

MINUTES

KENTUCKY BOARD OF PHARMACY Special Called Meeting held via Zoom

BOARD MEETING
June 25, 2024
10:00 a.m.

Members present: Board President Jonathan Van Lahr, Vice President Anthony Tagavi, John Fuller, Meredith Figg, Jason Belcher, Kimberly Croley.

Staff present: Christopher Harlow, Executive Director; Eden Davis, General Counsel; Paul Daniels, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Taylor Rostova, Pharmacy and Drug Inspector; and Nikki Holiday, Executive Assistant.

CALL TO ORDER: President Jonathan Van Lahr called the meeting to order at 10:02 a.m.

This meeting is to address all comments received on the following draft/proposed regulations: 201 KAR 2:220; 201 KAR 2:015; 201 KAR 2:465; and 201 KAR 2:030. The attached table lists each comment, the Board's response to that comment, the Staff's response to that comment, and any amendments made. The Board action on each comment is listed below in the order of the comments listed on the attached table.

201 KAR 2:220, Comment from UK Healthcare, Devlin McGrath provided both written and oral comments
Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:015, Comment from Emily Pierson, PharmD
Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:015, Comment from Frances Hall Sherrill, PharmD
Action: Motion: Kim Croley; Second: Anthony Tagavi; Motion carries

201 KAR 2:015, Comment from Phyllis Danford, PharmD
Action: Motion: Anthony Tagavi; Second: Meredith Figg; Motion carries

201 KAR 2:015, Comment from Russ Hynds
Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:015, Comment from Chris Wendling
Action: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:015, Comment from Kelly Whitaker, PharmD
Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:015, Susan P.
Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:015, Comment from Paul Mahan, DPh
Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:015, Comment from Tom Kaye

Action: Motion: Jason Belcher; Second: Kim Croley; Motion carries

201 KAR 2:015, Comment from Amanda J. Thompson

Action: Motion: John Fuller; Second: Kim Croley; Motion carries

201 KAR 2:015, Comment from Kristi L. Pierce, PharmD

Action: Motion: Kim Croley; Second: Anthony Tagavi; Motion carries

201 KAR 2:015, Comment from David Witmer, PharmD

Action: Motion: Anthony Tagavi; Second: Kim Croley; Motion carries

201 KAR 2:015, Comment from Steven Cummings, PharmD

Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:015, Comment from Liz Hess, PharmD (3 total comments; all addressed in one action)

Action: Motion: Kim Croley; Second: John Fuller; Motion carries

201 KAR 2:465, Comment from Heather Hughes, Publix (oral and written comments)

Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:465, Comment from Dan Lynch, PharmD and Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica

Action: Motion: Jason Belcher; Second: Kim Croley; Motion carries

201 KAR 2:465, Comment from Dan Lynch, PharmD and Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica

Action: Motion: Kim Croley; Second: Anthony Tagavi; Motion carries

201 KAR 2:030, Comment from KP, Canadian Pharmacist

Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:465, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy

Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:465, Chewy (no name provided)

Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Dan Lynch, PharmD and Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica

Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Dan Lynch, PharmD and Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica

Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Dan Lynch, PharmD and Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica

Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Dan Lynch, PharmD and Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica

Action: Motion: Jason Belcher; Second: Kim Croley; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: John Fuller; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: Meredith Figg; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: Kim Croley; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: John Fuller; Second: Anthony Tagavi; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: John Fuller; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: John Fuller; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: Meredith Figg; Second: Kim Croley; Motion carries

201 KAR 2:030, Comment from Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)

Action: Motion: Kim Croley; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy

Action: Motion: Kim Croley; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy

Action: Motion: John Fuller; Second Kim Croley; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy

Action: Motion: Meredith Figg; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy
Action: None; Legal comment; General Counsel to respond

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy
Action: Motion: Kim Croley; Second: Anthony Tagavi; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy
Action: Motion: Meredith Figg; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy
Action: Motion: Anthony Tagavi; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Talley Russell, Director Government Affairs, CenterWell Pharmacy
Action: Motion: Meredith Figg; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Chewy (no name provided)
Action: None; Legal comment; General Counsel to respond

201 KAR 2:030, Comment from Chewy (no name provided)
Action: None; Legal comment; General Counsel to respond

201 KAR 2:030, Comment from Chewy (no name provided)
Action: Motion: Anthony Tagavi; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Chewy (no name provided)
Action: Motion: Kim Croley; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Chewy (no name provided)
Action: Motion: Jason Belcher; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Chewy (no name provided)
Action: Motion: Anthony Tagavi; Second: Jason Belcher; Motion carries

201 KAR 2:030, Comment from Chewy (no name provided)
Action: None; Legal comment; General Counsel to respond

201 KAR 2:030, Comment from Chewy (no name provided)
Action: None; Legal comment; General Counsel to respond

201 KAR 2:030, Comment from Andy Bane, Vetsource
Action: Motion: Kim Croley; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Andy Bane, Vetsource
Action: Motion: Meredith Figg; Second: Anthony Tagavi; Motion carries

201 KAR 2:030, Comment from Andy Bane, Vetsource
Action: Motion: Anthony Tagavi; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Andy Bane, Vetsource

Action: Motion: John Fuller; Second: Anthony Tagavi; Motion carries

201 KAR 2:030, Comment from Ela Lourido, Vice President/General Manager, Biologics by McKesson

Action: Motion: Anthony Tagavi; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Ela Lourido, Vice President/General Manager, Biologics by McKesson

Action: Motion: Kim Croley; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Ela Lourido, Vice President/General Manager, Biologics by McKesson

Action: Motion: Meredith Figg; Second: Anthony Tagavi; Motion carries

201 KAR 2:030, Comment from Ela Lourido, Vice President/General Manager, Biologics by McKesson

Action: Motion: John Fuller; Second: Meredith Figg; Motion carries

201 KAR 2:030, Comment from Ela Lourido, Vice President/General Manager, Biologics by McKesson

Action: Motion: Kim Croley; Second: John Fuller; Motion carries

201 KAR 2:030, Comment from Ela Lourido, Vice President/General Manager, Biologics by McKesson

Action: Motion: Anthony Tagavi; Second: Kim Croley; Motion carries

201 KAR 2:030, Oral comment from Jordan Arnold suggesting changing “KY resident” to “Patients in KY”.

Action: Motion: Anthony Tagavi; Second: Kim Croley; Motion carries

ADJOURNMENT

Action: Anthony Tagavi motioned to adjourn. Kim Croley seconded, and the motion carries. Meeting adjourned at 2:21 p.m.

