AGENDA

Florida Board of Pharmacy
Rules Committee Meeting
August 7, 2018 – 9:00 a.m.

Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32818
(407)996-9700

Committee Members:
Jeffrey Mesaros, PharmD, JD – Chair
David Bisaillon
Jonathan Hickman, PharmD
Jeenu Philip, BPharm
Blanca Rivera, BPharm, MBA

Board Staff
C. Erica White, MBA, JD - Executive Director
Shay Marcelus, JD - Prog. Operations Administrator

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **Call to Order**

2. **Discussion Item:** Checking / Removing Expired Medications

3. **Rule 64B16-27.4001** - Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist

4. **Discussion Item:** Patient Accessed Automatic Pharmacy Systems

5. **Discussion Item:** Returning Medicinal Drugs to Stock

6. **Old Business / New Business**

7. **Public Comment**

8. **Adjourn**

TAB #2

DISCUSSION ITEM REGARDING INSPECTIONS AND REMOVALS OF OUTDATED PHARMACEUTICALS

AUGUST 2018 RULES COMMITTEE

64B16-28.110 Outdated Pharmaceuticals.
Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.
Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.17, 21S-1.017, 21S-28.110, 61F10-28.110, 59X-28.110.

465.022 Pharmacies; general requirements; fees.
(1) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:
(a) General drug safety measures.
(b) Minimum standards for the physical facilities of pharmacies.
(c) Safe storage of floor-stock drugs.
(d) Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.
(e) Procedures for the safe storage and handling of radioactive drugs.
(f) Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. 499.028.
(g) Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.
(h) Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.
(i) Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.

465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.
(1) The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term “readable” means conspicuous and bold.
(2) Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:
(a) The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or
(b) An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing. The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.
(3) This section does not impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

(4) The provisions of this section are intended to notify the patient receiving a medicinal drug of the information required by this section, and the dispensing pharmacist or practitioner shall not be liable for the patient's failure to heed such notice or to follow the instructions for storage.
History.—ss. 1, 2, ch. 93-44; s. 8, ch. 2004-387.

* * * *

499.0121 Storage and handling of prescription drugs; recordkeeping. The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.
(5) RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—
(a)1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.
2. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

499.0051 Criminal acts.
(11) ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS. Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:
(a) The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

499.006 Adulterated drug or device. A drug or device is adulterated:
(9) If it is a drug or device for which the expiration date has passed;

TAB #3

BOARD COUNSEL DRAFT LANGUAGE FOR DISCUSSION
AUGUST 2018

64B16-27.4001 Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist.

(1) Delegation: A pharmacist shall not delegate more tasks than he or she can personally supervise and ensure compliance with this rule. A pharmacist may delegate those non-discretionary delegable tasks enumerated in Rule 64B16-27.420, F.A.C., to the following types of pharmacy technicians:

(a) Registered Pharmacy Technicians (RPT): are those technicians who are duly registered with the board pursuant to Section 465.014(2), F.S.;

(b) Pharmacy Technicians in Training (PTT): are those technicians who are receiving practical (non-didactic) training in delegable tasks as part of employer-sponsored ~~based~~ or non-employer sponsored ~~based~~ board-approved pharmacy technician training programs who are not required to be duly registered with the board as pharmacy technicians.

(2) Supervision: Delegated tasks must be performed under the direct supervision of a pharmacist and pursuant to the following definitions and requirements:

(a) Direct Supervision: means supervision by a pharmacist who is readily and immediately available ~~on the premises~~ at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who ~~is readily available to~~ provides personal assistance, direction and approval throughout the time the delegated tasks are being performed. "Readily and immediately available" means the pharmacist and technician(s) are on the same physical premises, or if not, technology that enables real time, two-way communications between the pharmacist and technician(s).

(b) Use of Technology: A pharmacist, as an adjunct to assist in the direct supervision of the pharmacy technician, may employ technological means to communicate with or observe the pharmacy technician. A pharmacist shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide direct supervision of pharmacy technician(s), such technology shall be sufficient to provide the personal assistance, direction and approval required, including the ability to observe all aspects of the delegated tasks.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.014 FS. History–New 12-31-14.

TAB #4

DISCUSSION ITEM FOR NEW RULES REGARDING PATIENT ACCESSED AUTOMATIC PHARAMACY SYSTEMS (NON-DISPENSING) AND AUTOMATED PATIENT ACCESSED COMMUNITY PHARMACIES

AUGUST 2018

Pursuant to the statutes identified below, the Board may want to consider adopting rules to allow for expanded use of two (2) classes of automated devices.

1. Rules regarding the use of devices which perform the sales/delivery of medicinal drugs, but do not provide "storage" or "dispensing" of medicinal drugs and thus do not require a permit.

