

IN THE MATTER OF * BEFORE THE
ADVENTIST REHABILITATION * MARYLAND BOARD
HOSPITAL * OF PHARMACY
Permit No. P02549 *

* * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Adventist Rehabilitation Hospital's pharmacy (the "Pharmacy"), Permit No. P02549, on May 8, 2012. 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 did not keep required cleaning records, did not complete media fill testing or other personnel monitoring, and did not have personnel competency records on file. The Board's inspector informed the Pharmacy of these 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 on April 10, 2013. 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 P02549, and operated on the hospital premises located at 9909 Medical Center Drive, Rockville, Maryland.

2. On May 8, 2012, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
3. The May 8, 2012 inspection noted that the Pharmacy was not keeping required daily, weekly, or monthly training logs; that personnel competency training was not being completed every twelve months; and that the Pharmacy was not performing media fill testing. The Pharmacy was alerted to these violations.
4. At the CRC, the Pharmacy provided detailed documentation demonstrating corrective actions taken to address the deficiencies noted in the Board's inspection. The Pharmacy provided substantial records related to personnel competency, personnel monitoring (including medial fill and fingertip touch testing), and cleaning of the pharmacy.
5. The Pharmacy is located in a 77 bed acute care hospital. The majority of the IV bags dispensed by the Pharmacy in 2012 were "point of care activated devices," which are not assessed for USP 797 risk levels. The Pharmacy compounded approximately 1.3 low risk level IV bags per day in 2012.

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 (13), and COMAR 10.34.19.07 and .14.

ORDER

Based on an affirmative vote of a majority of the Board, it is this 17th day of July, 2013, 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 be subject to a random follow-up inspection within six (6) months following 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,

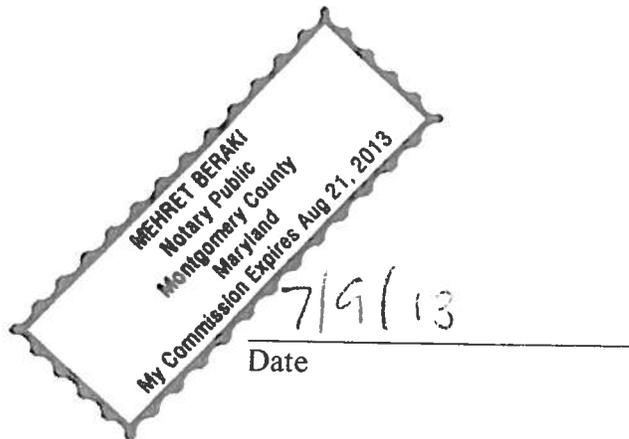
ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to the Maryland Annotated Code, State Government Article, Section 10-617 (h).

Date 7/19/2013

M. Souranis
-Michael Souranis, P.D. *Leanna Skutisnik*
President *Jamye Chian*

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.



07.09.13

ADVENTIST REHABILITATION
HOSPITAL
Permit No. P02549

Valerie Mull R.P.H.
Valerie Mull, R.Ph.
Director of Pharmacy

Debra King
Debra King, M.B.A., C.N.C.
Associate Vice-President

STATE OF MARYLAND
COUNTY/CITY OF MONTGOMERY

I hereby certify that on this _____ 9th day of July, 2013,
before me, a Notary Public of the State of Maryland and County/city aforesaid, personally
appeared VALERIE MULL, on behalf of ADVENTIS REHABILITATION HOSPITAL,
and made an oath in due form that the foregoing Consent was her voluntary act and deed.

Mehret Beraki (MEHRET BERAKI)
Notary Public

My commission expires: Aug 21, 2013