Comments Received 201 KAR 2:220	Board Response	Staff Response	Amendment?
UK Healthcare *Requests minimum requirements of CCA be amended to allow for more broad identification of parties authorized. For example: Section 1. A collaborative care agreement shall: 1. Be in writing 2. Identify the practitioner and pharmacist authorized to enter into the agreement. This may include: a. Individual names of practitioners and pharmacists b. Practitioner or pharmacist practice groups; or c. Identification based on institutional credentialing or privileging. 3. Provide the method for referral of patients to be managed under the agreement; and 4. State the method of termination of the agreement.		<i>Regulation committee has asked to revisit this, and at that time will address this concern. This regulation was sunseting, but a more thorough review will be performed soon by the regulation committee. UK Healthcare could attend.</i> KRS 315.010(5)"Collaborative care agreement" means a written agreement between a pharmacist or pharmacists and a practitioner or practitioners that outlines a plan of cooperative management of patients' drug-related health care needs where:	
Comments Received 201 KAR 2:015	Board Response	Staff Response	
Emily Pierson, PharmD. The need for yearly renewal/CE requirements, regardless of whether it is done calendar year or reporting year is a moot point.	We are attempting to make things simpler by aligning the licensing timeline and the CE timeline. This will be	Each state has their own cycle, some align and some don't. If a pharmacist is licensed in multiple states, there will likely be conflicting CE cycles, and	

<p>It makes more sense to align with other surrounding states and do a 2 year renewal cycle with the CE aligned to that reporting cycle. It is what the BOP for WV, IN, and OH all do. As written, the current requirements are cumbersome and difficult to keep track of, especially with the CE requirements off from the renewal dates.</p>	<p>one timeline instead of two timelines.</p>	<p>it's imperative that the pharmacist track when each state's cycle begins and ends.</p>	
<p>Frances Hall Sherrill , Pharm D. I believe the proposed change of our CE hours is a horrible idea. It will make it very difficult for pharmacist to remain compliant if the required hours are not based on a calendar year. Thank you.</p>	<p>We are attempting to make things simpler by aligning the licensing timeline and the CE timeline. This will be one timeline instead of two timelines.</p>	<p>Many states use the same cycle we have proposed in the amendment. It aligns the renewal cycle with the CE cycle rather than having two separate cycles.</p>	
<p>Phyllis Danford, Pharm.D. I completed all of my CE requirements for 2024 in January and February of 2024. This change should have been announced before January 1. I suggest that you postpone this new cycle and let me people know before January 1. Or, you make the 2024 CE cycle 14 months, January 1, 2024 to Feb 28, 2025. Beginning in 2025, the cycle would be 12 months, March to February.</p>	<p>The Board will include hours completed in January and February of 2024 in computing total hours. The Board will put out further communication to place licensees on notice.</p>	<p>The Board discussed offering a period of enforcement discretion where those hours completed in January and February of 2024 would count.</p>	

Russ Hynds Why the change? Simply change the licensing "year".	We are attempting to align the licensing and CE deadlines. Having the deadline fall at the end of February as opposed to the end of December at the New Year's holiday makes things simpler.	This is easier from an administrative perspective.	
Chris Wendling What if a pharmacist completed this years CE in January? I am always proactive in knocking out my requirements. With this change, I'll have to do another 15 hours??? Hardly seems fair or legal to change half way thru the year.	The Board will include hours completed in January and February of 2024 in computing total hours. The Board will put out further communication to place licensees on notice.	No, you would not have to do any additional hours. Those hours would count.	
Kelly Whitaker, Pharm.D. If this change is made, it should start next year instead of this year. I purposefully begin my CE in January of each year to get it completed quickly. This of us who completed it in January, February or March of this year, shouldn't be penalized for being organized by having to do more.	The Board will include hours completed in January and February of 2024 in computing total hours. The Board will put out further communication to place licensees on notice.	Those hours would count towards their total hours for the upcoming year.	
Susan P. Exactly how would this work with CEs?	We are attempting to make things simpler by aligning the licensing timeline and the CE timeline. This will be one timeline instead of two timelines. The Board will provide ongoing communication	The annual CE cycle would align with the annual renewal cycle.	

	during implementation to ensure licensee understanding of the changes.		
Paul Mahan, DPh. The proposed alignment of personal license renewal and the associated CE deadline for renewal is an incredibly logical step to maintain compliance and not put unnecessary burdens on the KY RPh licensees.	We agree with you. Thank you.	Agreed. Thank you.	
Tom Kaye Chris, in reading this proposal, I don't see any substantive importance to the changes. What is the boards concern? We, in the field do not desire additional burdens	The Board does not view this as burdensome, but rather a step taken to reduce burdens on Kentucky licensed pharmacists by aligning the licensing and CE periods.	The Board does not view this as burdensome, but rather a step taken to reduce burdens on Kentucky licensed pharmacists.	
Amanda J. Thompson I would like to say that I don't mind having the ce deadline changed ONLY if it includes what CE has been already completed since Dec 31, 2023. Reason being is that I typically get started on mine right after the new year. I don't really think it's fair or right to make such a sudden change which would result in inadvertently penalizing people like myself who like to stay on top of the CE requirements by not counting the CE obtained from Jan 1 -March 2024. As long as it's all included in the 2024 year I am fine with	The CE that you completed since the beginning of the year would be counted for year 2024. The Board recognizes that this is only fair since the amendment was filed after the beginning of the current CE cycle.	The CE that you completed since the beginning of the year would be counted for year 2024. The Board recognizes that this is only fair since the amendment was filed after the beginning of the current CE cycle.	

<p>the change. Or if it's not going to include CE obtained in Jan 2024 til March, then it shouldn't go into effect until 2025.</p> <p>Thank you!!</p>			
<p>Kristi L. Pierce, Pharm.D.</p> <p>Personal view - this will be even harder to keep up with than the calendar year. Not being able to renew when you get the card and having to wait to finish CE a month later seems like added burden. Current dates allow you to finish CE, get your reminder and have a reasonable window to get your license renewed.</p>	<p>We are attempting to make things simpler by aligning the licensing timeline and the CE timeline. This will be one timeline instead of two timelines. The Board will provide ongoing communication during implementation to ensure licensee understanding of the changes.</p>	<p>This will align the CE cycle with the license renewal cycle, simplifying the process for pharmacists.</p>	
<p>David Witmer, Pharm.D.</p> <p>This makes no sense to me and appears to be fixing a problem that doesn't exist. There is no explanation as to why the Board would take such an action. Is it just because the Board thinks this would be nice? Or is there a real issue that causes problems for the Board or KY pharmacists?</p> <p>Has the Board considered the challenges such an approach would create for pharmacists who are licensed in multiple states? Some pharmacists (especially those who work in Telepharmacy locations serving multiple states) may</p>	<p>The Board has 2-3% of pharmacists that we license that have a case opened against them for not completing 15 hours of CE. This is an attempt to reduce that number by aligning the licensing and CE timelines.</p>		

<p>need to maintain licenses in 10 or more states. Having differing calendars for each state would create another unnecessary burden for no apparent gain. At the very least the Board should explain why such a change is beneficial and necessary. I hope that the Board will listen to pharmacists and reconsider this unnecessary and confusing decision. It has worked fine as it is for the nearly 50 years I have been licensed. I see no real benefit of this change and many challenges or issues it may create. Please reconsider.</p>			
<p>Steven Cummings, Pharm.D. I don't like the change personally. I am a traveling pharmacist now and I carry a dozen Pharmacy licenses throughout the country. The February date made Kentucky unique. I understand the change aligns itself better for a calendar year and that is congruent with other states. However as busy as working pharmacists are I disagree over the timing of the change. Why not give your professionals till 2025 to get their CE courses to align with the new timeline? Anything you can do to make things easier for pharmacists to safely serve the public</p>	<p>We are attempting to make things simpler by aligning the licensing timeline and the CE timeline. This will be one timeline instead of two timelines. The Board will provide ongoing communication during implementation to ensure licensee understanding of the changes. We are extending the deadline by including all of calendar year 2024 plus January and February of 2025 to complete CE.</p>		