2. Rules to implement a subset of community pharmacy permitted entities - fully automated, direct patient accessed, community pharmacies. These pharmacies would be under common ownership with a permitted "full" community pharmacy, which would provide centralized prescription filling for the automated pharmacy, including consulting, drug utilization, and claims adjudication type activities. The rules would have to specify exemptions from the normal space and equipment requirements for community pharmacies and enumerate how the "prescription department" would be open through technological means that do not require the physical presence of a pharmacist.

465.003 Definitions. As used in this chapter, the term:

(6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. **The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.**
2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to

dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).
(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(16) "Centralized prescription filling" means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17) "Automated pharmacy system" means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.

465.0265 Centralized prescription filling. —
(1) A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.
(2) Each pharmacy performing or contracting for the performance of centralized prescription filling pursuant to this section must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:
(a) A description of how each pharmacy will comply with federal and state laws, rules, and regulations.
(b) The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient.
(c) The procedure for tracking the prescription during each stage of the filling and dispensing process.
(d) The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.
(e) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
(f) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.
(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as described in s. 465.026 or as a wholesale distribution as defined in s. 499.003.
(4) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.
History.—s. 2, ch. 2002-182; s. 40, ch. 2008-207; s. 38, ch. 2010-161; s. 34, ch 2014-89.

TAB #5

DISCUSSION ITEM REGARDING RETURN OF MEDICINAL DRUGS TO STOCK

AUGUST 2018 RULES COMMITTEE

465.016 Disciplinary actions.
(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
(l) Placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and the individual unit dose or unit-dose system labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any, the unused unit dose of medication may be returned to the pharmacy for redispensing. Each pharmacist shall maintain appropriate records for any unused or returned medicinal drugs.

465.003 Definitions. As used in this chapter, the term:
(6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. **The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.**

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.
(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.
(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.
(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.
(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.
(5) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns.

(1) Definitions. As used herein:

(a) A "unit dose system" means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this rule, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.

(b) A "customized patient medication package" means a system wherein all USP approved multi-dose units are physically connected (also referred to as a "container"). The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.

(c) A "closed drug delivery system" is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.

(d) For purposes of this rule, "facility" shall mean any health care institution operating with a Class I, Class II, Modified Class II, or Special ALF permit.

(2) No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:

(a) In a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

(b) In the case of controlled substances, as it is allowed by Federal Law.

(3) All pharmacies utilizing unit dose or customized patient medication packages shall address specific policies and procedures regarding their preparation and use in the pharmacy's Policy and Procedures Manual.

Final Order No. DOH-06-1101-DS-MQA
FILED DATE - 6-23-06
Department of Health
By: Heather Coleman
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: PETITION FOR DECLARATORY STATEMENT OF SARAH STEPHENS, R.PH., PHARMACIST-IN-CHARGE AETNA SPECIALTY PHARMACY, LLC

FINAL ORDER

THIS MATTER came before the Board of Pharmacy (hereinafter "the Board") pursuant to Section 120.565, Florida Statutes, at a duly-noticed public meeting held on June 8, 2006, in Ft. Lauderdale, Florida, for consideration of the Petition for Declaratory Statement of SARAH STEPHENS, R.PH., PHARMACIST-IN-CHARGE, AETNA SPECIALTY PHARMACY, LLC., (hereinafter "the Petitioner").

The Petition makes the following inquiries: 1) Under Section 465.003(6), Florida Statutes, are medicinal drugs that are returned to or recovered by a pharmacy, prior to delivery to the patient or patient's agent considered "dispensed?"; 2) Under Section 465.016(1)(l), Florida Statutes, is it permissible for a pharmacy to place back in the stock any part of any prescription which is returned to or recovered by a pharmacy, prior to delivery to the patient or patient's agent?

Petitioner was not present at the meeting and was not represented by counsel. The Board was represented by Reginald D. Dixon, Assistant Attorney General. Having considered the petition, the Board makes the following findings and conclusions:

FINDINGS OF FACT:

1. The Petitioner is a licensed Florida pharmacist, having been issued license number PS 14343, employed by Aetna Specialty Pharmacy, LLC. (hereinafter "ASRx").

2. ASRx is a community pharmacy with a special P/E license dispensing specialty drugs to patients throughout the United States.

3. ASRx ships most, but not all, of its drug orders via overnight delivery.

4. A percentage of ASRx shipments do not reach the patient or the patient's agent for various reasons, including, failure of the patient or patient's agent to sign for delivery, prescription changes prior to shipment resulting in refusal by patient or patient's agent (usually a medical office), delivery of medicines to the wrong address (usually by the shipping agent), and shipping errors by ASRx.

