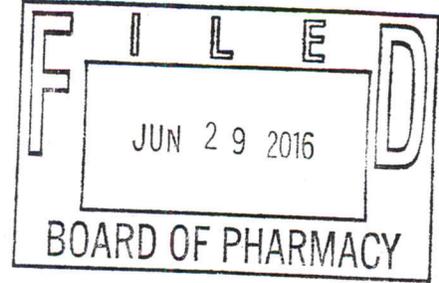


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STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF THE PERMIT OF :
:
INSPIRA MEDICAL CENTER - :
VINELAND :
Permit No. 28RS00586400 :
:
TO OPERATE AS A PHARMACY IN :
THE STATE OF NEW JERSEY :
:

Administrative Action
CONSENT ORDER

This matter was opened to the New Jersey State Board of Pharmacy (the "Board") upon receipt of information from the New Jersey Department of Health that the institutional pharmacy of Inspira Medical Center, located at 1505 West Sherman Avenue, Vineland, New Jersey ("Inspira"), did not immediately remove all recalled vials of Methylprednisolone Acetate ("MPA") after a voluntary recall of the product was issued by the New England Compounding Center ("NECC"). It was also alleged that four patients received injections of the recalled medication as a result of the failure to identify and remove all vial sizes of the recalled product.

Inspira has fully cooperated with the Board's investigation into this matter. Inspira informed the Board that on September 26, 2012, NECC notified Inspira that it was initiating a

voluntary recall of three lots of MPA due to possible contamination. Inspira advised that NECC made no mention of vial size, and based on the knowledge and past experience of the pharmacy staff, Inspira believed that only the 5mL vials of MPA were affected. As a result, Inspira removed and quarantined only the 5mL vials; the 1mL vials were neither checked for lot number nor quarantined. From September 26 through October 4, 2012, four patients received injections of the recalled product from 1mL vials. Inspira notified and followed the patients consistent with the requirements of the New Jersey Department of Health and the United States Centers for Disease Control and Prevention to ensure they remained asymptomatic. Subsequent to these incidents, in February 2013, Inspira instituted enhanced policies and procedures to ensure compliance with any future recalls and all applicable laws.

The Board finds that Inspira's failures to remove recalled product from its inventory on a timely basis constitute violations of N.J.A.C. 13:39-9.10(b) and N.J.A.C. 13:39-9.23(c), and provide a basis for disciplinary action against its permit to operate a pharmacy in New Jersey pursuant to N.J.S.A. 45:1-21(h).

The parties having agreed to the resolution of this matter without further formal proceedings, and the Order fully resolving and concluding the Board's investigation of Inspira's handling of the recall of MPA in September and October 2012 as to Inspira and its personnel that are regulated by the Board, and Inspira having agreed to the within Order and waiving any right to a hearing in this matter, and the Board finding the within disposition adequately protective of the public health, safety and welfare and other good cause having been shown;

IT IS, therefore on this 29th day of JUNE, 2016,

ORDERED AND AGREED THAT:

1. Inspira is hereby assessed civil penalties, pursuant to N.J.S.A. 45:1-25, in the amount of \$10,000. Payment shall be made contemporaneously with the signing of this order by certified check, bank check, money order, wire transfer or credit card payable to the State of New Jersey, delivered to Anthony Rubinaccio, Executive Director, State of Board of Pharmacy, P.O. Box 45013, Newark, New Jersey 07101. Any other form of payment cannot be accepted and will be returned to Inspira.

2. Inspira is hereby assessed costs of investigation in this matter in the amount of \$5,227.99. Payment for the costs shall be sent to Anthony Rubinaccio, Executive Director, at the address and in the form specified in paragraph 1, contemporaneously with the signing of this Order.

3. Inspira shall ensure that proper procedures are instituted to ensure compliance with the regulations and any future recalls of medication.

NEW JERSEY BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr., R.Ph.
Thomas F.X. Bender, Jr., R.Ph.,
President

I have read the within Order and agree to be bound by its terms. Consent is hereby given to the New Jersey Board of Pharmacy to enter this Order. I am authorized to sign this Order on behalf of Inspira.

John DiAngelo
John DiAngelo
Chief Executive Officer

4/3/16
Date

Consent is given as to form and entry of this Order.



Paul H. Zoubek, Esq.
Attorney for Inspira Medical Center-Vineland

6/23/16
Date