<p>is always appreciated. For example, I have a license in the state of Oklahoma. Oklahoma did something very unique and commendable in my opinion. They were getting complaints on CVS pharmacy, one store in particular and instead of coming into the pharmacy and reviewing the complaints with the PIC and handing out a small fine which CVS would laugh at. Then of course CVS would take the opportunity to terminate the employment of the PIC or give the PIC a bad evaluation over the fine regardless of the PIC control over the situation. Instead of doing that, the Oklahoma BOP fined CVS \$150,000. The expectation was made clear that it was CVS responsibility to hire an appropriate amount of staff to safely continue pharmacy operations at that location. That amount of money doesn't fall on the PIC it would be directed where it should be at the regional manager. Chain retail pharmacy has made our profession a very difficult place to go into business for yourself. I applaud pharmacists who have been able to successfully navigate independent ownership since the turn of the century.</p>			
---	--	--	--

<p>Thank you for giving us advanced notice of the change and the opportunity to respond!</p> <p>Pharmacists need their BOP to help now more than ever</p>			
<p>Liz Hess, PharmD.</p> <p>I personally store my CE by year, e.g. 2024. Adjusting the CE period to over two years, would be disruptive to a well established workflow for myself. I suspect many others also keep their CE by calendar year.</p>	<p>We are attempting to make things simpler by aligning the licensing timeline and the CE timeline. This will be one timeline instead of two timelines. The Board will provide ongoing communication during implementation to ensure licensee understanding of the changes.</p>		
<p>Liz Hess, PharmD.</p> <p>Many pharmacists are licensed in other states and also have CE requirements. While I personally am only licensed in 2 other states, those states also use a calendar year. Changing the requirements would make Kentucky different, which does not make it easy for those licensed in multiple states.</p>	<p>The proposed change is an attempt to simplify things by aligning two cycles and making it just one. This should make it simpler for those licensed in multiple states.</p>		
<p>Liz Hess, PharmD.</p> <p>If the KY BOP wishes to sync up CE cycle and licensing cycle, I would suggest either doing calendar year like many states OR doing fiscal year (which is more common than Mar-Feb). If there is another benefit that is not obvious, please let me know. It could be considered to change the licensing date</p>	<p>We are picking March-February so that the end of the CE cycle does not occur during the holiday period when many people are taking vacation.</p>		

from February to December or January instead for better syncing with CE.			
Comments Received 201 KAR 2:465			
<p>Heather Hughes, Publix (oral and written comments)</p> <p>This additional regulation would pose an undue burden on pharmacies attempting to provide these specialized prescription services by requiring out-of-state pharmacists, who are already licensed and regulated by their home state pharmacy boards to obtain additional licensure to comply with this rule. We request that the Board delete this portion of the proposed rule and maintain the status quo in its current regulations, which require only the PIC to be licensed in Kentucky. This approach aligns with the standards in other states where Publix operates and has proven beneficial in facilitating the hiring and onboarding of pharmacists. Given the projected decrease in pharmacy graduates, imposing additional licensing requirements could further strain staffing resources and negatively impact patient access to care.</p>	<p>Patient care is and should always be our primary concern. Pharmacy has become very global. Our structure/regulation of pharmacy as a multi-state actor is behind. This is an important step to ensure that Kentucky has jurisdiction over those pharmacists dispensing into the state of Kentucky to ensure our patients are protected. We have to protect our consumers; we cannot rely on someone else to do it. We cannot choose not to fulfill our obligations because of the administrative burden placed on pharmacies.</p>	<p>Do we want to rely on another state to protect the people of Kentucky? The Kentucky Board of Pharmacy would have no control on the actions or the timing of potential actions by the other state board of pharmacy. Let me be clear, the citizens of Kentucky should have assurances from the Kentucky Board of Pharmacy. That is our charge and mission. Lack of licensure provides no such assurances.</p>	

<p>Dan Lynch, Pharm.D., Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica</p> <p>We believe that the addition of 201 KAR 002:465, Section 4, subsection 8: <i>“A person who engages in the practice of the profession of pharmacy for a Kentucky resident shall hold an active Kentucky pharmacist license except under Section 3 of this regulation.”</i> creates an unnecessary burden on a pharmacy.</p> <p>Currently, the out of state pharmacy must have a pharmacist-in-charge licensed in Kentucky as well as take responsibility for the pharmacy following all appropriate Kentucky rules and regulations. Likewise, each pharmacist in a non-resident state requires the pharmacist to hold an active pharmacist license in the resident state to practice the profession of pharmacy. Requiring each pharmacist who engages in the practice of pharmacy for a Kentucky resident could result in delays in therapy. For a pharmacy operating 24 hours per day, 7 days per week, this could result in a patient not being provided care due to a pharmacist on staff not holding the appropriate licensing or registration in Kentucky. A patient who calls with a question related to medication therapy may have to be</p>	<p>The ability to protect our patients is valuable. Pharmacists outside of Kentucky are no different than our pharmacists in Kentucky. It’s our job and duty to protect Kentucky patients.</p> <p>It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows.</p> <p>We cannot replace our relationship with patients; if we do, we no longer have a profession.</p>	<p>The Board considered the burdens to the pharmacy when evaluating the financial impact statement. The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows.</p> <p>The Board must maintain the jurisdiction to ensure the safety of the Kentucky citizen. This is why we are proposing rules that make it clear when licensure is required. Without jurisdiction, we cannot effectively protect the people of the Commonwealth from a pharmacist in violation of pharmacy law or bad actors. Industry is asking for our guidance, and we are responding to ensure</p>	
--	--	---	--

<p>deferred to another pharmacy location or must wait for a call back due to the pharmacist on duty not holding the appropriate license. This regulation is counterproductive to the goal of promoting, preserving, and protecting the health, safety, and welfare of Kentucky residents due to these reasons. No other state in the nation has this strict requirement for the provision of pharmacy services by an out of state licensed pharmacy. The process to obtain a Kentucky license also will incur substantial costs for a pharmacist and discourage pharmacists from providing important services to Kentucky residents.</p>		<p>the continued safety of the citizens of the Commonwealth.</p>	
<p>Dan Lynch, Pharm.D., Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica We believe the addition of Section 4, subsection 1(b): <i>“a letter from the regulatory or licensing agency of the state in which the pharmacy is located that certifies the pharmacy is in good standing.”</i> is not always feasible for some out of state pharmacies. There are other Boards of Pharmacy that refuse to provide this form of documentation. One of these Boards is the NY State Board of Pharmacy. We believe a primary source verification from the resident Board of Pharmacy’s website is sufficient since it shows the</p>	<p>Adoption of amendment.</p>		<p>(1) A prerequisite for receiving a permit as an out-of-state pharmacy is that the facility must be in good standing in the state where it is located and submit evidence consisting of the following: (b) letter from the regulatory or licensing agency of the state in</p>

pharmacy is good standing and provides documentation of any previous disciplinary action.			which the pharmacy is located that certifies the pharmacy is in good standing. <u>If the licensing agency does not provide a letter, primary source verification may be utilized.</u>
Applies to 201 KAR 2:030 KP, Canadian Pharmacist He is in the process of immigrating from Canada. He has been a Canadian pharmacist for over ten years. He has a bachelors in pharmacy from India. He wants to understand why he has to go through FPGEC instead of having reciprocity options and taking the law exam and increased intern hours.	Not applicable to 465 or the amendment or 030. Misidentified subject matter.		
Talley Russell, Director Government Affairs, CenterWell Pharmacy If adopted, proposed rule 201 KAR 2:465 will require each non-resident pharmacy to develop and provide the Board with a policy and procedure manual that includes “the procedure for shipping products pursuant to FDA approved and manufacturer guidelines.” This criterion should be amended to ensure it also includes nationally recognized	Proceed with amendment. Will include in temp tracking regulation.		(3) Each non-resident pharmacy shall develop and provide the Board with a policy and procedure manual that sets forth: (a) normal delivery protocols and times; (b) the procedure to be followed if the patient's

<p>standards such as the United States Pharmacopeia.</p> <p>Georgia has done this successfully in its pharmacy regulations. For example, Georgia Rule 480-48-.02 Conditions for Use of Delivery by Mail² states in part (emphasis added),</p> <p><i>(3) A mail order pharmacy shall ensure that all prescription medications are delivered to the patient in accordance with standards of the manufacturer, United States Pharmacopeia, Federal Food and Drug Administration and other recognized standards. A pharmacy shall ensure integrity of any drug requiring temperature control other than “room temperature storage” that is delivered by mail order and provide a notification to the patient of the timeliness in addressing the proper storage of the medication.</i></p>			<p>medication is not available at the out-of-state pharmacy, or if delivery will be delayed beyond normal delivery time;</p> <p>(c) the procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the out-of-state pharmacy at the earliest possible time, or an alternative that assures the patient the opportunity to obtain medication at the earliest possible time;</p> <p>(d) the procedure to be followed when the out-of-state pharmacy is advised that the patient’s medication has not been</p>
---	--	--	---

			<p>received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available; and</p> <p>(e) the procedure for shipping products pursuant to FDA approved and manufacturer guidelines.</p>
<p>Chewy (no name provided)</p> <p>In addition to including a reference to the non-resident licensure, this regulation requires the toll-free number on the prescription label to be routed directly to the PIC six days a week and a minimum of forty hours per week. If the PIC is unavailable, a staff pharmacist with access to patient records may answer but must notify the PIC of the call and provide the PIC with a patient call back number. If the staff pharmacist is unable to resolve the patient's question, the PIC shall return the call of the patient within forty-eight hours. This regulation creates additional restrictions on pharmacy workflows and is</p>	<p>Unchangeable requirements due to statutory language.</p> <p>Refer to statutory language, KRS 315.0351 requiring PIC six days a week. (f) Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each</p>		

<p>unduly burdensome. These are tasks that any properly trained staff pharmacist can and do resolve daily. Reporting every patient encounter to the PIC, the vast majority of which have already been easily and promptly resolved, is unnecessary, burdensome and does not further promote patient care. Every pharmacist at Chewy has access to patient records and our Kentucky patients have access to a pharmacist 24/7.</p>	<p>licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth;</p>		
<p>Comments Received 201 KAR 2:030</p>			
<p>Dan Lynch, Pharm.D., Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica As previously mentioned in the prior comment above, our pharmacy employs several pharmacists who do not hold a Kentucky Pharmacist license while operating under a resident state pharmacist license and Kentucky Out of State pharmacy permit. No other state in the United States currently requires a pharmacist practicing through an out of state pharmacy license to be licensed in the state (outside of a pharmacist-in-charge in a several states).</p>	<p>Our specific concerns are regarding Kentucky patients. We are not concerned with what other states may or may not do. If other states do choose to adopt similar language, it would be slowly, not all at once.</p>	<p>The Board must maintain the jurisdiction to ensure the safety of the Kentucky citizen. This is why we are proposing rules that make it clear when licensure is required.</p> <p>Without jurisdiction, we cannot effectively protect the people of the Commonwealth from a pharmacist in violation of pharmacy law or bad actors. Industry is asking for our guidance, and we are responding to ensure the continued safety of the citizens of the Commonwealth.</p>	

<p><u>This regulation only creates an administrative hurdle for out of state pharmacies in their attempt to provide safe and reliable medication services to the residents of Kentucky.</u></p>			
<p>Dan Lynch, Pharm.D., Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica The additional use of the NABP Verify Program not only increases the costs to a pharmacist to obtain the non-resident pharmacist license, but also adds another layer of complexity to obtain this license. Looking at other health professions practicing within the state of Kentucky, this regulation runs counter to the progress the state has made with providing competent, accessible care for patients. While this would add more complexity, as well as care through compact agreements. Most notably, Kentucky joined the Enhanced Nurse Licensure Compact (eNLC) in January 2018, which allows nurses to provide care in state without needing to obtain an additional resident or non-resident license. Other health professions in which Kentucky has joined as part of an interstate compact include Audiology/Speech Language Pathology, Counseling, Occupational Therapy, Physical</p>	<p>We are utilizing NABP Verify as a compromise. Licensees would not have to take the MPJE.</p>	<p>Unfortunately there is not a compact available for pharmacists. NABP Verify is the closest thing available and does make out of state practice much simpler by waiving CE requirements and not requiring the MPJE to be taken.</p>	

Therapy and Social Work. We believe that requiring a pharmacist who is licensed in another state to obtain licensure is inconsistent with other licensed professions.			
Dan Lynch, Pharm.D., Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica We believe that this rule will have a negative impact on the provision of care to Kentucky residents and result in a loss of pharmacy services, especially those in rural communities who rely on mail order or long-term care services from neighboring states. The BOP did not state how the addition of this regulation will improve in the protecting of the health, safety, and welfare of Kentucky residents. Also, the BOP has not provided any commentary on why the current process of only requiring an out of state pharmacy be licensed in the Commonwealth, and with a Kentucky licensed pharmacist in charge, has negatively impacted the health, safety, and welfare of the residents in Kentucky.	Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.	Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.	
Dan Lynch, Pharm.D., Cameron Franklin, MPA, BrightSpring Health Services/Onco360/PharMerica With these proposed changes, there is tremendous potential for patient harm when the same pharmacists and their	If the associated pharmacies are no longer able to serve Kentucky patients, that is a business decision that the company has made. There is	Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current	

