

RECEIVED
MAY 21 2012
Board of Pharmacy

IN THE MATTER OF *
HEALTHSOUTH CHESAPEAKE *
REHAB HOSPITAL PHARMACY *
Permit No. PW0301 *

BEFORE THE
MARYLAND BOARD
OF PHARMACY

* * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of HealthSouth Chesapeake Rehab Hospital's pharmacy (the "Pharmacy"), Permit No. PW0301, on March 4, 2011. The inspection report indicated that the Pharmacy was not in compliance with Board regulations, contained in COMAR 10.34.19, and Federal USP 797 standards governing sterile compounding. Specifically, the inspector noticed that the Pharmacy was performing sterile compounding in a clean room that was not up to standards, and that the Pharmacy was unable to provide documentation of staff training in sterile processes. The Board's inspector informed the Pharmacy of the violations.

In lieu of instituting formal proceedings against the Pharmacy, the Board sent the Pharmacy a letter highlighting the various deficiencies on June 22, 2011. In response, the Pharmacy sent the Board two letters, dated July 18, 2011, and August 26, 2011, setting forth a proposed action plan to address the stated deficiencies. As a result of these communications, 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. PW0301, and operated on the hospital premises located at 220 Tilghman Rd., Salisbury, Maryland.
2. On March 4, 2011, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
3. The March 4, 2011 inspection noted that the Pharmacy was performing sterile compounding in a clean room with counters and cabinetry that were not USP 797 compliant, that there was no separate anteroom area for garbing, and that the Pharmacy was unable to provide documentation of staff training in sterile processes. The Pharmacy was alerted to the violations.
4. On June 22, 2011, the Board sent the Pharmacy a letter fully detailing the deficiencies found during the inspection. The Board cited various provisions of its regulations on sterile compounding, COMAR 10.34.19. Specifically, the letter noted deficiencies in the surfaces in the clean room, stated policies and procedures, recording keeping, and the quality assurance program.
5. The Pharmacy sent the Board two letters addressing the deficiencies noted in the Board's June 22, 2011 letter. In its letter dated July 18, 2011, the Pharmacy informed the Board that it had hired a consultant to recommend steps the Pharmacy could take to become fully compliant, and it was waiting for the consultant's final report. The Pharmacy reported that in the meantime, it was revising its policies and procedures, improving its record keeping, and implementing a new training system for its staff.

6. In its letter dated August 26, 2011, the Pharmacy reported to the Board physical changes it planned on making to the compounding area to come into compliance with USP 797 and COMAR 10.34.19.09. Attached to this letter were three diagrams, one of which ("Attachment Three") proposed extensive modifications to the clean room, including the replacement of the wood veneer countertop with a non-porous material and the establishment of a separate anteroom outside of the designated compounding area.
7. The Board reviewed the information provided by the Pharmacy, and it believes that the physical changes outlined in Attachment Three, along with the improved written policies, recording keeping, and training program outlined by the Pharmacy, will bring the Pharmacy into compliance with USP 797 and Board regulations contained in COMAR 10.34.19.

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 12-409(a)(2) and COMAR 10.34.19.

ORDER

Based on an affirmative vote of a majority of the Board, it is this 30th day of May, 2012, 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 the improved written policies and training program implemented by the Pharmacy within thirty (30) days of the date of this Order; and be it further,

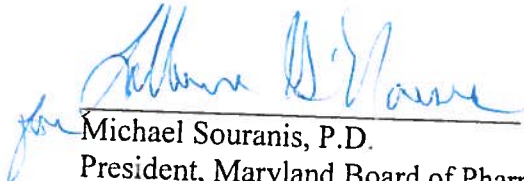
ORDERED that the Pharmacy shall be subject to a re-inspection after six (6) months following the date of this Order, at which the physical modifications made by the Pharmacy shall be observed; and be it further

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, or failure to make the above-mentioned physical modifications after six (6) months following 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

5/30/12


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.

HEALTHSOUTH CHESAPEAKE
REHAB HOSPITAL PHARMACY
Permit No. PW0301

5/17/2012
Date

Carol L. Gleason
Carol L. Gleason, RPh
Title: Director of Pharmacy

STATE OF MARYLAND
COUNTY/CITY OF Wicomico _____:

I hereby certify that on this 17th day of May, 2012, before me, a Notary Public of the State of Maryland and County/city aforesaid, personally appeared CAROL L. GLEASON, on behalf of HEALTHSOUTH CHESAPEAKE REHAB HOSPITAL PHARMACY, and made an oath in due form that the foregoing Consent was her voluntary act and deed.

Linda A. McCann

Notary Public

My commission expires: 2-24-2014