

IN THE MATTER OF * **BEFORE THE**
ST. AGNES HOSPITAL * **MARYLAND**
CANCER INSTITUTE * **BOARD OF**
PHARMACY * **PHARMACY**
Permit No. P05930 * **Case No. PI-16-148**

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PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) conducted an annual inspection of St. Agnes Hospital Cancer Institute Pharmacy (the “Pharmacy”), Permit No. P05930, on February 5, 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. P05930, and operated on the hospital's Cancer Institute's premises located at 4307 Wilkens Avenue, Baltimore, Maryland.
2. The Pharmacy compounds sterile drug products, including hazardous drug compounds for use in chemotherapy.
3. On February 5, 2016, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
4. The inspection report indicated that the Pharmacy's August 2015 environmental sampling noted two locations of actionable excursions in the cleanroom. No follow-up testing was performed.
5. The Pharmacy's February 2016 environmental sampling indicated mold growth in the anteroom. The Pharmacy conducted a root cause analysis of this adverse event.
6. Retesting was not conducted until May 2016 due to internal departmental miscommunication. The May environmental and facility retesting showed no excursions.
7. In addition, the Pharmacy did not have documentation of certain quality assurance measures related to fingertip testing of its staff.
8. At the time of the Case Resolution Conference, the Pharmacy had just undergone another semi-annual certification in August 2016. The results of environmental samplings taken during the certification were intended to be provided to the Board to ensure that the Pharmacy's 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. The Pharmacy received the results on October 8, 2016, which indicated microbial growth and mold in the chemo room.
10. Due to the testing issues with the above vendor, the Pharmacy also contracted with another testing vendor to conduct environmental sampling. The results from the second testing vendor were received on October 4, 2016, and did not indicate any actionable excursions in the Pharmacy.
11. Notwithstanding the disparate testing results from the two vendors, the Pharmacy has engaged in corrective response measures to address the excursions noted including review of staff garbing procedures, re-cleaning of the Pharmacy, engagement with the hospital's environmental services regarding staff training, and retesting.
12. The Pharmacy has also amended its policies and procedures to specifically address any cleaning protocols and responsibilities; quality assurance testing for personnel; corrective response protocols, timelines and assignment of responsibilities.
13. The Pharmacy has been fully cooperative with the Board throughout its investigation.

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 formal 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

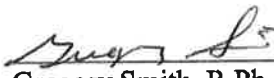

Mitra Gavvani, Pharm.D.
President, Maryland Board of Pharmacy

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 CANCER INSTITUTE
PHARMACY
Permit No. P05930

10/20/14
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 CANCER INSTITUTE 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