<p>associated pharmacies are no longer able to provide services to their patients in Kentucky.</p> <p>Given the burdens the proposed changes would impose on the pharmacies supplying critical medications for the people of Kentucky, we are unable to identify any benefits to patients, pharmacies, pharmacists, the BOP, or a reduction in potential patient harm.</p>	<p>potential for harm in all manner of ways. By not having structure and regulations, there is also great potential for harm. We're building out the regulatory structure to benefit the patients of Kentucky.</p>	<p>licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)</p> <p>The Proposed Rules do not further any discernible health, safety, or welfare purpose. In fact, the Proposed Rules would hinder the health, safety, and welfare of Kentucky patients by imposing unnecessary requirements, burdens, and costs on nonresident pharmacies and pharmacists that provide important and unique pharmacy services to Kentucky patients. For example, the Proposed Rules will make it more burdensome for CoverMyMeds' free drug pharmacies to serve the most needy and vulnerable patients in Kentucky who qualify for PAPs and other free goods programs.</p>	<p>There is potential for harm in all manner of ways. By not having structure and regulations, there is also great potential for harm. We're building out the regulatory structure to benefit the patients of Kentucky. There are many entities that want to provide spectacular patient care. They are innovative.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)</p> <p>Additionally, the Proposed Rules will impair the ability of CoverMyMeds pharmacies to</p>	<p>There's nothing in this regulation that prevents an out of state pharmacist from consulting with an expert on</p>		

<p>staff pharmacists on disease-specific care teams. In other words, instead of ensuring that patients with blood cancer diseases are treated by pharmacists specializing in that disease state, the Proposed Rules will encourage (and even necessitate) that such patients are routed to pharmacists based on their individual licensure footprint. Put simply, the Proposed Rules require pharmacies to prioritize geography over disease-state expertise.</p>	<p>a disease state. Moreover, this regulation does not prevent a pharmacist from becoming an expert on a disease state.</p>		
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members) However, the Proposed Rules still would require pharmacists to submit initial and annual licensure maintenance fees to the Board, in addition to fees required to pursue enrollment in the NABP Verify process. Of note, the Kentucky Board has no oversight over the fees charged by the NABP Verify program. Tying nonresident pharmacy compliance to this external entity's credentialing and fees process has unknowable financial impact on pharmacists and pharmacies alike.</p>	<p>We are a member board of NABP and would have influence over the fees charged by the program. The NABP Verify program is a monitoring program across all fifty states. As additional states adopt Verify, there is no additional cost. It is a one-time, once a year cost. If you practice in multiple states, there is not an increased fee.</p>	<p>All states that utilize NABP for license transfer or initial licensing have fees tied to NABP regarding licensing.</p>	
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members) Even if a pharmacy is able to cover as-yet unknown licensing costs for its pharmacists and schedule Kentucky-licensed</p>	<p>This comment extrapolates having one pharmacist on duty licensed to having all pharmacists on</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure.</p>	

<p>pharmacists to cover all shifts, unplanned illnesses or emergencies may prevent a pharmacist from working on any given day. The pharmacy would then have to halt any care for Kentucky patients while another Kentucky-licensed pharmacist is identified. Any potential delay, halt, or disruption in treatment access for patients with specialty conditions threatens their health and livelihood.</p> <p>Without access to their specialty pharmacy and medications, a patient could face immense setbacks in their treatment, leading to increased emergency room visits, hospital admissions, healthcare costs, or worse.</p>	<p>duty licensed. Staffing challenges are everywhere. We are asking no more than we would of an in-state pharmacy in Kentucky.</p>	<p>While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)</p> <p>These Proposed Rules, however, do not appear to effectively serve such a purpose. To the contrary, we are concerned that the Proposed Rules will make it harder to pharmacies and pharmacists located within and outside of Kentucky to pursue normal operations and in turn, effectively serve Kentucky patients.</p>	<p>Every pharmacy is faced with a new challenge everyday with workflow and challenges to workflow. Pharmacists live through this every day. We work together to make system changes to improve conditions. We feel certain that entities that want to provide this important service will continue to do so.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	

<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)</p> <p>Adding supplementary administrative requirements and financial burdens through state-specific licensing applications and fees does not impart any additional knowledge or improve individuals’ ability to deliver patient care. Instead, these requirements merely add to the long list of growing obligations that are now becoming synonymous with the practice of pharmacy. To make matters worse, these proposed changes may cause many nonresident pharmacies to cease dispensing into Kentucky, leaving already stretched resident Kentucky pharmacies and pharmacists to absorb that volume, which will lead to delays in patient care and an increase in pharmacist burnout. Given the NABP’s findings, which appear to be consistent with the Board’s own, there is reason to pause and thoughtfully consider whether additional administrative requirements like these advance the profession, support pharmacists’ mental health, improve workforce conditions, streamline burdensome practice requirements, and optimize technology workflow efficiencies.</p>	<p>Every pharmacy is faced with a new challenge everyday with workflow and challenges to workflow. Pharmacists live through this every day. We work together to make system changes to improve conditions. We feel certain that entities that want to provide this important service will continue to do so.</p> <p>Patient care is and should always be our primary concern. Pharmacy has become very global. Our structure/regulation of pharmacy as a multi-state actor is behind. This is an important step to ensure that Kentucky has jurisdiction over those pharmacists dispensing into the state of Kentucky to ensure our patients are protected. We have to protect our consumers; we cannot rely on someone else to do it. We cannot choose not to fulfill our obligations</p>	<p>The administrative and financial requirements are to provide the Board with jurisdiction over each pharmacist dispensing drugs into the Commonwealth. Jurisdiction is key to ensure that Kentucky patients are safe.</p> <p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
--	--	---	--

	because of the administrative burden placed on pharmacies		
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)</p> <p>Under this well-established policy, the Board already has adequate oversight mechanisms available to it today, such as disciplining the nonresident pharmacy (i.e., fines and other discipline against the pharmacy facility), disciplining the Kentucky-licensed PIC if appropriate, and/or referring the matter to the pharmacy's home state Board of Pharmacy to impose other or additional discipline. At most, the Proposed Rules ostensibly provide the Board with an additional and unnecessary pathway to control pharmacists working at nonresident pharmacies.</p>	<p>Instead of disciplining an entire pharmacy or a PIC, it's better to oversee each individual pharmacist. If we shut down a pharmacy because of one pharmacist's actions, that has a large impact whereas pinpointed discipline would only impact a specific pharmacist.</p> <p>Liability does not automatically transfer from the actions of the pharmacist to the pharmacy or pharmacist in charge. Our laws are very specific in the creation of specific responsibilities of the pharmacy, pharmacist in charge and the pharmacist.</p> <p>We are treating the non-resident pharmacies and pharmacists with the same standards</p>	<p>Liability does not automatically transfer from the actions of the pharmacist to the pharmacy or pharmacist in charge. Our laws are very specific in the creation of specific responsibilities of the pharmacy, pharmacist in charge and the pharmacist.</p> <p>We are treating the non-resident pharmacies and pharmacists with the same standards as our in-state pharmacists and pharmacies because both are serving citizens of the Commonwealth. The people of Kentucky expect our protection and we must have equitable rules for any pharmacy or pharmacists caring for our citizens.</p>	

	as our in-state pharmacists and pharmacies because both are serving citizens of the Commonwealth. The people of Kentucky expect our protection and we must have equitable rules for any pharmacy or pharmacists caring for our citizens.		
<p>Matt Ottiger, Covermymeds Pharmacy (also sent to ARRS committee members)</p> <p>Given the existing powers granted to state pharmacy boards, no other state has implemented and enforced such a broad individual pharmacist licensure rule or statute. Nevada considered such a requirement in 2021 but was prevented from doing so by Assembly Bill 107 in recognition of the negative patient impact such a practice would impose. While North Carolina requires NABP Verify for nonresident pharmacists engaged in central processing, it does not require broad NABP Verify membership or state licensure for all nonresident pharmacists serving North Carolina patients</p>	<p>Our primary role is to protect the patients of Kentucky. Technology is always ahead of regulation, and we are trying to catch up to ensure Kentucky patients are safe. Our job is to regulate the industry and we have to respond to industry changes. We don't know what is happening in other states, but we need to stay focused on Kentucky.</p>		

