DEPARTMENT OF STATE

DIVISION OF PROFESSIONAL REGULATION

2500 Board of Pharmacy

Statutory Authority: 24 Delaware Code, Section 2509 (24 **Del.C.** §2509)
24 **DE Admin. Code** 2500

FINAL

ORDER

The Board of Pharmacy ("Board") was established to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications and such other materials as may be used in the diagnosis and treatment of injury, and prevention of illness and disease. The Board is authorized by 24 **Del.C.** §2509 to make, adopt, amend, and repeal regulations as necessary to effectuate those objectives.

Pursuant to 24 **Del.C.** §2509, the Board proposed amendments to its regulation 9.0 relating to hospital pharmacies. Specifically, the amendment to 9.0 Hospital Pharmacy removes provisions relating to hospitals served by off-site pharmacies.

Pursuant to 29 **Del.C.** §10115, notice of the public hearing and a copy of the proposed regulatory changes was published in the Delaware Register of Regulations, Volume 10, Issue 5, at page 821 on November 1, 2006. However, notice was not published in two (2) Delaware newspapers of general circulation, as required by 29 **Del.C.** §10115, so the public hearing could not be conducted on January 17, 2007 as originally scheduled. The public hearing was, therefore, rescheduled for March 21, 2007. Notice of the rescheduled hearing was published in the *Delaware Register of Regulations*, Volume 10, Issue 9, at page 1468 on March 1, 2007.

Summary of the Evidence and Information Submitted

No written or verbal comments were received.

Findings of Fact

The Board finds that adoption of the proposed amendments is in the best interest of the public health, safety, and welfare. The provisions being removed are either unnecessary or unenforceable.

Decision and Effective Date

The Board hereby adopts the proposed amendments to the regulations to be effective 10 days following final publication of this order in the *Register of Regulations*.

Text and Citation

The text of the final regulations is attached hereto as Exhibit A and is formatted to show the amendments.

IT IS SO ORDERED this 21st day of March, 2007 by the Board of Pharmacy of the State of Delaware.

Don Holst, R.Ph., Chair
Angelo Chiari, R.Ph., Vice Chair
Carolyn Calio
Sandra Robinson, R.Ph.
Sebastian Hamilton, R.Ph.
Geoffrey Christ, R.Ph.
David Bonar

2500 Board of Pharmacy; 9.0 Hospital Pharmacy

(Break in Continuity of Sections)

9.0 Hospital Pharmacy

9.1 Definition:

A hospital pharmacy is defined as a pharmacy registered with the Board located in a hospital facility. "Hospital pharmacy" shall not include a pharmacy operated by a hospital facility at a location other than the site of a permanent facility at which in-patient care and medical services are rendered.

9.2 Personnel

9.2.1 Director of Pharmacy. The storage, compounding, repackaging, dispensing and distribution of drugs by a hospital pharmacy shall be under the direction, supervision and responsibility of the pharmacist-in-charge, hereinafter referred to as the Director of Pharmacy, who shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations. Written policies and procedures will be established defining the operation and scope of services provided by the hospital pharmacy. The Manual shall include policy and procedures concerning:

9.2.1.1 Preparation and sterilization of parenteral medications if done within the hospital pharmacy.

9.2.1.2 Establishment of specifications for procurement of drugs, chemicals and biologicals. The procedures are subject to the approval of the appropriate committee of the hospital.

9.2.1.3 Maintaining readily available inventory of emergency drugs both in the pharmacy and patient care areas. Current antidote information and telephone numbers of regional poison control centers must also be available.

9.2.1.4 Participation in the development of a Formulary or drug list for the hospital.

9.2.1.5 The filling and labeling of all containers from which drugs are to be administered in compliance with applicable Statutes and Regulations.

9.2.1.6 The records of the transactions of the pharmacy that are required by applicable law and that are necessary for accurate control and accountability. This should include procedures for wastage of controlled substances in all areas of the hospital.

9.2.1.7 Polices and procedures shall specify the duties to be performed by pharmacy personnel.

9.2.1.8 Discontinued drug procedures to insure that discontinued drugs and containers with worn, illegible or missing labels are returned to the pharmacy for proper disposition or disposal. All outdated products should be removed from all areas and stored in a separate section in the pharmacy for proper disposition or disposal.

9.2.1.9 A recall procedure that can be implemented to insure proper disposition of the recalled materials.

9.2.1.10 A policy for drugs brought in by patients.

9.2.1.11 A policy for the proper handling of investigational drugs must be in compliance with FDA and State requirements.

