

STATE OF FLORIDA
BOARD OF PHARMACY

FILED
DEPARTMENT OF HEALTH
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In the Matter of:

GALENCARE, INC.,
d/b/a BRANDON REGIONAL HOSPITAL,

Petitioner.

Case No.: 2010_____

Petition for Declaratory Statement Before the
State of Florida Board of Pharmacy.

PETITION FOR DECLARATORY STATEMENT

GALENCARE, INC., d/b/a BRANDON REGIONAL HOSPITAL ("Brandon"), pursuant to Section 120.565, Florida Statutes, and Chapter 28-105, Florida Administrative Code, hereby petitions the State of Florida Board of Pharmacy (the "Board") for a declaratory statement concerning Rule 64B16-28.605, Florida Administrative Code, and states as follows:

Name, address, and telephone number of Petitioners and representative

1. Brandon is a licensed acute care hospital located at 119 Oakfield Drive, Brandon, Florida 33511, phone number (813) 681-5551. Brandon is also the holder of a Class II Institutional Pharmacy Permit issued by the Board, Permit No. PH6752.
2. Brandon's Class II Institutional Pharmacy (the "Hospital Pharmacy") is supervised by its licensed Consultant Pharmacist, Shawn C. Myers. Mr. Myers holds a Consultant Pharmacist Permit issued by the Board, Permit No. PU4865.
3. Brandon is represented by the undersigned counsel in this proceeding, whose name, address, phone number, and fax number are given below.

Subject matter of Petition

4. This Petition is filed to seek the Board's determination as to whether a minor modification in the Hospital Pharmacy's current automated dispensing procedures would be permissible under Rule 64B16-28.605, Florida Administrative Code (the "Rule").

General Operation of the Rule

5. The Rule expressly authorizes automated dispensing of medications by a Class II Institutional Pharmacy. Section (1) of the Rule provides in pertinent part:

(a) "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:

1. Distribute medications in a licensed health care facility; or
2. Package medications for final distribution by a pharmacist.

(Emphasis added)

6. The Rule also provides for "centralized" and "decentralized" automated medication systems, and for distribution of medications by qualified and licensed health professionals other than the Consultant Pharmacist or the attending physician. To facilitate such medication systems and distribution, Section (1) provides the following terms:

(b) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.

(c) "Decentralized automated medication system" means an automated medication system that is located outside of a pharmacy department but within the same institution.

(d) "Distribute" or "Distribution" means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.

7. The Consultant Pharmacist is ultimately responsible for automated dispensing procedures, quality assurance, and security. Section (2) of the Rule provides as follows:

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation;
2. Controlling access to the system;
3. Maintaining policies and procedures for:
 - a. Operation of the automated medication system;
 - b. Training personnel who use the automated medication system;
 - c. Maintaining patient services whenever the automated medication system is not operating; and
 - d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.
4. Security of the system;
5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;
6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;
7. Establishing a comprehensive Quality Assurance program;
8. Establishing a procedure for stocking or restocking the automated medication system; and
9. Ensuring compliance with all requirements for packaging and labeling.

Description of how the Rule affects Petitioner

8. Brandon has a substantial interest in ensuring that the Hospital Pharmacy's practice complies with the Rule. The Hospital Pharmacy is an integral part of Brandon's day-to-day hospital operations, and what it is and is not able to provide in terms of patient care.

9. Consistent with the requirements of the Rule, medications at Brandon are kept in the central location of the Hospital Pharmacy, but are also kept in Automated Dispensing Machines ("ADMs") located at the nursing station on the medical/surgical floor (the "Floor"). When a drug is prescribed by an inpatient's attending physician, the order is entered into the Hospital Pharmacy's computerized system, which is linked to the ADMs. The ADM's own internal technology recognizes when a prescribed drug has been verified by the Hospital

Pharmacy. The Floor nurse may then obtain the verified drug from the ADM by inputting an access code that allows the nurse to view the patient's profile and access the particular drug prescribed.

10. This automated process has been an unqualified success in reducing the rate of medication errors. However, it does require programming the ADMs for passcode-protected access that includes new users and ongoing proper maintenance of existing user access. Programming the ADMs at Brandon is currently the sole responsibility of the Consultant Pharmacist. This specific activity constitutes an additional administrative burden for the Consultant Pharmacist and, in some cases, requires considerable training. By comparison, programming the ADMs could be easily undertaken by Brandon's Information Technology ("IT") Department, which already has the experience and expertise required.

11. In the course of programming the ADMs, the IT department would work with the Consultant Pharmacist in advance to determine the level of access based on the employee licensure status, job class, and hospital unit location of the employee. The IT department would in no way be involved with accessing the ADM once it was programmed. Access to the ADM for removal or refill of drugs would be strictly limited to Floor nurses and qualified Hospital Pharmacy personnel, pursuant to the Hospital Pharmacy's automated dispensing protocol. At all events, the Consultant Pharmacist would remain responsible for automated dispensing procedures, as provided in Section (2) of the Rule.

12. Once programmed, access to the ADMs for removal of medications is facilitated by inputting two data elements: (1) a unique User Identification Code ("User ID"); and (2) a password. Significantly, the IT Department would not need to generate or obtain knowledge of the user's password in the course of programming the ADMs. The ADMs can be programmed

such that the user creates their own password on their initial use of the ADM, after they enter their User ID. This will ensure no authorized third-party access to the ADMs by anyone in the IT Department.


13. The simple addition of assistance by the IT Department would constitute an extremely minor change in the Hospital Pharmacy's automated dispensing procedures, and would not create any risk of unauthorized access to drugs or patient safety concerns. It would simply bring greater expertise to bear on the programming of Brandon's ADMs, and relieve the Consultant Pharmacist of the administrative burden involved in programming the ADMs.

Conclusion and Relief Requested

14. Brandon therefore seeks the Board's Declaratory Statement concerning whether the assistance of its IT Department in programming the ADMs, as described herein, is permissible under Rule 64B16-28.605, F.A.C.

WHEREFORE, Brandon respectfully requests that the Board issue a Declaratory Statement, declaring whether Brandon may utilize the assistance of its IT Department in programming the ADMs, as described herein, under Rule 64B16-28.605, F.A.C.

RESPECTFULLY SUBMITTED this 15th day of June, 2010.



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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the original of this Petition for Declaratory Statement was Hand-Delivered to R.S. Power, Agency Clerk, Florida Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399; to Rebecca Poston, R.Ph., Executive Director, Florida Board of Pharmacy, 4052 Bald Cypress Way, Tallahassee, Florida 32399; and to Michael S. Weizer, Pharm.D., Chair, Florida Board of Pharmacy, 4052 Bald Cypress Way, Tallahassee, Florida 32399, this 1st day of June, 2010.



Attorney