CONCLUSIONS OF LAW:

5. The Board has authority to issue this Final Order pursuant to Section 120.565, Florida Statutes, and Rule 28-105, Florida Administrative Code.

6. Section 465.003(6), Florida Statutes, provides:

> "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

7. Webster's dictionary defines "transfer" as to convey from one person, place, or situation to another. Webster's dictionary defines "possession" as control or occupancy of property without regard to ownership.

8. According to Black's Law Dictionary, the law generally recognizes two kinds of possession: actual possession and constructive possession. A person who knowingly has direct physical control over a thing, at a given time, is then in actual possession of it. A person who, although not in actual possession, knowingly has both the power and the intention at a given time to exercise dominion or control over a thing, either directly or through another person or persons, is then in constructive possession of it.

9. The Board interprets "transfer of possession" within Section 465.003(6), Florida Statutes, to mean the conveyance of control over the medicinal drugs from the pharmacy or pharmacy's agent, including carrier and or delivery services, to the ultimate consumer or the consumer's agent.

10. The Board interprets Section 465.003(6), Florida Statutes, to mean that if the control over the medicinal drug is not conveyed to the consumer or the consumer's agent, that medicinal drug has not been "dispensed."

11. Section 465.016(1)(l), Florida Statutes, provides that it is a disciplinary offense for a pharmacist to place in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient. Section 465.016 (1)(l), Florida Statutes, further provides that in a hospital, nursing home, correctional facility, or extended care facility in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and the individual unit dose or unit-dose system labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any, the unused unit dose of medication may be returned to the pharmacy for redispensing.

12. The unambiguous language of Section 465.016(1)(l), Florida Statutes, clearly states that it applies to medicinal drugs that have been compounded or dispensed and returned by a patient. If a medicinal drug has not been compounded or dispensed and returned by a patient this provision does not apply.

13. It is the Board's opinion that medicinal drugs that have been shipped to the consumer or the consumer's agent, but not delivered to the consumer or the consumer's agent, have not been dispensed within the meaning of Section 465.003(6), Florida Statutes, and these medicinal drugs may be returned to the stock of the pharmacy.

14. It is the Board's opinion that although it is legally permissible to return non-dispensed medicinal drugs to the stock of a pharmacy, it is the responsibility of the pharmacist making the decision to return the medicinal drugs to the stock of the pharmacy to exercise his or her professional judgment in deciding whether or not it is appropriate to return the medications to the stock of the pharmacy in light of the conditions under which the medications were stored prior to the return to the pharmacy.

15. The Board's response to the Petition is with regard only to the questions propounded by the Petitioner and only applies to the facts set forth therein. It does not in any way address the appropriateness of returning medicinal drugs to stock when such drugs, although not dispensed, have been potentially compromised due to storage conditions.

DONE AND ORDERED this 22 day of June, 2006.

BOARD OF PHARMACY

Rebecca R. Poston

Rebecca R. Poston, R. Ph.
Executive Director
Florida Board of Pharmacy

NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEAL, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail to: **Sarah Stephens, R.Ph.,** 503 Sunport Lane, Orlando, Florida 32809: by interoffice mail to **Reginald D. Dixon**, Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050 this 23 day of June, 200_.

Harmony L. Elias

Deputy Agency Clerk

Aetna Specialty Pharmacy
503 Sunport Lane
Orlando, FL 32809

March 3, 2006

Rebecca Poston, R.Ph.
Executive Director
Florida Board of Pharmacy
4052 Bald Cypress Way
Bin C-04
Tallahassee, FL 32399-3254

Re: Declaratory Statement - Restocking Unused, Returned Prescription Drugs

Dear Ms. Poston:

I have enclosed a Petition for the above-captioned Declaratory Statement. Thank you very much for your attention to this matter.

Sincerely,

Sarah Stephens
Pharmacist-in-Charge

Enc.

Aetna Specialty Pharmacy
503 Sunport Lane
Orlando, FL 32809

PETITION FOR DECLARATORY STATEMENT BEFORE THE FLORIDA DEPARTMENT OF HEALTH, BOARD OF PHARMACY

Petitioner: **Sarah Stephens, R.Ph.**
Pharmacist-in-Charge
Aetna Specialty Pharmacy, LLC
503 Sunport Lane
Orlando, Florida 32809

Date: **March 3, 2006**

INQUIRY

Pursuant to Section 120.565, Florida Statutes, I hereby request a formal opinion from the Florida Board of Pharmacy regarding the meaning of "dispense" as that term is used in Sections 465.003(6) and 465.016(1)(l) and employed by Aetna Specialty Pharmacy, LLC ("ASRx") in order to permit the restocking of unused, returned prescription drugs under certain circumstances as described below.