<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>If the proposed rules are promulgated in their current form, home delivery pharmacies like CenterWell Pharmacy must ensure only Kentucky-licensed pharmacists dispense prescriptions to Kentuckians. While every effort would be made so that prescriptions are not delayed, routing medications to pharmacists specifically licensed by Kentucky, in addition to the license already held by the state where the pharmacist practices, is a departure from current industry practice and could lead to processing and delivery delays. Timely delivery of medications is critical, and potential delays could create access to care issues for Kentucky patients.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>There is no additional benefit to a patient who receives a prescription filled by a Kentucky-licensed pharmacist. A patient should be managed by the pharmacist best equipped to handle that patient's specific need and not based on the pharmacist's geographic location or individual state licensure. If the proposed rules go into effect, Kentucky will become an</p>	<p>The benefit is to the Board having jurisdiction over the pharmacist.</p> <p>Having regulations that help companies build their structure out in ways that are innovate and provide excellent patient care makes the industry better.</p>	<p>The benefit is to the Board having jurisdiction over the pharmacist</p>	

<p>outlier and the only state to require all non-resident pharmacists to be individually licensed in an additional state even though they work for a pharmacy licensed by and dispensing into that state.</p>			
<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>The Board already requires out-of-state pharmacies and their pharmacists-in-charge to be licensed by Kentucky. Should the need arise, the Board can refer any issues to the pharmacy's and/or pharmacist's resident Board of Pharmacy for review and appropriate action. Pharmacies are required to report their own disciplinary actions and those of their staff to many Boards. Disciplinary actions are also reported to the National Practitioner Databank. These resources and processes provide pertinent information that Boards of Pharmacy and other regulatory entities can utilize to determine if further oversight or discipline of its licensees is necessary.</p>	<p>Liability does not automatically transfer from the actions of the pharmacist to the pharmacy or pharmacist in charge. Our laws are very specific in the creation of specific responsibilities of the pharmacy, pharmacist in charge and the pharmacist.</p> <p>Do we want to rely on another state to protect the people of Kentucky? The Kentucky Board of Pharmacy would have no control on the actions or the timing of potential actions by the other state board of pharmacy. Let me be clear, the citizens of Kentucky should have assurances from the Kentucky Board of Pharmacy. That is our charge and mission. Lack of licensure provides no such assurances.</p>	<p>Liability does not automatically transfer from the actions of the pharmacist to the pharmacy or pharmacist in charge. Our laws are very specific in the creation of specific responsibilities of the pharmacy, pharmacist in charge and the pharmacist.</p> <p>Do we want to rely on another state to protect the people of Kentucky? The Kentucky Board of Pharmacy would have no control on the actions or the timing of potential actions by the other state board of pharmacy. Let me be clear, the citizens of Kentucky should have assurances from the Kentucky Board of Pharmacy. That is our charge and mission. Lack of licensure provides no such assurances.</p>	

<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>The proposed rules would also require a pharmacist to obtain an additional background check. Background checks are typically done before a pharmacist is hired by their employer, and many resident states require this as part of their licensure process. Requiring pharmacists to undergo an additional background check for Kentucky licensure would be duplicative since background checks are already conducted during the normal course of the hiring and licensure processes.</p>	<p>**Legal Comment, GC to Respond</p>		
<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>Home delivery pharmacies, like CenterWell Pharmacy, have successfully delivered medications to Kentucky patients for many years. We are unaware of widespread complaints or concerns with home delivery, so we are unclear what outcome these additional restrictions will achieve for Kentuckians. If the Board has information to the contrary, we would appreciate the opportunity to review the data driving this change.</p>	<p>We have seen a litany of complaints where a non-resident pharmacist has violated Kentucky law but we are unable to take action against the pharmacist because we do not have jurisdiction. It is challenging and unfair to impute liability to the permit holder or PIC for actions specifically committed by the unlicensed non-resident pharmacist.</p>		

<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>While the Board’s fiscal analysis considers the fixed costs associated with non-resident pharmacists obtaining licensure, it does not adequately address the costs pharmacies will incur to upgrade technology infrastructure or increase staffing needs to maintain compliance.</p> <p>To ensure Kentucky-licensed pharmacists manage prescriptions sent to Kentucky patients, non-resident pharmacies will need to invest in costly pharmacy software upgrades since many software systems do not account for the states where a pharmacist is licensed. To limit processing and delivery delays, non-resident pharmacies will need all or most of its pharmacists to be licensed in Kentucky and will need to adjust staffing and workflows daily to ensure compliance. Software upgrades, along with staffing and licensing impacts, will increase costs to the pharmacy.</p>	<p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows. Completing a financial impact analysis for every type of business model is simply not feasible. Each pharmacy may offer different services, technology, number of patients served, or number of employees.</p>	<p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows. Completing a financial impact analysis for every type of business model is simply not feasible. Each pharmacy may offer different services, technology, number of patients served, or number of employees.</p>	
--	---	---	--

<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>Additionally, the fiscal impact statement does not appear to factor in the costs for each non-resident pharmacist to obtain a NABP Verify credential and criminal background check as contemplated by the proposed rules. The fiscal impact statement also does not consider the cost of the pharmacists' time and wages to complete necessary paperwork and fingerprinting. Those tasks will pull pharmacists away from their primary focus of patient care.</p>	<p>These are not costs incurred by the Board of Pharmacy directly and therefore they were not included. KRS 218A requires every pharmacist to have a background check. Moreover, the cost to utilize NABP Verify was not included because many pharmacists have already paid to become a member and that cost is an annual cost that is only paid one time annually no matter how many states the pharmacist is licensed or registered.</p>	<p>These are not costs incurred by the Board of Pharmacy directly and therefore they were not included. KRS 218A requires every pharmacist to have a background check. Moreover, the cost to utilize NABP Verify was not included because many pharmacists have already paid to become a member and that cost is a one-time cost.</p>	
<p>Talley Russell, Director Government Affairs, CenterWell Pharmacy</p> <p>The Board's proposed rules will substantially increase costs (i.e., initial and ongoing licensing fees, staffing needs, system/process enhancements, etc.) for pharmacies, which will in turn increase the cost of providing care to patients. The Board</p>	<p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure</p>	<p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type</p>	

<p>should complete a sufficient fiscal impact analysis to adequately forecast the financial impact of these proposed changes. As part of that analysis, it would also be helpful to understand any initial and ongoing fiscal impacts the state may incur to fully operationalize these proposed changes.</p>	<p>compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows.</p> <p>Completing a financial impact analysis for every type of business model is simply not feasible. Each pharmacy may offer different services, technology, number of patients served, or number of employees.</p>	<p>of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows.</p> <p>Completing a financial impact analysis for every type of business model is simply not feasible. Each pharmacy may offer different services, technology, number of patients served, or number of employees.</p>	
<p>Chewy (no name provided) Kentucky statutes do not authorize the Board to license non-resident pharmacists beyond the pharmacist in charge. Kentucky statutes specifically create licenses for a pharmacist, pharmacy, out of state pharmacy, a</p>	<p>**Legal Comment, GC to respond.</p>		

