly involved in the dispensation of dangerous drugs, which includes “immunizations, medication management... and refill reminders.” The rule 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.

In ORC 4729.01, "dangerous drug" means any drug dispensed only upon a prescription or intended for administration by injection into the human body. One could argue that vaccines are therefore a dangerous drug and not an ancillary service. Considering pharmacies are now the primary location where the public receives vaccinations, it is no longer ancillary, but a standard of care. Medication management and refill reminders are also now a standard of care related to dispensation of dangerous drugs and should not be considered ancillary but part of the process.

The length of time a pharmacist works in a shift requiring a break is arbitrary, as is the maximum length of time one is permitted to work in a single shift. How did the board arrive at six hours and 12 hours, respectively? Is there any data to support these numbers? There are large chain locations that will often have two pharmacists working in a day to allow shorter shifts and prevent one pharmacist from working a 12-hour day. This situation does not necessarily provide overlap for the afternoon/evening pharmacist to be able to close the pharmacy again for a 30-minute break during their six- to eight-hour shift. If the rule language is adopted, it will force large chain pharmacist schedules to go to 11- or 12-hour days in order to be compliant with one closed lunch break, which is not conducive to overall work-life balance.

The proposed rule 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 language on access points, without truly defining what is or is not an unsafe condition, 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.

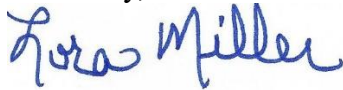
RETAIL MERCHANTS

Section (F) and (G) are also unnecessary and create undue burden, paperwork and unintentional consequences. Anything reported to a Board-owned system would become a public record. This creates an opportunity that when someone reports, they could unintentionally, or intentionally, submit proprietary or confidential information for a company. This puts both the reporting person and the company at risk. As the Board already has a process for a pharmacist to report an issue to them and the Board already documents incidents, investigations, audits, corrective actions, etc., this rule is redundant and will only increase the costs for record-keeping.

I close by reiterating that we find the proposed rule to be completely unnecessary, overly vague and unduly burdensome and would result in many unintended consequences. We respectfully request that the Board members vote to reject the rule 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
50 W. Broad St., Ste.1111
Columbus, OH 43215
614-271-8262
loram@ohioretailmerchants.com

cc: CSIPublicComments@governor.ohio.gov
joseph.baker@governor.ohio.gov
stephanie.mccloud@governor.ohio.gov
Joshua.eck@governor.ohio.gov
Matthew.kelly@governor.ohio.gove
jmccormack@nacds.org
Ohio Chain Drug Committee

Walgreens

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

May 5, 2023

Via Email:
RuleComments@pharmacy.ohio.gov, CSIPublicComments@governor.ohio.gov

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

Re: Proposed rules 4729:5-5-02 Establishes minimum standards in an outpatient pharmacy and rest breaks.

Dear Executive Director Schierholt,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the state of Ohio, Walgreens thanks the Board for the opportunity to comment on the rules related to establishing minimum standards in an outpatient pharmacy. Walgreens appreciates the Board's time and effort related to working conditions and thanks the Board for considering public comments to obtain a variety of perspectives on these rules.

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:

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

In addition, 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

Walgreens

effectively and responsibly and that an additional form and process may not only add an additional burden to the staff but also is not necessary. Therefore, we recommend striking the following language:

~~(3)(E) Staffing requests or concerns shall be communicated by the responsible person or pharmacist on duty to the terminal distributor using a form or reporting system developed by the board and accessible via the board's website (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;~~

~~(F) 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;~~

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

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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:

~~(11) Not establish any productivity or production quotas relating to the provision of ancillary services;~~

~~(a) 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.~~

~~(b) For purposes of this rule, "quota" does not mean any of the following:~~

~~(i) 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.~~

~~(ii) 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.~~

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

The Board should consider moving away from such prescriptive language. The language within section (3)(b) is ample to cover both legal and clinical requirements for references. (a) is overly prescriptive and unnecessary; we therefore recommend striking:

~~(B)(3)(a)~~

~~(3) Provide pharmacy staff with access to the following:~~

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

~~(i) The board's website (www.pharmacy.ohio.gov);~~

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

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

~~(iv) The code of federal regulations.~~

In addition, the following language is also overly prescriptive and unnecessary, we therefore recommend striking:

~~(B)(6)~~

~~Maintain a stock of prescription containers necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and~~

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~~compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.~~

Walgreens appreciates the work of the Pharmacist Workload Advisory Committee (PWAC) and the opportunity to comment on these proposed rules.

If the Board would like additional information, please feel free to contact me.

Sincerely,

Nichole Cover, R.Ph.



May 5, 2023

Steven Schierholt, Esq.
Executive Director
Ohio State Board of Pharmacy
77 S High Street
Columbus, OH 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 concerns have been addressed in the newly published rule 4729:5-5-02.

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

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 Mann.414@osu.edu.

Sincerely,

Henry J. Mann, PharmD, FCCP, FCCM, FASHP
Dean and Professor
The Ohio State University College of Pharmacy
Mann.414@osu.edu