DEPARTMENT OF HEALTH, BOARD OF PHARMACY

ORDER FACT SHEET

(For use by Board Counsel and Board Staff)

Order # <u>07-101</u> ZDS Date Order Filed <u>@9.01</u>
1) Respondent's/Petitioner's/Applicant's Name: CVS Pharmacy
2) License Number: 3) Profession Type:Pharmacy
4) Type of Order: Discipline Licensure _x Declaratory Statement
5) DOH Case Number 6) DOAH Case Number
7) File Number
8) Statutory reference for Violations/Reasons for Denial:
9) Violation Codes:n/a
10) Penalties Imposed:
11) Closure Code:
12) Exhibits to be Attached to Final Order: (3)
a) Administrative Complaint
a) Voluntary relinquishment form
b) Recommended Order
Exceptions: Petitioner's Respondent's
c) Motions (specify)
d) Other (specify)Petition for Declaratory Statement
13) Special Handling Instructions
14) Fact Sheet Prepared By: Reginald D. Dixon
15) Codes Added to Fact Sheet By:
16) Exhibits Attached to Order By: Makine Wennyer

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Final Order No. DOH-07 FILED DATE -Department of Health Deputy Agency Clerk

STATE OF FLORIDA BOARD OF PHARMACY

IN RE: PETITION FOR DECLARATORY STATEMENT OF CVS PHARMACY

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 12-13, 2007, in Ft. Lauderdale, Florida, for consideration of the Petition for Declaratory Statement of CVS Pharmacy (hereinafter "the Petitioner").

The Petition inquiries as to the appropriate standard of care to be followed by Petitioner's pharmacists when filing prescriptions written by out-of state doctors for nonresident patients visiting the State of Florida. The Petition is attached hereto and incorporated by reference as Exhibit 1.

Petitioner was represented by Edwin Bayo, Esquire, at the meeting. The Board was represented by Reginald D. Dixon, Assistant Attorney General. Having considered the petition, and the testimony of those present, the Board makes the following findings and conclusions:

FINDINGS OF FACT:

1. The Petitioner operates numerous community pharmacies in Florida.

2. Many of Petitioner's pharmacists are called upon to fill prescriptions written by out-of-state doctors.

CONCLUSIONS OF LAW:

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

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5. Section 465.003(14), Florida Statutes, provides:

"Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

6. It is the Board's interpretation that the following constitutes the appropriate

standard of care when filling a prescription written by an out-of-state doctor for a no-

resident patient visiting the State of Florida:

a. In order for a prescription to be valid it must be based upon a documented physician-patient relationship.

b. A non-resident patient who is visiting Florida and is under his/her out-of-state doctor's care for a chronic condition can have his/her out-of-state doctor call in or otherwise legally transmit a prescription to be filled by a Florida licensed pharmacist for that condition.

c. A non-resident patient who is visiting Florida and is under his/her out-of state doctor's care for a recurring condition can have his/her out-of-state doctor call in or otherwise legally transmit a prescription to be filled by a Florida licensed pharmacist for that condition.

d. The Florida licensed pharmacist can exercise his/her professional judgment by calling the out-of-state doctor. The Florida licensed pharmacist can also ask questions of the

non-resident patient designed to elicit the nature of the condition/illness and that the non-resident patient is under the out-of-state doctor's care for that condition/illness. The presumption that a non-resident patient visiting Florida is under the care of an out-of-state doctor is stronger if they both reside in the same city or geographical area.

e. Telemedicine is a recognized field in the medical community. A pharmacist in the exercise of his/her professional judgment may receive and fill a prescription from an out-of-state doctor for a non-resident patient visiting Florida that has been generated through telemedicine practice.

f. A pharmacist must review the totality of the circumstances, including the patient's age and condition, the nature of the medication prescribed, the out-of-state addresses of the patient and the out-of state doctor, and other applicable factors to determine the validity of the prescription and that it is necessary for the treatment of a chronic or recurrent illness. Calling the out-of-state doctor may be necessary in certain cases but is not required in every case.

The Board's response to the Petition is with regard only to the specific questions

propounded by the Petitioner and only applies to the facts set forth therein.

DONE AND ORDERED this <u>8</u> day of <u>Uugust</u>, 2007.

BOARD OF PHARMACY

Ribura 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, 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: **CVS Pharmacy, c/o Edwin A. Bayo, Esquire,** 301 S. Brounough Street, Suite 600, Tallahassee, Florida 32302-3189; and by interoffice mail to **Reginald D. Dixon**, Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050 this <u>d</u> day of <u>August</u>, 2007.

reputy Agency Clerk

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GRAY ROBINSON ATTORNEYS AT LAW

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April 10, 2007

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

Re: Petition for Declaratory Statement

Dear Ms. Poston:

Enclosed please find an original Petition for Declaratory Statement being filed on behalf of our client, CVS/pharmacy. By copy of this letter I am forwarding a copy of this Petition to Mr. Dixon to ensure that this matter will be properly noticed. I will appreciate receiving a Notice of Hearing in due course.

