

STATE OF FLORIDA
BOARD OF PHARMACY

By: Heather Coleman
Deputy Agency Clerk

IN RE: PETITION FOR DECLARATORY STATEMENT
OF SARAH STEPHENS, R.P.H., 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.P.H., 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, 2006.

Harmony L. [Signature]

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)(I) 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)(I), 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)(1) 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)(1) 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)(j) 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/hcr 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