IN	THE MA	ATTER	R OF		*				BEFORE THE				
ATLANTIC GENERAL						*			MARYLAND BOARD				
HOSPITAL						*			OF	OF PHARMACY			
Per	rmit No.	P01751				*							
	*	*	4	*	7:	*	*	*	*	*	de		

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Atlantic General Hospital's pharmacy (the "Pharmacy"), Permit No. P01751, on June 14, 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

At all times relevant hereto, the Pharmacy possessed a Maryland pharmacy permit,
 Permit No. P01751, and operated on the hospital premises located at 9733 Healthway
 Drive, Berlin, Maryland.

- 2. On June 14, 2012, the Board performed an annual inspection of the Pharmacy in accordance with Md. Code Ann., Health Occ. § 12-604(b).
- 3. The June 14, 2013 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 admitted that although it was following USP 797 cleaning requirements, it was not properly documenting the cleaning. The Pharmacy also admitted that it was not adequately performing or documenting personnel testing, and stated that it was not able to locate documentation of its staff training at the time of the inspection.
- The Pharmacy also stated at the CRC that all the deficiencies had been corrected since
 the time of the inspection, and it provided documentation substantiating its corrective
 actions
- 6. The Pharmacy is located in a hospital with fewer than 50 beds and performs a low amount of sterile compounding.

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.

<u>ORDER</u>

Based on an affirmative vote of a majority of the Board, it is this 4^{900} day of $\frac{14^{900}}{1000}$, 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).

7/18/w13

Michael Souranis, P.D.

President

Lenna Israbian Jamgochia-

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.

ATLANTIC GENERAL HOSPITAL

Permit No. P01751

Date

James McGinnis, R.Ph.

Director of Pharmacy

STATE OF MARYLAND COUNTY/CITY OF Worcester:

appeared JAMES MCGINNIS, on behalf of ATLANTIC GENERAL HOSPITAL, and made an oath in due form that the foregoing Consent was his voluntary act and deed.

Notary Public My commission expires: Aug 25, 2014

BETTY J. MITCHELL **NOTARY PUBLIC** WORCESTER COUNTY MARYLAND MY COMMISSION EXPIRES AUG. 25, 2014