



December 8, 2021

North Carolina Office of Administrative Hearings
Rules Review Commission
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Board of Pharmacy Rulemaking Coordinator
Clinton R. Pinyan
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Sent via email.

Re: SUBMISSION OF WRITTEN COMMENTS CONCERNING PERMANENT RULES TO THE RRC

Dear Rules Review Commission and Board of Pharmacy Rulemaking Coordinator,

The purpose of this letter is to provide written comments concerning a permanent rule for consideration in front of the Rules Review Commission ("RCC"). Specifically, Board of Pharmacy rule 21 NCAC 46.1816, which address the Procedures for Centralized Processing of Prescription Orders. CVS Health is submitting these written comments, under 26 NCAC 05 .0103(b), because the rule does not comply with the statutory grounds for the RRC's review set out in G.S. 150B-21.9. Per N.C.G.S.A. § 150B-21.9(a)(4), the Commission must determine whether a rule was adopted in accordance with Part 2 of this Article. "Part 2 of this article" includes the Adoption of Rules. Specifically, that the North Carolina Board of Pharmacy is trying to adopt a rule that differs substantially from the text of a proposed rule published in the North Carolina Register without publishing the text of the proposed different rule in the North Carolina Register and accepting comments on the proposed different rule, due to the inclusion of "NABP Verify" in the rule. In short, we believe the North Carolina Board of Pharmacy is violating the North Carolina Administrative Procedures Act under N.C.G.S.A. § 150B-21.2(g).

On July 20, 2021, the North Carolina Board of Pharmacy conducted a public hearing for the repeal of 21 NCAC 46 .1417, Remote Medication Order Processing Services, and an amendment to 21 NCAC 46.1816, Procedures for Centralized Processing of Prescription Orders. There were several concerns with the proposed amendments to 21 NCAC 46.1816, voiced during the July 20, 2021 and in writing, by many industry stakeholders including comments provided by CVS Health. Please refer to the minutes of the July 20, 2021 found at <http://www.ncbop.org/about/Agendas%20and%20Minutes/Minutes07.21.pdf> . Specifically, CVS Health opposed a proposed requirement for pharmacists and technicians employed by a permitted out-of-state pharmacy, engaged in the centralized processing of prescription orders, to be licensed or registered by the North Carolina Board of Pharmacy articulated in proposed rule 21 NCAC 46 .1816 (d)(3)(F). The objections



were due to the proposed rules presenting an unnecessary burden on pharmacies to optimize patient care for North Carolina patients and the proposed rule raising significant concerns with the requirements imposed on agencies in the rule-making process under N.C.G.S.A. § 150B-19.1.

First, we do not believe the North Carolina Board of Pharmacy had the statutory authority to require pharmacists and technicians employed by a permitted out-of-state pharmacy to be licensed or registered by the North Carolina Board of Pharmacy. Licensed out-of-state pharmacies are permitted to ship, mail, or deliver prescriptions into North Carolina, without the explicit authority to mandate personnel licensure in NC Statute 90-85.21A. If the North Carolina Legislature contemplated such authority, it would be articulated in statute, which it is not.

Second, the constraints in the proposed rules were not necessary to serve the public interest. N.C.G.S.A. § 150B-19.1(1) states that an agency may adopt only rules that are expressly authorized by Federal or State law and that are necessary to serve the public interest. CVS Health does not believe that adoption of the initially proposed rules was necessary to serve the public interest. Existing rules have been in place for over 20 years, without concern over whether they were adequate to protect the public health, safety, and welfare, which is the legislative charge of the Board of Pharmacy per N.C.G.S.A. § 90-85.2.

Third, the Board of Pharmacy's initial proposal would increase the burden upon those persons or entities who must comply with the rule. N.C.G.S.A. § 150B-19.1(2) states that an agency shall seek to reduce the burden upon those persons or entities who must comply with the rule. To the contrary, the burden on licensees encompassed in the proposed rule would significantly increase. An out-of-state pharmacy would have to facilitate the licensure and registration of all pharmacy personnel within the domicile state of the pharmacy, as well as the State of North Carolina. This may place existing and prospective licensees in a position to make decisions as to whether performing these functions for North Carolina patients would be too cumbersome to comply with, which may present North Carolina patients with an unnecessary barrier to prescription medication access.

Lastly, the proposed rules were not based on sound, reasonably available scientific, technical, economic, and other relevant information under N.C.G.S.A. § 150B-19.1(5), which is a standard that CVS Health does not believe has been met. The reason for the proposed action posted by the Board, indicates that the rule changes would consolidate two existing rules (21 NCAC 46 .1417 and 21 NCAC .1816) into one rule that governs situations where two pharmacies provide services with respect to a prescription, among other substantive changes. This description is misleading in its simplicity. To date, the Board has not produced any evidence or data to support the proposed rules would further foster public safety as opposed to the existing rules.

On November 9, 2021, the North Carolina Board of Pharmacy held a meeting where the Board voted to adopt a revision to the proposed rule, based on public comment. This meeting was set to be an in-person meeting but changed on November 5, 2021 to a "conference call", which was a deviation from the usual live link accessible via YouTube. The call was filled with static and very difficult for the public and pharmacy stakeholders to hear or participate. What could be heard is that the Executive Director of the Board of Pharmacy and the Board attorney recommending that the Board vote to approve the updated proposed rules and not republish for public comment because the changes were not "substantial". The primary change was an alternative to the requirement for pharmacists and technicians employed by a permitted out-of-state pharmacy to be licensed or registered by the North Carolina Board of Pharmacy by registering through a program called "NABP Verify". While the change on its face seems small, the addition of NABP Verify is a substantial, unknown, difference and justifies these rules being republished for public comment to debate its merits.



