

IN THE MATTER OF * BEFORE THE
MILLENNIUM PHARMACY * MARYLAND
SYSTEMS, INC. * BOARD OF
* PHARMACY
PERMIT NO. PW0299 *

* * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Millennium Pharmacy Systems, Inc. (the "Pharmacy"), Permit No. PW0299, on July 28, 2011. The inspection report indicated that the Pharmacy was not in compliance with the Board's regulations, COMAR 10.34.19, and federal USP 797 standards governing sterile compounding. Specifically, the inspector noted that the Pharmacy lacked appropriate air quality monitoring, a documented quality assurance program, and certain required policies and procedures were not available upon inspection.

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 March 21, 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. PW0299, and operated on the premises located at 202 Perry Parkway, Suite 8, Gaithersburg, Maryland.
2. On July 28, 2011, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
3. The July 28, 2011 inspection noted that the Pharmacy was lacked a appropriate air quality monitoring, a documented quality assurance program, and failed to provide policies and procedures relating to staff training and competency in accordance with COMAR 10.34.19. The Pharmacy was alerted to the violations.
4. The Pharmacy moved to a new location in Columbia, Maryland in March 2012. The Pharmacy has passed the Board's initial opening inspection at the new location.
5. The Pharmacy has submitted policies and procedures to the Board addressing quality assurance and staff training and competency evaluation in compliance with the Board's sterile compounding regulations.
6. The Pharmacy has installed a HEPA air filter system at its new Columbia location.
7. The Pharmacy does not prepare total parental nutrition products or chemotherapy solutions.
8. 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.

ORDER

Based on an affirmative vote of a majority of the Board, it is this 14th day of May, 2012, hereby:

ORDERED that the Pharmacy shall pay a fine in the amount of \$1,500.00, payable to the Maryland Board of Pharmacy, within sixty (60) days of the date of this Order; and be it further,

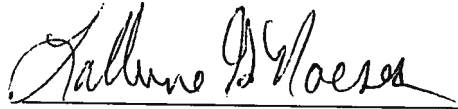
ORDERED that the Pharmacy shall develop and submit to the Board within sixty (60) days of this Order a Quality Assurance checklist that outlines the Pharmacy's QA measures with defined frequencies; and be it further,

ORDERED that the Pharmacy shall be re-inspected within 6-8 months 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 civil monetary penalties; 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).

5/14/2012
Date

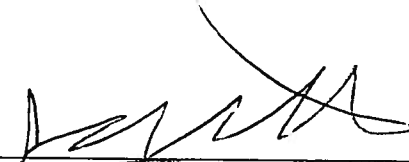

Michael Souranis, P.D.
President

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.

MILLENNIUM PHARMACY
SYSTEMS, INC.
Permit No. PW0299

5-11-12
Date


Name: James C. Luthin
Title: CEO & EVP

STATE OF ILLINOIS
COUNTY/CITY OF DU PAGE:

I hereby certify that on this 11th day of May, 2012,
before me, a Notary Public of the State of Illinois and County/city aforesaid, personally
appeared James C. Luthin, on behalf of MILLENNIUM PHARMACY SERVICES, INC.,
and made an oath in due form that the foregoing Consent was his/her voluntary act and deed.


Notary Public
My commission expires:

