

IN THE MATTER OF * **BEFORE THE**
JOHNS HOPKINS * **MARYLAND**
BAYVIEW MEDICAL CENTER * **BOARD OF**
INPATIENT PHARMACY * **PHARMACY**
Permit No. P01092 *

* * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) conducted an annual inspection of Johns Hopkins Bayview Medical Center’s inpatient pharmacy (the “Pharmacy”), Permit No. P01092, on October 19, 2011, with a follow-up inspection on November 22, 2011. The inspection report indicated that the Pharmacy was not in compliance with Board regulations, specifically COMAR 10.34.19, and Federal USP 797 standards governing sterile compounding. The inspector noted that the Pharmacy’s sterile IV preparation room was out of compliance in a number of areas. The Board’s inspector informed the Pharmacy of the violations.

In lieu of instituting formal proceedings against the Pharmacy, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board held a Pre-Charge Case Resolution Conference (“CRC”) with the Pharmacy and its counsel on March 14, 2012. As a result, the Board and the Pharmacy have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. At all times relevant hereto, the Pharmacy possessed a Maryland pharmacy permit, Permit No. P01092, and operated on the hospital premises located at 4940 Eastern Avenue, Baltimore, Maryland.
2. On October 19 and November 22, 2011, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
3. The annual inspection noted that the Pharmacy was performing sterile compounding in a room that failed to meet the standards of COMAR 10.34.19 and USP 797 in the following ways:
 - a) The room lacked positive air pressurization;
 - b) There were four pass-through windows that were kept partially or completely open;
 - c) There were two-piece swing doors with gaps between the door and floor at the bottom and door and ceiling at the top;
 - d) The ceiling appeared to be porous;
 - e) The floor was not properly sealed;
 - f) Curved, metal, stand-alone shelving units on tracks for self-adjustment were built in front of structured walls and did not reach the ceiling;
 - g) Drugs and supplies were kept in the buffered area, and
 - h) The seats on the chairs in the room had ripped covers and exposed foam.
4. The Pharmacy was alerted to the violations at the time of the inspection.

5. Sometime between November 2011 and March 2012, before any further action was taken by the Board, the Pharmacy took steps to address the concerns noted by the Board's inspector.
6. At the CRC, the Pharmacy informed the Board of improvements it had made to its sterile IV preparation room:
 - a) Positive pressure was attained and a monitoring system was installed to monitor proper pressurization of the room;
 - b) An interlocking system was installed on the half-windows, and other windows have been locked;
 - c) The swing doors were lengthened to reach the floor and ceiling, and any remaining gaps were sealed;
 - d) The stand-alone shelving units were removed, and the tracks for the shelving units were either removed or covered with laminate;
 - e) Excess drugs and supplies were removed from the room; and
 - f) The chairs in the room were replaced.
7. The Pharmacy informed the Board that, although the ceiling may have appeared to be porous, the ceiling tiles were, in fact, clean room rated. The Pharmacy also informed the Board that the ceiling tiles were caulked to the support structure to ensure that any possible gaps were sealed.
8. Additionally, the Pharmacy informed the Board that the floor only appeared to be unsealed because of the removable shelving units.

9. The Board finds that the steps taken by the Pharmacy resolved the deficiencies related to COMAR 10.34.19 and USP 797 compliance noted by the Board at the annual inspection that took place on October 19 and November 11, 2011.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Pharmacy is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§12-403(b)(1) and (2), and COMAR 10.34.19.

ORDER

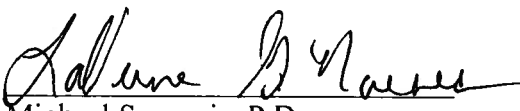
Based on an affirmative vote of a majority of the Board, it is this 24th day of May, 2012, hereby:

ORDERED that the Pharmacy shall pay a fine in the amount of \$1,000.00, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and be it further,

ORDERED that failure to pay in full the above fine within thirty (30) days of the date of this Order shall be considered a violation of this Order, and after notice and opportunity for a show cause hearing shall subject the Pharmacy to further discipline such as suspension, revocation or further fines based on the violations cited in this Order; and be it further,

ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to the Maryland Annotated Code, State Government Article, Section 10-617 (h).

May 24, 2012
Date

for 
Michael Souranis, P.D.
President, Maryland Board of Pharmacy

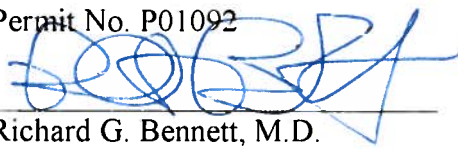
CONSENT

1. By signing this Consent, the Pharmacy submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded the Pharmacy the right to a full evidentiary hearing. The Pharmacy consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which the Pharmacy would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on the Pharmacy's behalf and to all other substantive and procedural protections provided by law.
2. By signing this Consent, the Pharmacy waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
3. The Pharmacy acknowledges that this is a formal order of the Board and as such is a public document.
4. The Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
5. The Pharmacy signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Pharmacy fully understands the language, meaning, and effect of this Consent Order.
6. I affirm that I am a duly authorized representative of the Pharmacy and am legally authorized to sign this Consent Order on behalf of the Pharmacy.

Date

5/13/12

JOHNS HOPKINS BAYVIEW MEDICAL
CENTER INPATIENT PHARMACY
Permit No. P01092


Richard G. Bennett, M.D.
President, Johns Hopkins Bayview Medical
Center

STATE OF MARYLAND
COUNTY/CITY OF Howard :

I hereby certify that on this 15th day of May, 2012,
before me, a Notary Public of the State of Maryland and County/city aforesaid, personally
appeared RICHARD G. BENNETT, M.D, on behalf of JOHNS HOPKINS BAYVIEW
MEDICAL CENTER INPATIENT PHARMACY, and made an oath in due form that the
foregoing Consent was his voluntary act and deed.

Kimberly Monson
Notary Public
My commission expires: 9/22/14