<p>manufacturer, out of state outsourcing facilities and home medical equipment. See, KRS §§ 315.030, 315.035, 315.0351, 315.036, 315.342 and 315.514. The out of state pharmacy license is currently the only out of state pharmacy licensure structure permitted by the legislature and does not extend to non-resident pharmacists outside of requiring licensure of the pharmacist-in-charge (PIC).</p>			
<p>Chewy (no name provided) The Board’s acknowledgement of its limited scope of statutory authority is evidenced by its responses to the National Association of Boards of Pharmacy Annual Survey of Pharmacy Law where the Board has consistently responded, “If pharmacy is shipping a prescription into Kentucky, must have Kentucky pharmacy permit and <u>a</u> Kentucky-licensed pharmacist as a PIC,” in response to the question of whether non resident pharmacists must be licensed. The Board is attempting to sidestep the legislative process by using administrative regulations to create a new license category.</p>	<p>**Legal Comment, GC to respond.</p> <p>The survey of law states that we enforce non-resident licensure for central fill and common database.</p>		
<p>Chewy (no name provided) There is no additional knowledge imparted, practice enhancement, or patient safety improvement achieved by requiring non-resident pharmacists to complete an</p>	<p>If this is the case, then we don’t need to license pharmacists in Kentucky. Jurisdiction is the only way that we</p>	<p>Jurisdiction is achieved. The Board must maintain the jurisdiction to ensure the safety of the Kentucky citizen. This is why we are proposing rules that make</p>	

<p>application and pay additional fees in Kentucky.</p>	<p>can ensure that our residents and patients are safe.</p> <p>Industry is asking for our guidance, and we are responding to ensure the continued safety of the citizens of the Commonwealth.</p>	<p>it clear when licensure is required.</p> <p>Without jurisdiction, we cannot effectively protect the people of the Commonwealth from a pharmacist in violation of pharmacy law or bad actors. Industry is asking for our guidance, and we are responding to ensure the continued safety of the citizens of the Commonwealth.</p>	
<p>Chewy (no name provided)</p> <p>Moreover, requiring every nonresident pharmacist employed by a multistate pharmacy to be licensed in Kentucky would have significant negative consequences on those pharmacists, their employing pharmacies, and the people and pets of Kentucky in need of medication. Companies invest in their infrastructure, including pharmacy management systems, based on current and stable laws, and pharmacy infrastructure is typically built to be both efficient and accurate ensuring that prescriptions are handled by the most qualified pharmacist rather than based on state of licensure or physical geography. To do otherwise risks inefficiencies and delays and requires significant additional investment in enhancing technology and workflows, without benefiting patient care or patient safety.</p>	<p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with</p>		

	advances in systems, technologies, and workflows.		
<p>Chewy (no name provided)</p> <p>If every state adopted laws or regulations like the one under consideration by the BOP, every pharmacist in every pharmacy (e.g., retail, specialty, mail-order, long-term pharmacies, etc.) with a multistate footprint would be required to hold individual licensure in every state in which the pharmacy dispenses. This would be untenable across the industry and cause significant administrative and monetary burdens on these pharmacies and individual pharmacists. As such, pharmacies may be forced to limit their state scope, leading to lack of patient choice when obtaining necessary medications for themselves and their pets.</p>	<p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows.</p>		

<p>Chewy (no name provided)</p> <p>Furthermore, the additional expenses of acquiring and renewing these licenses, along with the administrative task of monitoring them for expiration, could have a negative impact on existing resources. Expensive technological safeguards would need to be implemented to ensure compliance with this regulation. Even with a “smart logic” system, requiring nonresident pharmacist licensure could result in staffing shortages due to sickness, weather, or other uncontrollable events, that would make nonresident pharmacies unable to meet the Kentucky residents’ pharmacy needs.</p>	<p>NABP Verify has implemented a dashboard to make it easy for licensees to see renewal dates, etc.</p> <p>The board understands that any regulatory requirement may come with increased cost or administrative burden. We also acknowledge that certain system or enhancements will need to be put into place to ensure compliance. It is important to understand that regulations are not put into place for specific type of business models. But rather, regulations are established for any individual or entity under the purview of the regulatory agency. We are confident that pharmacies and pharmacists will achieve compliance at the lowest possible costs with advances in systems, technologies, and workflows.</p>		
--	--	--	--

<p>Chewy (no name provided) Additionally, while we appreciate that the BOP's current proposal provides for an alternative to full pharmacist licensure, the proposed language still creates an undue burden on the pharmacist's time and expense by requiring each pharmacist to apply and obtain fingerprints for a background check that has already been performed as part of the pharmacist's resident state board licensing and, typically, as part of the pharmacist's hiring. This requirement does not increase patient safety or otherwise benefit the Kentucky patient.</p>	<p>**Legal Comment, GC to respond.</p>		
<p>Chewy (no name provided) A viable alternative to non-resident licensure is to only require the NABP Verify credential. This credential ensures that the pharmacist holds at least one active, unconditional licensure in good standing and has no current or unresolved disciplinary sanctions. Currently, North Carolina uses this credential to allow non-resident pharmacists to practice into their state and does not require an additional license for these pharmacists.</p>	<p>*Legal response. This does not give us jurisdiction. It is separate and apart from licensure or registration by the state.</p>		

<p>Andy Bane, Vetsource 201 KAR 2:030 has the potential to hinder medication access by limiting licensed pharmacists' ability to provide clinical services to Kentucky residents and may impact the ability of non-resident pharmacies to maintain adequate staffing to service the state's residents. The time and cost associated with the new licensure requirements in Section 6 are particularly concerning. The application process, which includes background checks and fingerprinting, is time consuming and prone to delays which are often beyond personal control. These factors, along with the time involved with reciprocity of licensure, would place an additional burden on non-resident outlets and pharmacists, diverting time and focus away from clinical practice without offering measurable improvement in standards of care.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p> <p>Animals are patients, and any pharmacist wishing to take care of patients in Kentucky will understand the need.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
<p>Andy Bane, Vetsource Moreover, the rule may increase the number of individuals licensed but may not impact the level of compliance at a practice site. Maintaining the current process of licensure reciprocity for the non-resident Pharmacist-in-Charge (PIC) ensures regulatory alignment and a clear process for accountability. This model is especially effective at outlets with low PIC turnover and large pharmacist</p>	<p>Jurisdiction is the key to why licensure is being proposed. The PIC may be doing everything they can but they may not increase compliance of the individual pharmacists.</p>	<p>Jurisdiction is the key to why licensure is being proposed. The Board must maintain the jurisdiction to ensure the safety of the Kentucky citizen. This is why we are proposing rules that make it clear when licensure is required. Without jurisdiction, we cannot effectively protect the people of the Commonwealth from a pharmacist in violation of pharmacy law or bad</p>	

