

IN THE MATTER OF \* BEFORE THE  
FORT WASHINGTON \* MARYLAND  
MEDICAL CENTER \* BOARD OF  
PHARMACY \* PHARMACY  
Permit No. P01619 \*

\* \* \* \* \*

**PRE-CHARGE CONSENT ORDER**

**Background**

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Fort Washington Medical Center's pharmacy (the "Pharmacy"), Permit No. P01619, on February 25, 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 noted that the Pharmacy was performing sterile compounding without a required clean room or anteroom area.

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 24, 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. P01619, and operated on the medical center premises located at 11711 Livingston Road, Fort Washington, Maryland.
2. On February 25, 2011, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
3. The February 25, 2011 inspection noted that the Pharmacy was performing sterile compounding using an LAW hood without a clean room or anteroom area. The Pharmacy was alerted to the violation.
4. The Pharmacy has been awaiting the expansion of the medical center prior to building the clean room and anteroom area for the Pharmacy. The Pharmacy performed a gap analysis to identify deficiencies in compliance. While the Pharmacy has not resolved the deficiencies, it has taken some steps towards resolution and appeared at the Pre-Charge Case Resolution Conference with proposals to bring the Pharmacy into compliance.
5. The Pharmacy performed environmental testing on an inconsistent basis.
6. The Pharmacy does not compound chemotherapy solutions or sterile pediatric products.
7. The Pharmacy compounds a low volume of sterile preparations, approximately 15-25 per day. The majority of the Pharmacy's sterile preparations are purchased pre-mixed.

**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 11<sup>th</sup> day of January, 2012, hereby:

**ORDERED** that the Pharmacy shall pay a fine in the amount of \$2,000.00, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and be it further,

**ORDERED** that the Pharmacy install and certify a compounding aseptic isolator within sixty (60) days of the date of this Order; and be it further,

**ORDERED** that the Pharmacy shall conduct training and testing of pharmacy staff on the compounding aseptic isolator prior to its use; and be it further,

**ORDERED** that, within sixty (60) days of the date of this Order, the Pharmacy shall develop a training and performance evaluation program in accordance with COMAR 10.34.19.14;

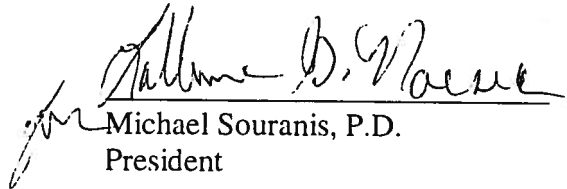
**ORDERED** that the Pharmacy shall submit to the Board documentation evidencing compliance with the above terms within sixty (60) days of the date of this Order; and be it further,

**ORDERED** that failure to pay the above fine or fully comply with the terms of this Order shall be considered a violation of this Order, and after notice and opportunity for a show

cause hearing may subject the Pharmacy to further discipline such as suspension, revocation or additional 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 1/11/12

  
Michael Souranis, P.D.  
President

**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.

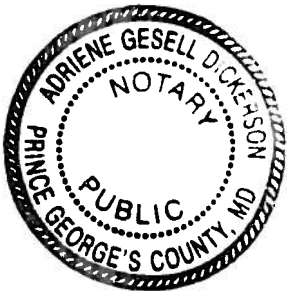
FORT WASHINGTON  
MEDICAL CENTER  
Permit No. P01619

12/13/2011  
Date

Verna S. Meacham  
Verna S. Meacham,  
President and CEO

STATE OF MARYLAND  
COUNTY/CITY OF PG/Fort Washington

I hereby certify that on this 13<sup>th</sup> day of December, 2011, before me, a Notary Public of the State of Maryland and County/city aforesaid, personally appeared VERNA S. MEACHAM, on behalf of FORT WASHINGTON MEDICAL CENTER, and made an oath in due form that the foregoing Consent was her voluntary act and deed.



Adriene M. Dickerson  
Notary Public  
My commission expires: 6/16/14