Title 10 MARYLAND DEPARTMENT OF HEALTH Subtitle 34 BOARD OF PHARMACY Chapter 04 Transfer and Outsourcing of Prescriptions and Prescription Orders Authority: Health Occupations Article, §12-205(a)(3)(ii), Annotated Code of Maryland

.01 Scope.

This chapter governs the:

A. Transfer of prescriptions for non-controlled dangerous substances between pharmacies;

B. Filling of prescriptions at one pharmacy pursuant to the request of staff of a second pharmacy;

and

C. Preparation of medication for stock and investigational use.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Outsourcing" means the transmitting of a prescription order from a primary pharmacy to a secondary pharmacy that prepares the prescription.

(2) "Patient specific" means a prescription order prepared and labeled for a specific individual.

(3) "Preparation" means compounding or packaging of medication.

(4) "Primary pharmacy" means the pharmacy that initially receives a prescription order.

(5) "Secondary pharmacy" means the pharmacy to which a prescription order is transmitted for subsequent dispensing to a patient.

(6) "Stock medication" means medication that is not labeled for, or intended for, use by a specific patient when it leaves the pharmacy, but is intended to be stored and ultimately administered by a licensed health care professional in accordance with applicable laws and regulations.

.03 Permanent Transfer of a Prescription Between Pharmacies.

A pharmacist from a primary pharmacy may permanently transfer a prescription order to a secondary pharmacy to be dispensed to a specific patient if the pharmacist transferring the prescription from the primary pharmacy indicates on the prescription, within the prescription computer database and within any appropriate other records

used for dispensing:

A. That the prescription has been permanently transferred;

B. The name of the secondary pharmacy;

C. The name of the pharmacist who transferred the prescription to the secondary pharmacy;

D. The name of the pharmacist at the secondary pharmacy to whom the prescription was

transferred if the transfer occurred in an oral manner; and

E. The date on which the prescription was transferred to the secondary pharmacy.

.04 Refilling of Permanently Transferred Prescriptions.

A. A pharmacist at the primary pharmacy may not refill a prescription that has been permanently transferred to a secondary pharmacy.

B. The use of unified prescription records by more than one pharmacy through a computerized prescription database does not constitute a permanent transfer of a prescription order.

.05 Documentation by the Secondary Pharmacy Receiving a Permanent Prescription Transfer.

The pharmacist at the secondary pharmacy who receives a permanently transferred prescription document is responsible for maintaining documentation in a readily retrievable and identifiable manner which includes:

A. That the prescription was transferred from another pharmacy;

B. The name and information identifying the specific location of the primary pharmacy;

C. The name of the pharmacist who transferred the prescription to the secondary pharmacy;

D. The name of the pharmacist at the secondary pharmacy who accepted the transferred

prescription;

E. The date of issuance of the original prescription order;

F. The date on which the prescription order was first filled;

G. The date of the last refill;

H. The number of remaining refills;

I. The original prescription number; and

J. The date on which the prescription was transferred to the secondary pharmacy.

.06 Transfers of Prescriptions for Controlled Dangerous Substances.

A pharmacist may transfer a prescription for a controlled dangerous substance in accordance with federal law.

.07 Outsourcing of a Prescription Order.

A pharmacist from a primary pharmacy may transmit a prescription order to a secondary pharmacy for preparation and final dispensing to a specific patient or for return to the primary pharmacy for final dispensing to a specific patient if: A. The label contains the name, address, and phone number of the primary pharmacy;

B. The patient is informed in writing of the name and address of the secondary pharmacy;

C. The patient is informed in writing that the prescription order was prepared at a secondary pharmacy;

D. The original prescription order is filed as a prescription order at the primary pharmacy;

E. The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner:

(1) That the prescription order was prepared by a secondary pharmacy;

(2) The name of the secondary pharmacy;

(3) The name of the pharmacist who transmitted the prescription order to the secondary pharmacy;

(4) The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner;

(5) The date on which the prescription was transmitted to the secondary pharmacy; and

(6) The date on which the medication was sent to the primary pharmacy;

F. Both the primary and secondary pharmacies are licensed in this State, or operated by the federal government; and

G. The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy.

.08 Documentation by the Secondary Pharmacy when a Prescription Order is Outsourced.

The permit holder at the secondary pharmacy is responsible for maintaining documentation in a readily retrievable and identifiable manner, which includes:

A. That the prescription order was transmitted from another pharmacy;

B. The name and information identifying the specific location of the primary pharmacy;

C. The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner;

D. The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order;

E. The name of the pharmacist at the secondary pharmacy who prepared the prescription order;

F. The date on which the prescription order was received at the secondary pharmacy; and

G. The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

.09 Preparation of Stock and Investigational Medications.

A. A pharmacist may provide medication for use as stock medication for a licensed health care facility in accordance with applicable laws, if the pharmacy providing the medication also serves as the primary provider of patient specific medication for the facility.

B. A pharmacist may provide medication for use as stock medication for final dispensing or administration by an authorized prescriber who is permitted by law to administer or dispense medication if the pharmacist receives a written stock medication order from the authorized prescriber for each delivery of medication to the authorized prescriber.

C. A pharmacist may prepare, package, and label investigational drugs not destined for a specific individual at the time of preparation, packaging, and labeling if:

(1) The study for which medications are prepared, packaged, and labeled is approved by an institutional review board as defined in federal law; and

(2) The pharmacy permit holder ensures that records disclosing the identity of the subject who eventually receives the medication are:

(a) Received by a pharmacist on duty at the pharmacy within 30 days after being provided to a patient; and

(b) Maintained in the pharmacy.

.10 Permit and Quality Assurance.

A. The permit holder of a pharmacy which prepares patient specific prescriptions as a secondary pharmacy such that these prescriptions account for 5 percent or more of the pharmacy's total number of prescriptions filled shall submit to the Board of Pharmacy, for approval by the Board or a designee of the Board, a plan detailing the steps it has taken to ensure the safety and quality of prescriptions filled as a secondary pharmacy.

B. The plan under §A of this regulation shall include:

(1) Measures to be taken to comply with State and federal laws;

(2) The method by which each pharmacist responsible for each prescription is identified in the records;

(3) Measures taken to maintain the security, integrity, and confidentiality of patient records; and

(4) The establishment and maintenance of a quality assurance program.

C. Except as provided in Regulation .06 of this chapter, a permit holder of a pharmacy shall obtain manufacturing and distribution permits in order to compound or package medication that is not prepared as a prescription destined for a specific patient, but is forwarded to another pharmacy, authorized prescriber, licensed distributor, or other person or entity.