

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In The Matter Of:

**Pharmacy Permit Application of
Elite Rx**

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**ORDER DENYING
PERMIT APPLICATION**

THIS MATTER came before the North Carolina Board of Pharmacy (“Board”) on the application of Jeffrey Khleif, as pharmacist-manager of Elite Rx, 135 Gemini Circle, Suite 201, Birmingham, Alabama 35209 (“Petitioner”), to obtain an out-of-state pharmacy permit. This matter was heard on January 21, 2014 by the Board located at 6015 Farrington Rd., Suite 201, Chapel Hill, North Carolina, before Board members Minton, Marks, McLaughlin, Chesson, Day, and Mixon. Having heard the evidence presented and assessed the credibility of the testifying witnesses, the Board makes the following:

FINDINGS OF FACT

1. Elite Rx is a pharmacy located at 135 Gemini Circle, Suite 201, Birmingham, Alabama 35209.
2. On August 13, 2014, Jeffrey Khleif, a pharmacist licensed by the Alabama Board of Pharmacy and the identified pharmacist-manager of Elite Rx, filed an application to obtain a North Carolina out-of-state pharmacy permit.
3. The application included a required Pharmacy Services Affidavit, which Mr. Khleif signed. By signing the affidavit, Mr. Khleif acknowledged his understanding that “under North Carolina law . . . the North Carolina Board of Pharmacy . . . may ‘suspend, revoke, or

refuse to grant or renew any permit' if any person has '[m]ade false representations or withheld material information in connection with securing a license or permit."

4. By signing the affidavit, Mr. Khleif acknowledged understanding that "the information sought in this Affidavit by the Board is material to the Board's determination of whether to issue a permit to the Applicant Pharmacy."

5. Question 5 on the Pharmacy Services Affidavit asked: "Does the Applicant Pharmacy engage, or will the Applicant Pharmacy engage, in pharmacy compounding?" Mr. Khleif answered "Yes."

6. Question 8 on the Pharmacy Services Affidavit asked: "If the answer to inquiry number 5 is yes, are the Applicant Pharmacy's compounding practices accredited by any organization?" Mr. Khleif answered "No." Mr. Khleif further stated, however, "PCAB Accreditation [sic] In Progress."

7. PCAB is an acronym for the Pharmacy Compounding Accreditation Board, an organization that, as the name suggests, provides an accreditation program for compounding pharmacies.

8. As a result of Mr. Khleif's statement, on August 26, 2013, Board staff contacted PCAB to inquire about Elite Rx's accreditation progress. PCAB reported that Elite Rx had not applied for PCAB accreditation and that PCAB had received no information from Elite Rx.

9. On October 29, 2013, Ryan Robnett, the owner of Elite Rx, sent a letter to the Board that sought to "clarify" statements made by Mr. Khleif in the Pharmacy Services Affidavit. Mr. Robnett stated: "We have yet to submit our PCAB application, but have spent the past several months preparing/updating SOP's to prepare for the application process. Our intent on the

original affidavit was simply to inform you of our intent to submit our application to PCAB in the near future and that we are in the process of preparing.”

10. Mr. Robnett did not sign the Pharmacy Services Affidavit. Mr. Khleif testified, however, that Mr. Robnett’s letter correctly stated Mr. Khleif’s position.

11. The Board does not find Mr. Khleif’s explanation credible. The Board finds that Mr. Khleif’s statement on the Pharmacy Services Affidavit – “PCAB accredi[t]ation in progress” – is false and misleading. Mr. Khleif’s statement communicated to the Board that Elite Rx had applied for PCAB accreditation and that an accreditation review by PCAB was in progress. Neither circumstance was true.

12. If, as Mr. Khleif testified, he had merely sought to inform the Board of Elite Rx’s “intent to submit our application to PCAB in the near future,” he could have so stated. Instead, Mr. Khleif stated that PCAB accreditation was “in progress,” a statement that cannot reasonably be read as one of intent to begin an application process at some point in the future. Moreover, Mr. Khleif’s testimony that he made this statement because compounding pharmacies were “under the microscope” tends to confirm that he intended the false and misleading statement to provide the Board with reassurance about the quality and competency of Elite Rx’s compounding practices.

13. Question 1 on the Pharmacy Services Affidavit asked “Has the Applicant Pharmacy, any pharmacist affiliated with the Applicant Pharmacy, or any pharmacy technician affiliated with the Applicant Pharmacy ever been subject to discipline by any licensing, permitting, or other regulatory authority, federal or state?” Mr. Khleif answered “Yes.”

14. Question 1 further states that “[i]f the answer ‘yes,’ please attach all relevant documents concerning this discipline, including the charging document, any order or letter issued

by the disciplining body, and any decision issued by a court, administrative law judge, or other adjudicatory body” Mr. Khleif attached an October 14, 2009 final order of the Alabama Board of Pharmacy issued to Stephen John Newton, a pharmacist practicing at Elite Rx. That order noted that on February 28, 2005, Mr. Newton’s license to practice pharmacy in Alabama was suspended. The October 14, 2009 order converted Mr. Newton’s suspension to a five-year probationary period. The October 14, 2009 order did not state the facts underlying Mr. Newton’s 2005 suspension, and Mr. Khleif did not submit the Alabama Board’s February 28, 2005 suspension order.

15. Mr. Khleif testified that he did not know the facts or basis for the Alabama Board of Pharmacy suspension of Mr. Newton’s license in 2005.

16. Mr. Khleif testified that Mr. Newton is the pharmacist at Elite Rx tasked with creating and maintaining standard operating procedures and documentation concerning Elite Rx compounding practices.

17. Because Mr. Khleif did not produce documentation of the facts underlying Mr. Newton’s suspension, and because Mr. Khleif was unable to testify as to the facts underlying Mr. Newton’s suspension, the Board is unable to make a determination as to Mr. Newton’s fitness to provide pharmacy services to North Carolina residents or his fitness to oversee critical compounding procedures and documentation at Elite Rx.

CONCLUSIONS OF LAW

Petitioner “made false representations or withheld material information in connection with securing a license or permit.” N.C.G.S. § 90-85.38(a)(1).

Petitioner has not satisfied his burden to demonstrate to the Board that "at all times qualified personnel have been secured . . . to properly render pharmaceutical service in the manner prescribed by law." 21 N.C.A.C. 46.1601.

IT IS, THEREFORE, ORDERED that Petitioner's application to obtain an out-of-state pharmacy permit is **DENIED**.

This the 21st day of January, 2014.

NORTH CAROLINA BOARD OF PHARMACY

By: _____


Jack W. Campbell IV
Executive Director