First, the public, which includes pharmacy stakeholders, does not know what NABP Verify is. It is not posted online. It is not currently in effect. Pharmacies do not know what the fiscal impact would be and essentially, the Board of Pharmacy is proposing to incorporate a tool by reference in the regulation that, in the eyes of the pharmacy industry, is yet to come into existence. By incorporating NABP Verify by reference, every time the program changes, the rule essentially changes without the public having the ability to comment on those changes. We believe, National Association of Boards of Pharmacy (“NABP”) Verify is likely a verification program to determine if a pharmacist, pharmacy intern, or pharmacy technician’s license is in good standing. We also believe, the applicant’s license will be subject to ongoing monitoring to ensure an active status in good standing. Of specific concern is whether applicants will need to pay an annual fee for the initial verification and ongoing monitoring. The Boards of Pharmacy would need to enter into a Memoranda of Understanding (“MOU”) with NABP, which would define the responsibilities for both NABP and the participating states as part of the NABP Verify program and require that participating states to report disciplinary actions against licenses to a central repository.

If there are fees or subscription costs associated with NABP Verify, it will likely be passed onto their respective employers, who include licensees of the North Carolina Board of Pharmacy. When compounded over several employees across the country, who may be participating in the centralized processing of prescription orders for North Carolina pharmacies and patients, this is a sizable expense annually. Furthermore, there is a cost associated with the ongoing monitoring and operational processes a pharmacy licensee would need to undertake for their employees to participate in the program. Since only North Carolina licensees or NABP Verify credentialed persons may participate in the centralized processing of prescription orders for North Carolina pharmacies and patients, efforts need to be taken to exclude those individuals that are not credentialed. This has a negative fiscal impact to pharmacies and negative overall impact to North Carolina patients if they cannot be serviced due to the inability to comply with these rules and this unknown program. Therefore, we believe a fiscal impact analysis needs to be conducted to account for these expenses.

Lastly, as it applies to NABP Verify, a state may direct NABP to remove a NABP Verify credential holder from active status in the state if the credential holder failed to comply with state or federal laws or rules applicable to the practice of pharmacy in the state. In essence, the use of NABP Verify is a mechanism for the North Carolina Board of Pharmacy to extend its reach across state lines and effect the employment and reputation of an out of state pharmacy employee by removing that individual’s NABP Verify credential. This process will allow for a Board of Pharmacy to gain interstate power that was likely not contemplated by state legislatures. In essence, a Board of Pharmacy under this circumstance would create jurisdiction over an out of state pharmacist, pharmacy intern or pharmacy technician, where no statutory jurisdiction currently exists. If an NABP Verify credential is inactivated, there is no known established way to appeal the decision of that Board of Pharmacy. Furthermore, the ability to directly affect the employment and reputation of an out of state pharmacy employee may be viewed as an undue interference in interstate commerce, which is prohibited under the Dormant Commerce Clause of the United States Constitution.

The motivations for including NABP Verify in the second iteration of these proposed rules and the lack of taking this proposal to public comment are questionable. The Board of Pharmacy put forth a process whereby the initial proposed rules were made available for public comment that pharmacy stakeholders would heavily comment against and did. Subsequently, any changes would appear to be a non-substantial change to the rule in a further iteration and therefore allow for the Board of Pharmacy to adopt this rule without further public comment from said pharmacy stakeholders.



In May of 2019, NABP, then led by the current Executive Director of the Board of Pharmacy, committed to exploring opportunities to expand licensure portability. Specifically, a plan was put in place to pursue expansion of NABP's Electronic Licensure Transfer Program by developing a model that addresses current interstate activities and practices. This initiative would include developing an interstate endorsement to expedite the licensure process by offering credible alternatives to certain, existing requirements. This led to the establishment of a "work group" in September of 2019, to study the feasibility of an interstate endorsement credential. Two years later, without any input or knowledge from the public, outside of a small workgroup, or any other state incorporating NABP Verify, the Board of Pharmacy proposes to make North Carolina the first state to incorporate by reference an NABP initiative that no one understands, and the public, including pharmacy stakeholders, does not have the ability to comment on.

The North Carolina Board of Pharmacy is trying to adopt a rule that differs substantially from the text of a proposed rule published in the North Carolina Register without publishing the text of the proposed different rule in the North Carolina Register and accepting comments on the proposed different rule. For all the aforementioned reasons, the inclusion of "NABP Verify", while insubstantial in word count, does differ substantially in substance. NABP Verify, is subject matter that is being included by reference into a rule, that is subject matter that is not addressed in the proposed text of the rule. Furthermore, the inclusion of NABP Verify produces an effect that could not reasonably have been expected based on the proposed text of the rule. In short, we believe the North Carolina Board of Pharmacy is violating the North Carolina Administrative Procedures Act under N.C.G.S.A. § 150B-21.2(g).

CVS Health formally requests that the Rules Review Commission not approve the amendments to 21 NCAC 46.1816, so that a proper fiscal analysis may be conducted, and the public have an opportunity to review and comment on the rules.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Lavino", written over a horizontal line.

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