9.2.1.12 The pharmacist shall be involved with the utilization review process as it pertains to drug therapy.

9.2.2 Registered Pharmacists. The Director of Pharmacy may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws.

9.2.3 Supportive Personnel. Supportive personnel may be utilized in assisting the pharmacist. These persons must be supervised by a registered pharmacist who is present within the hospital and is responsible for the activities of those persons.

9.3 Absence of Pharmacist. When a pharmacist is not on duty, drugs may be provided for use by physicians and other authorized staff via night cabinets or other areas designated by the hospital, and in emergency circumstances by access to the pharmacy. A pharmacist shall be available to provide professional services.

9.4 Night Cabinets or Other Designated Areas

9.4.1 These drug storage areas must be securely locked and substantially constructed in a manner which prevents easy entry.

9.4.2 Access must be limited to authorized personnel.

9.4.3 Contents and use procedures should be determined by the pharmacy and those departments with access to the night cabinet or other designated areas in accordance with the hospital's policies and procedures.

9.4.4 Drugs must be properly labeled and prepackaged in sufficient quantities as defined by the hospital.

9.4.5 Accountability records documenting withdrawal and replacement of controlled drugs must be readily available.

9.4.6 The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.5 Access to Pharmacy. When a pharmacist is not available and medications cannot be obtained immediately from any other source, authorized persons may enter the pharmacy and obtain drugs per procedures established by the hospital. The procedures must include the following stipulations:

9.5.1 Entry shall be by two persons; registered nurse or physician with another nurse, physician, or security person present approved by the hospital.

9.5.2 Persons authorized to enter the pharmacy shall indicate the name and strength and amount of drug removed, the date, time and their signature, and the name and location of the patient. The transaction shall be reviewed by the pharmacy when it reopens and incorporated into the hospital pharmacy's medication recordkeeping system.

9.6 Emergency Drugs. Emergency drugs must be available for use by authorized personnel at strategic locations throughout the hospital. The drugs must be available to authorized personnel and must be stored in a manner to preserve the integrity of the contents.

9.6.1 Emergency Drugs Defined - Emergency drugs are those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk or harm to patients.

9.6.2 Emergency drug supplies shall be clearly identified for emergencies. A list showing the contents and the strength and quantity of each item shall be attached to the exterior.

9.6.3 Removal of Drugs - Drugs shall be removed from an emergency drug supply only pursuant to a valid physician's order or by authorized personnel.

9.6.4 Notification - Whenever an emergency drug supply is accessed, the pharmacy or its designee shall be notified within 24 hours, and the pharmacy or its designee shall restock and reseal or replace the kit or cart within forty-eight hours.

9.7 Equipment and Texts. Each hospital pharmacy shall have the equipment and texts required by Board Regulation 3.0 and Regulation 10.0.

9.8 Drug Storage. Drugs must be stored in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.

9.9 Labeling

9.9.1 The drug dispensed for inpatient use shall contain a label, shall show the brand or established name and the strength of the medication. If the medication is prepacked, it must also show the source, lot number and expiration date, in compliance with the Board's prepacking regulation.

9.9.2 All drugs dispensed for outpatients must be labeled in compliance with the Pharmacy Statutes.

9.9.3 Admixtures in parenteral bags and bottles shall be labeled in accordance with Regulation 10.0.

9.10 Abbreviations. The hospital should establish a standard list of abbreviations to be used whenever medications are prescribed.

9.11 Outpatient Orders. Medication dispensed for outpatients via prescriptions are governed by applicable State and Federal Statutes Regulations. A patient profile must be maintained and counseling must be provided for each person according to Regulation 5.0.

9.12 Suspected Adverse Drug Reaction. When an adverse reaction is documented, the pharmacy department shall receive a copy.

9.13 Maintenance of Medication Orders. Patient Profile - A patient medication profile must be maintained for each inpatient whose medication is directly dispensed from the pharmacy. It must show the patient's name, location, age, allergies and diagnosis(es) as available. The profile must show the name, strength and

quantity of the drug dispensed and appropriate directions and the initials of the dispenser. Prior to administration of the first dose, the pharmacist must examine the profile to determine the possibility of a harmful drug interaction or reaction. Upon recognizing a significant potential for harm, the pharmacist should notify the prescriber and other appropriate persons. The profile must be retained and readily retrievable for 30 days after discharge.

9.14 Medication Error. Medication error as defined by the hospital shall be documented and reported immediately to the pharmacy. It should also be reported to the attending physician.

