

IN THE MATTER OF * **BEFORE THE**
SOUTHERN MARYLAND * **MARYLAND BOARD**
HOSPITAL * **OF PHARMACY**
Permit No. P00763 *

* * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Southern Maryland Hospital's pharmacy (the "Pharmacy"), Permit No. P00763, on March 2, 2011. The inspection report indicated that the Pharmacy was not in compliance with Board regulations (COMAR 10.34.19) and Federal USP 797 standards governing sterile compounding. Specifically, the inspector noticed that the Pharmacy was performing sterile compounding of hazardous drugs in a non-negative pressure room. The Board's inspector informed the Pharmacy of the violation.

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 with the Pharmacy and its counsel on August 31, 2011. 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. P00763, and operated on the hospital premises located at 7503 Surratts Road, Clinton, Maryland.
2. On March 2, 2011, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
3. The March 2, 2011 inspection noted that the Pharmacy was performing sterile compounding of chemotherapy drugs in a non-negative pressure room. The Pharmacy was alerted to the violation.
4. Sometime in April 2011, before any further action was taken by the Board, the Pharmacy began to compound chemotherapy drugs using closed system transfer devices (CTSDs) within a biological safety cabinet (BSC). According to Federal USP 797 standards, it is acceptable for facilities that prepare a low volume of hazardous drugs to do the compounding using two tiers of containment (e.g., CTSD within a BSC) in a non-negative pressure room. Board regulations require that pharmacies that perform sterile compounding using cytotoxic agents do so “consistent with USP 797 Standards.” COMAR 10.34.19.09(B)(4).
5. The Pharmacy prepares a low volume of chemotherapy drugs, at an average of one regiment (3 chemotherapy bags) per week.
6. The Pharmacy’s self-corrective action brought them into compliance with Board regulations and Federal USP 797 standards as of April 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), (2), and (11), and COMAR 10.34.19.09.

ORDER

Based on an affirmative vote of a majority of the Board, it is this 15th day of Nov., 2011, hereby:

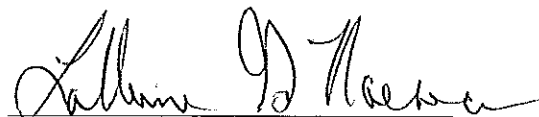
ORDERED that the Pharmacy shall pay a fine in the amount of \$500.00, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and be it further,

ORDERED that the Pharmacy shall submit to the Board documentation establishing that its employees are fully trained in compounding hazardous drugs using closed system transfer devices in a biological safety cabinet within thirty (30) days of the date of this Order; and be it further,

ORDERED that failure to pay in full the above fine or submit the above-mentioned documentation 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).

Date 11/15/11


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

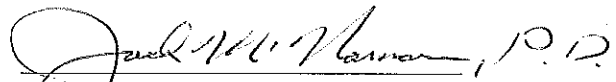
CONSENT

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 the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order.
4. 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.

SOUTHERN MARYLAND HOSPITAL

Permit No. P00763

Date 10/31/2011


Jack McNamara, P.D.
Title: DIRECTOR OF PHARMACY

STATE OF MARYLAND
COUNTY/CITY OF

Prince Georges

I hereby certify that on this 31st day of October, 2011,
before me, a Notary Public of the State of Maryland and County/city aforesaid, personally
appeared JACK McNAMARA, on behalf of SOUTHERN MARYLAND HOSPITAL, and
made an oath in due form that the foregoing Consent was his voluntary act and deed.

Case A. Humphreys

Notary Public

My commission expires:

April 16, 2013