

**IN THE MATTER OF
ST. AGNES HOSPITAL
PHARMACY**

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**BEFORE THE
MARYLAND
BOARD OF
PHARMACY
Case No. PI-16-170**

Permit No. P00735

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PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) conducted an annual inspection of St. Agnes Hospital Pharmacy (the “Pharmacy”), Permit No. P00735, on February 17, 2016. The inspection indicated that the Pharmacy’s environmental sampling and facility controls showed actionable excursions. The Board conducted follow-up activities with the Pharmacy to obtain documents relating to relevant policies and procedures, certifications and retesting. The Board and the Pharmacy have engaged in ongoing communication regarding updates and response measures to the adverse events discovered.

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 and its counsel on August 31, 2016. 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. P00735, and operated on the hospital premises located at 900 Caton Avenue, Baltimore, Maryland.
2. The Pharmacy has three (3) locations within the hospital: (1) the main pharmacy; (2) the operating room pharmacy; and (3) the IV pharmacy. All pharmacy locations operate under Permit No. P00735.
3. All pharmacy locations compound sterile drug products. No high-risk compounds are produced in the Pharmacy.
4. On February 17, 2016, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
5. The annual inspection noted that the Pharmacy's February 2016 certification indicated actionable excursions in the air sampling for the anteroom of the main pharmacy as well as in the IV pharmacy. The Pharmacy did not measure, nor log, air differential daily in the main pharmacy location.
6. The Pharmacy did not have documented corrective response measures although it conducted a root cause analysis of the excursions.
7. Retesting of these areas was not conducted until May 2016 due to internal departmental miscommunication. The May environmental and facility retesting showed no excursions.
8. At the time of the Case Resolution Conference, the Pharmacy had just undergone another semi-annual certification in August 2016. The results of such certification were intended to be provided to the Board to ensure that the Pharmacy environmental and facility controls continued to meet standards.

9. Due to quality control issues experienced by the testing vendor, the Pharmacy was delayed in providing certification results to the Board until October 3, 2016. Such results indicated no mold growth or other actionable excursions in the Pharmacy.
10. The Pharmacy has amended its policies and procedures to specifically address any limitations on compounding in the IV and operating room pharmacy locations; clarification in identifying the various pharmacy locations; cleaning protocols and responsibilities; quality assurance testing for personnel; corrective response protocols, timelines and responsibilities.
11. The Pharmacy has been fully cooperative with the Board throughout its investigation.
12. The Board finds that the Pharmacy, with the provisions of this Order, has resolved the deficiencies related to COMAR 10.34.19 and USP 797 compliance noted by the Board.

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 (2), and COMAR 10.34.19.

ORDER

Based on an affirmative vote of a majority of the Board, it is this 16th day of November, 2016, hereby:

ORDERED that, within thirty (30) days of the date of this Order, the Pharmacy shall submit to the Board an action plan with respect to personnel training, quality assurance, monitoring, and compliance to ensure that USP 797 standards are met; and be it further,

ORDERED that, within sixty (60) days of the date of this Order, the Pharmacy shall submit to the Board an action plan to ensure USP 797 compliance with respect to environmental and facility controls; and be it further,

ORDERED that the Pharmacy shall test air and surface samplings on at least a monthly basis. Such tests shall be conducted by an outside vendor, and the results sent to the Board together with a root cause analysis and corrective response measures, if applicable; and be it further,

ORDERED that the Board reserves the right to initiate disciplinary or emergency action against the Pharmacy should any environmental test results indicate actionable excursions which, in the Board's sole opinion, may pose a risk to public health and safety; 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, General Provisions Article, Section 4-333.

11/16/2016
Date

Mitra Gavani
Mitra Gavani, Pharm.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.

ST. AGNES HOSPITAL PHARMACY
Permit No. P00735

10/20/16
Date



Gregory Smith, R.Ph.
Director of Pharmacy

STATE OF MARYLAND

COUNTY/CITY OF Anne Arundel

I hereby certify that on this 20th day of October, 2016, before me, a Notary Public of the State of Maryland and County/city aforesaid, personally appeared GREGORY SMITH, on behalf of ST. AGNES HOSPITAL PHARMACY, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

Sue Marie Mangum
Notary Public
My commission expires: 4-19-2017