

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF)
)
OUT-OF-STATE PERMIT) **FINAL CONSENT ORDER**
APPLICATION OF CARDINAL)
HEALTH 414, LLC)
_____)

THIS MATTER came on to be heard before the North Carolina Board of Pharmacy (the “Board”) at a prehearing conference on June 18, 2012, on the consent of the parties. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, the permit applicant, Cardinal Health 414, LLC (“Cardinal”), located at 2820 Middlebrook Pike, Suite 101, Knoxville, Tennessee, waives its right to appeal this Final Consent Order. Cardinal also stipulates that the findings of fact and conclusions of law are legally sufficient to support this Final Consent Order and agrees not to challenge the legal adequacy of the findings and conclusions in any potential future proceeding regarding this Final Consent Order. With the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. Cardinal is a limited liability company that was formed as Cardinal Health 414, Inc. on October 15, 1985, and converted to a limited liability company on June 30, 2007. Cardinal was organized under the laws of the State of Delaware. Cardinal operates a nuclear pharmacy located in Knoxville, Tennessee. Cardinal holds a pharmacy permit in the State of Tennessee and an out-of-state permit in the Commonwealth of Kentucky.

2. Cardinal makes the following representations: Cardinal Health 414, LLC also operates nuclear pharmacies in a number of other states, including North Carolina. In November 2011, the Cardinal permit applicant began to consider applying for a North Carolina permit, with the plan that it would serve as a contingency option in the event that Cardinal's North Carolina pharmacies could not service their customers. On November 23, 2011, before Cardinal had completed its application for a North Carolina permit, Cardinal's North Carolina PET manufacturing facility suffered from equipment malfunctions that prohibited it from manufacturing Fluorodeoxyglucose (F-18 FDG). Because the manufacturing facility was down, Cardinal's North Carolina nuclear pharmacy was unable to fulfill four orders for F-18 FDG. Due to the exigency, the Cardinal permit applicant fulfilled those orders without an out-of-state pharmacy permit having been issued under North Carolina General Statutes § 90-85.21A. At no other time has this Cardinal permit applicant shipped, mailed or dispensed prescription drugs into the State of North Carolina.

3. On December 28, 2011, Cardinal submitted an out-of-state permit application in which it truthfully disclosed that it had previously shipped prescription drugs into the State of North Carolina without an out-of-state pharmacy permit.

4. The Board accepts Cardinal's representation that the permit applicant has made only one shipment consisting of 4 prescriptions into the State of North Carolina, and that shipment was made on November 23, 2011.

5. As of the date of this order, Cardinal does not operate an Internet Pharmacy as defined in 21 NCAC 46 .1317(17).

6. With respect to the prior prescriptions shipped into North Carolina, the Board is unaware of instances where Cardinal and its pharmacists actually knew or reasonably should

have known that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship in violation of 21 NCAC 46 .1801(b) or otherwise was not a valid prescription, and Cardinal represents that there were no such instances.

7. Cardinal represents and the Board accepts that Cardinal has never had any disciplinary action or investigation by any federal or state pharmacy regulatory authority involving this pharmacy or any of the pharmacists associated with this Cardinal pharmacy.

CONCLUSIONS OF LAW

Based on the above findings, the Board concludes as a matter of law:

1. Cardinal violated North Carolina General Statutes §§ 90-85.21A and 90-85.38(b) by shipping prescription drugs into the State of North Carolina without an out-of-state pharmacy permit on November 23, 2011.

2. Respondent admits that the conduct in this matter violated North Carolina law and constitutes sufficient grounds for disciplinary action in connection with its permit application under North Carolina General Statutes § 90-85.38.

3. The Board has considered the following as substantial mitigating factors in this case:

- a. Cardinal's violations were of a very limited number and occurred on one day.
- b. Cardinal had a good faith belief that the shipments were justified by an exigency, although that belief was incorrect, because the shipments were illegal and the orders could have been transferred to another permitted pharmacy.

- c. The Board has no information that Cardinal and its pharmacists have ever shipped prescription drugs into the State of North Carolina in circumstances where they actually knew or reasonably should have known that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship in violation of 21 NCAC 46 .1801(b) or otherwise was not a valid prescription.
- d. Cardinal is not an Internet Pharmacy and otherwise does not have a business model that is likely to encourage or facilitate the shipment of drugs based on invalid prescriptions.

Based upon the foregoing, and with the consent of the parties, IT IS THEREFORE ORDERED that the permit application of Cardinal Health 414, LLC, is hereby GRANTED. However, the permit of Cardinal Health 414, LLC, is hereby INDEFINITELY SUSPENDED, but that suspension is stayed for a period of one year, upon the following conditions:

1. Respondent's permit is conditioned upon the accuracy of the information in its permit application, the information that it previously provided to the Board in connection with the review of the permit application, and the stipulated Findings of Fact above;
2. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs, whether federal, North Carolina or the laws of any other state;
3. Respondent shall violate no rules and regulations of the Board;

4. Respondent shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation and compliance with the provisions of this Consent Order.

This the 19th day of June, 2012.

NORTH CAROLINA BOARD OF PHARMACY

By: 
Jack W. Campbell, IV
Executive Director

Cardinal Health 414, LLC, has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Final Consent Order. The undersigned understands and agrees that by entering into this Final Consent Order, it certifies that it has read the foregoing Final Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter. The undersigned further understands that should it violate the terms and conditions of this Final Consent Order, the Board may take additional disciplinary action. The undersigned understands and agrees that this Final Consent Order will not become effective unless and until approved by the Board. The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Final Consent Order, and represents that it enters this Final Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel.

The undersigned certifies that its agent executing this Final Consent Order is duly authorized to accept the Final Consent Order on behalf of Cardinal Health 414, LLC, and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

CARDINAL HEALTH 414, LLC

Timothy A. Burriss Date 4/17/12

By: Timothy A. Burriss

Title: Territory Pharmacy Manager

STATE OF Tennessee

Knox COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that personally appeared before me this day, and each acknowledged the due execution of the foregoing document: Timothy A Burriss

[PRINT NAME OF INDIVIDUAL SIGNING]

Date: 4/17/2012

[Signature]
Notary Public

My commission expires: 10/28/2015