As always, thanks for your cooperation. Please let me know if you have any questions.

Sincerely

Edwin A. Bayó

Cc: Susan DelMonico, R.Ph., J.D. Tom Davis, R.Ph. Reginald Dixon, Board Counsel

STATE OF FLORIDA BOARD OF PHARMACY

IN RE: THE PETITION FOR DECLARATORY STATEMENT OF CVS/PHARMACY

COMES NOW Petitioner, CVS/Pharmacy, by and through undersigned legal counsel and pursuant to Rule 28-105.002, F.A.C., hereby petitions the Florida Board of Pharmacy (hereinafter "Board") for a Declaratory Statement regarding the scope and operation of §465.003(14, F.S. The following is submitted in support of this Petition:

1. Petitioner, CVS/Pharmacy, operates numerous Community Pharmacies in Florida. For purposes of this proceeding, Petitioner's address and phone number shall be that of the undersigned counsel.

2. Section 465.003(14), F.S., defines the term "prescription" to also include "an order written or transmitted by a practitioner licensed in a jurisdiction other than this state, but only if the pharmacist called upon to dispense the prescription determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness."

3. A pharmacy inspector with the Department of Health has instructed some of Petitioner's staff pharmacists regarding the filling of prescriptions written by out-of-state physicians.

4. Undersigned Counsel discussed this matter with the Manager of the Statewide Inspection Program. After said discussion, the undersigned believes that reasonable minds may have different opinions as to the interpretation of §465.003(14), F.S. and the proper standard of practice in this particular area.

5. Due to Florida's large seasonal population, many of Petitioner's pharmacists are called upon to fill such prescriptions on a regular basis.

6. Petitioner wishes to comply with all applicable pharmacy laws and rules,

and wishes to instruct its pharmacists on the proper way to receive, interpret, and

fill such prescriptions.

7. Petitioner wishes to advise its pharmacists that the following statements

constitute the proper standard of practice on this area:

(a) §465.003(14), F.S., defines "prescription" to include an order written or transmitted by a practitioner licensed in a jurisdiction other than this state, but only if the pharmacist called upon to dispense the prescription determines, in the exercise of her/his professional judgment that the order is valid and necessary for the treatment of a chronic or recurrent illness.

(b) In order for a prescription to be valid it must be based upon a documented physician-patient relationship.

(c) A non-resident who is visiting Florida and is under his/her doctor's care for a chronic condition (i.e. COPD, hypertension, erectile dysfunction, arthritis) can have his/her out of state doctor call in or mail a prescription to be filled by a Florida Pharmacist.

(d) A non-resident who is visiting Florida and is under his/her doctor's care for a recurring condition (i.e. allergies, sinus infections, ear infections) can have his/her out of state doctor call in or mail a prescription to be filled by a Florida Pharmacist.

(e) The Florida Pharmacist can exercise his/her professional judgment by calling the physician. The Florida Pharmacist can also ask questions of the patient designed to elicit the nature of the condition/illness and that the patient is under the physician's care for that condition/illness. The presumption that an out-of state resident/patient is under the care of an out-of state physician is stronger if they both reside in the same city or geographical area.

(f) In the absence of emergency circumstances, an out-of-state resident who contracts a new illness or condition in Florida should not be able to have his/her out-of-state physician call in or write a prescription. However, the Standards for Telemedicine Practice recognize that in cases where a physician has previously examined the patient and has records for said patient, that the out-of-state physician can issue a legitimate prescription. An emergency situation is one where the physician determines that the immediate administration of the medication is necessary for the proper treatment of the patient.

(g) A pharmacist must review the totality of the circumstances, including the patient's age and condition, the nature of the medication prescribed, the out-of-state addresses of the patient and physician, and other applicable factors to determine the validity of the order and that it is necessary for the treatment of a chronic or recurrent illness. Calling the prescribing physician may be necessary in certain cases, but is not required in every case.

8. Petitioner submits that the above statements constitute the proper standard of practice for a Florida pharmacist who is presented with an order issued by an out-of-state physician for an out-of-state resident/patient located in Florida.

9. Petitioner is substantially affected by the issue presented in this Declaratory Statement in that it must ensure that its pharmacists and pharmacies are abiding by the proper standard of practice when called upon to handle this recurring issue.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy grant this Petition for Declaratory Statement, rule on whether some or all of the specific items listed under paragraph 7 above constitute the proper standard of practice, and/or provide any other guidance regarding this issue. Respectfully submitted, this <u>10</u> day of April, 2007.

Edwin A. Bayó GrayRobinson, P.A. 301 So. Bronough Street, Suite 600 Tallahassee, FL 32302-3189 (850)577-9090/fax(850)577-3311 Counsel for Petitioner