FACTS

Aetna Specialty Pharmacy, LLC ("ASRx") is a Community Pharmacy with a Special P/E license (Florida License No. PH 21035) dispensing specialty drugs to patients throughout the United States. While the lion's share of all drug shipments reaches the hands of the patient or his/her medical office, there remain a very small, but extremely expensive number of shipments that *do not* reach the patient or the medical office, through the fault of the patient (failure to sign for delivery notwithstanding prior verbal confirmation thereof), the medical office (prescription changed post shipment), the shipping agent (delivery to wrong address) and ASRx (inadvertent shipping error). When the delivery is unsuccessful, the drug is returned to and wasted by ASRx. With an average cost of approximately $1,200/shipment, ASRx is currently wasting tens of thousands of dollars on returned drugs that could potentially be reused under certain circumstances as set forth below.

CHAPTER 465, FLORIDA STATUTES

Section 465.016(1)(l), Florida Statutes, provides in part that "[p]lacing in the stock of any pharmacy any part of any prescription compounded or *dispensed* which is returned by a *patient*" constitutes grounds for disciplinary action as specified in Section 456.072(2). (Emphasis added.)

Section 465.003(6), Florida Statutes, provides in part that "'[d]ispense' means the *transfer of possession* of one or more doses of a medicinal drug by a pharmacist to the *ultimate consumer or her or his agent* ... [and] ... [t]he actual sales transaction and *delivery* of such drug shall not be considered dispensing." (Emphasis added.)

ARGUMENT

One may reasonably conclude from a fair and unambiguous reading of Sections 465.016(1)(l) and 465.003(6) of the Florida Statutes that a drug recovered by a pharmacy prior to its receipt by the intended patient or agent (generally speaking, his/her medical office) does not constitute a *dispensed* drug within the meaning of Florida law because the transfer of possession was not, in fact, made to such patient or agent. For the most part, ASRx ships its drug orders via overnight delivery; no drug will ever be "dispensed" until it is actually delivered to, and accepted by, the patient or the medical office. Therefore, if the drug can be recovered by the pharmacy *prior* to its receipt by the patient or medical office, neither Sections 465.016(1)(l) or 465.003(6) will strictly prohibit the restocking of the recovered drug; because, in this instance, the drug has *not* been "dispensed".

Of course, if the restocking of prescription drugs under this scenario is to be permitted, certain guidelines must be imposed by the pharmacy to ensure that the integrity of such unused drugs remains intact. In conjunction with the American Society of Consultant Pharmacists, the American Medical Association supports the return and reuse of medications to the dispensing pharmacy (in long-term care facilities) provided that certain conditions are satisfied (the "AMA Conditions"). ASRx supports the logic underlying the AMA Conditions and intends to comply therewith as follows:

- Controlled substances cannot be returned.
- Medications are shipped in tamper-evident packaging and returned with packaging intact. [Please note that ASRx also ships the medications in the manufacturers' original packaging thereby affording extra precaution.]
- Medications meet all federal and state standards for product integrity in the professional judgment of the pharmacist.
- A system is in place to track restocking and reuse to allow medications to be recalled if required.

Finally, the largest question that should come to mind under this petition is how can ASRx be confident that the returned drug is safe for reuse, given that virtually all shipments are under refrigeration and temperature sensitive? Again, ASRx ships the drugs in the original manufacturer's and tamper-evident packaging. If such packaging is tainted upon return, the drug will be wasted right away. If such packaging is not tainted, the return will be closely examined by a pharmacist to ensure the integrity of the drug. If the integrity has not been compromised, the drug will be restocked in conformance with the AMA Conditions. This process is no different than the process used to check the integrity of drugs shipped to ASRx by the manufacturer/wholesaler. In both scenarios,

the pharmacist assumes responsibility for ensuring that the integrity of all drugs accepted and ultimately dispensed by ASRx is never compromised.

CONCLUSION

I hereby request a formal opinion that it is not a violation of either Section 465.016(1)(l) or Section 465.003(6) of the Florida Statutes to restock unused prescription drugs which are returned to ASRx provided that (i) the drugs are recovered *prior* to the receipt thereof by either the patient or his/her agent and (ii) the return and reuse of the drugs conform to the AMA Conditions as defined herein.

I am, indeed, extremely interested in putting this huge cost savings policy in place as soon as possible and look forward to a favorable reply from the Board. Thank you very much for your attention to this matter.

Sincerely,

Sarah Stephens
Pharmacist-in-Charge