<p>teams. Vetsource has managed our compliance very effectively with this model providing consistent and comprehensive services nationally. Maintaining the PIC-licensed only model centralizes the necessary state-specific regulatory knowledge, while ensuring the outlet maintains a robust system for compliance via policies and procedures and thorough staff training.</p>		<p>actors. Industry is asking for our guidance, and we are responding to ensure the continued safety of the citizens of the Commonwealth.</p>	
<p>Andy Bane, Vetsource</p> <p>We believe this rule increases the administrative burden on pharmacies without directly improving patient care, especially in veterinary pharmacy practice where misuse and diversion of controlled substances is exceptionally low when compared to human pharmacies. We respectfully request the Board to reconsider the need for this rule especially when an outlet has been in good standing and maintains high standards to ensure patient safety and proper medication access. Should the Board proceed with the amendment, we recommend ensuring there is reasonable opportunity for a pharmacy to be granted a waiver or exception in consideration of veterinary pharmacy sites.</p>	<p>Pets are part of the family, and they shouldn't be treated any differently than other members of the human family. Controlled substances and diversion are not our only concern. Medication errors are also critically important and we want to ensure we have jurisdiction.</p>		
<p>Andy Bane, Vetsource</p> <p>The intent of the non-resident state licensure requirement should be to enhance the health, safety, and</p>	<p>We appreciate the care that each of the commentators has on this issue. This is a growth</p>		

<p>welfare of the people. Vetsource has maintained high standards of performance and accountability in all states. Implementing this amendment without a veterinary exemption would likely reduce access by increasing the licensure burden, negatively impacting an already under-considered population of providers and the services extended to those in need.</p>	<p>process for all of us, and a process that is critical whether the patients be human or animal.</p> <p>Patients are patients, whether human or animal.</p>		
<p>Ela Lourido, Vice President/General Manager, Biologics by McKesson</p> <p>The Proposed Rules do not further any discernible health, safety, or welfare purpose. In fact, the Proposed Rules would hinder the health, safety, and welfare of Kentucky patients by imposing unnecessary requirements, burdens, and costs on nonresident pharmacies and pharmacists that provide important and unique pharmacy services to Kentucky patients. For example, the Proposed Rules will make it more burdensome for Biologics' free drug programs to serve the most needy and vulnerable patients in Kentucky who qualify for patient assistance programs (PAPs) and other free goods programs. Additionally, the Proposed Rules will impair Biologics' ability to staff pharmacists on disease-specific care teams.</p>	<p>There is potential for harm in all manner of ways. By not having structure and regulations, there is also great potential for harm. We're building out the regulatory structure to benefit the patients of Kentucky. There are many entities that want to provide spectacular patient care. They are innovative. The Kentucky licensed pharmacist may still consult with the disease-state specialist prior to counseling a patient.</p>		

<p>Ela Lourido, Vice President/General Manager, Biologics by McKesson</p> <p>Even if a pharmacy is able to cover as-yet unknown licensing costs for its pharmacists and schedule Kentucky-licensed pharmacists to cover all shifts, unplanned illnesses or emergencies may prevent a pharmacist from working on any given day. The pharmacy would then have to halt any care for Kentucky patients while another Kentucky-licensed pharmacist is identified. Any potential delay, halt, or disruption in treatment access for patients with specialty conditions threatens their health and livelihood. Without access to their specialty pharmacy and medications, a patient could face immense setbacks in their treatment, leading to increased emergency room visits, hospital admissions, healthcare costs, or worse.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p> <p>We believe that you can find solutions and implement non-resident licensure well.</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support</p>	
<p>Ela Lourido, Vice President/General Manager, Biologics by McKesson</p> <p>Of note, the Kentucky Board has no oversight over the fees charged by the NABP Verify program. Tying nonresident pharmacy compliance to this external entity's credentialing and fees process has unknowable financial impact on pharmacists and pharmacies alike.</p>	<p>We want to work in lockstep with our NABP partners, but at any point we believe a cost is unreasonable or would cause massive industry problems, we can remove this language from the regulation.</p>	<p>All states that utilize NABP for license transfer or initial licensing have fees tied to NABP regarding licensing.</p>	
<p>Ela Lourido, Vice President/General Manager, Biologics by McKesson</p> <p>Biologics acknowledges and understands that laws and regulations come with some degree</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However,</p>	<p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support</p>	

<p>of compliance burden and associated cost. Typically, those compliance burdens and associated costs serve a valid health, safety, or welfare purpose. These Proposed Rules, however, do not appear to effectively serve such a purpose. To the contrary, we are concerned that the Proposed Rules will make it harder to pharmacies and pharmacists located within and outside of Kentucky to pursue normal operations and in turn, effectively serve Kentucky patients.</p>	<p>I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	<p>pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	
<p>Ela Lourido, Vice President/General Manager, Biologics by McKesson Adding supplementary administrative requirements and financial burdens through state-specific licensing applications and fees does not impart any additional knowledge or improve individuals' ability to deliver patient care. Instead, these requirements merely add to the long list of growing obligations that are now becoming synonymous with the practice of pharmacy. To make matters worse, these proposed changes may cause many nonresident pharmacies to cease dispensing into Kentucky, leaving already stretched resident Kentucky pharmacies and pharmacists to absorb that volume, which will lead to delays in patient care and an increase in pharmacist burnout.</p>	<p>Every pharmacy is faced with a new challenge everyday with workflow and challenges to workflow. Pharmacists live through this every day. We work together to make system changes to improve conditions. We feel certain that entities that want to provide this important service will continue to do so.</p> <p>Patient care is and should always be our primary concern. Pharmacy has become very global. Our structure/regulation of pharmacy as a multi-state actor is behind. This is an important step to</p>	<p>The administrative and financial requirements are to provide the Board with jurisdiction over each pharmacist dispensing drugs into the Commonwealth. Jurisdiction is key to ensure that Kentucky patients are safe.</p> <p>Imposing this requirement may indeed limit access if pharmacists chose not to pursue licensure. However, I'm not sure there is data to support pharmacists will not pursue licensure. While our current licensure and reciprocity process is effective and efficient, the use of NABP Verify creates an expedited pathway to licensure to increase access.</p>	

	<p>ensure that Kentucky has jurisdiction over those pharmacists dispensing into the state of Kentucky to ensure our patients are protected. We have to protect our consumers; we cannot rely on someone else to do it. We cannot choose not to fulfill our obligations because of the administrative burden placed on pharmacies</p>		
<p>Ela Lourido, Vice President/General Manager, Biologics by McKesson</p> <p>Nonresident pharmacist licensure is at odds with the longstanding regulatory framework in Kentucky and every other state. Virtually every state, including Kentucky, requires a nonresident pharmacy to hold a state-issued facility license if it dispenses medications to patients in that state. Eighteen states, including Kentucky, also require licensure of a single pharmacist-in-charge (“PIC”) who is responsible for ensuring proper oversight of the pharmacy staff and compliance with any relevant nonresident state’s laws. However, other pharmacists in the facility are not required to hold pharmacist licenses in nonresident states.</p>	<p>The practice of pharmacy has changed and we have adjusted our regulations accordingly to ensure the patients of Kentucky are safe.</p>		