9.15 Monthly Inspections. A member of the pharmacy staff shall conduct monthly inspections of each nursing station and patient care areas where medications are dispensed, administered or stored. Such documented inspections shall verify that:

9.15.1 Disinfectants and drugs for external use are stored separately.

9.15.2 Drugs are stored under proper conditions.

9.15.3 No outdated drugs are present.

9.15.4 Distribution, administration, and disposition of controlled substances audits indicates proper recordkeeping and administration.

9.15.5 Emergency drug supplies and floor stock drug levels are properly maintained.

9.15.6 Drugs are properly secured.

~~9.16 Hospital Operating with an Off-site Pharmacy Provider.~~

~~9.16.1 Definition. A hospital operating with an off-site pharmacy is one that obtains pharmacy services from another hospital, community pharmacy, or infusion pharmacy that can provide services as necessary for operation.~~

~~9.16.2 Personnel.~~

~~9.16.2.1 There must be a Director of Pharmacy or Consultant Pharmacist available on an on-call procedure 24 hours per day. The storage, compounding, repackaging, dispensing and distribution of drugs by an off-site Provider Pharmacy shall be under the direction, supervision and responsibility of a Pharmacist-in-Charge or Director of Pharmacy. This person shall be responsible for operating the pharmacy in compliance with appropriate State and Federal Statutes and Regulations.~~

~~9.16.2.2 The Director of Pharmacy or Pharmacist-in-Charge may be assisted by additional registered pharmacists who are also responsible for compliance with the applicable laws. Any of these registered pharmacists may act as the Consultant Pharmacist for the institution if he/she is licensed to practice pharmacy in the State of Delaware. Additional supportive personnel may be utilized as required.~~

~~9.16.2.3 The Director of Pharmacy or Pharmacist-in-Charge must provide written policies and procedures establishing the operation and scope of services provided by the off-site Pharmacy Provider. The Policy and Procedure Manual shall include all items as outlined in 9.2 of this section. In addition, the manual shall include a written statement of pharmaceutical services provided and the responsibilities of the off-site Provider Pharmacy.~~

~~9.16.3 Monthly Inspections. The Director of Pharmacy or Consultant Pharmacist must perform monthly medication area inspections as outlined in 9.15 of this section.~~

~~9.16.4 Storage~~

~~9.16.4.1 Drugs must be stored at the off-site Pharmacy Provider in compliance with State and Federal Statutes and Regulations and according to USP/NF requirements.~~

~~9.16.4.2 The Pharmacy Provider must also provide any special handling and/or packaging and/or storage conditions for compounded sterile preparations when delivering from the pharmacy to the institution as necessary to maintain the sterility and stability of the preparation. This includes any product that is frozen or that requires refrigeration.~~

~~9.16.5 Patient Profiles. The off-site Pharmacy Provider must maintain complete patient profiles as outlined in Regulation 5.0.~~

~~9.16.6 Medication Errors or Adverse Reactions~~

~~9.16.6.1 Any medication errors or adverse drug reactions, as defined by the hospital, shall be documented and reported to the off-site Pharmacy Provider.~~

~~9.16.6.2 This information shall also be reported to the Director of Pharmacy, Pharmacist-in-Charge, or Consultant Pharmacist for their review and documentation for the patient profile.~~

~~9.16.7 Emergency Use Medications~~

~~9.16.7.1 Emergency use medications are those which may be required to meet the immediate therapeutic needs of patients, as determined by the prescriber, and which are not available from any~~

~~other authorized source in sufficient time to prevent risk or harm to patients by delay resulting from obtaining such drugs from other sources.~~

~~9.16.7.2 It is the responsibility of the facility and provider pharmacy to determine the supply of emergency use medication that are to be stocked as well as documenting their locations within the facility. A list of current contents must be attached to the medication supply.~~

~~9.16.7.3 Accountability for emergency use medications.~~

~~9.16.7.3.1 The pharmacy provider must be contacted within 24 hours after medication is used from the supply and the pharmacy must restock the supply within a reasonable time to prevent harm to patients.~~

~~9.16.7.3.2 The provider pharmacy is responsible for the accuracy of all emergency use medications at the time of the filling of the medication. This check must also include any medication that became available when the medication is accessed. Records documenting use of an emergency medication must be kept for a minimum of 2 years at the provider pharmacy and must be readily available for inspection by the Board.~~

~~9.16.7.3.3 Failure to comply with these procedures can result in the suspension or denial of the use of emergency use medications.~~

~~9.16.7.3.4 Violations of accountability procedures for emergency use medications may result in review proceedings before the Board.~~

9 DE Reg. 85 (7/1/05)
10 DE Reg. 1629 (04/01/07) (Final)