

**STATE OF FLORIDA
BOARD OF PHARMACY**

IN RE: PETITION FOR DECLARATORY STATEMENT

UNIVERSITY OF MIAMI

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 April 8, 2008, in Orlando, Florida, for consideration of the Petition for Declaratory Statement of UNIVERSITY OF MIAMI (hereinafter "the Petitioner").

The inquiry posed by the declaratory statement is: under Rule 64B16-27.615, Florida Administrative Code, does the term "possession" mean that pharmacies may possess sample medications only if the practitioner who requested the delivery of the sample medication to the pharmacy is the same practitioner that prescribes the drug to be dispensed (without charge) to a patient?

Petitioner was present at the meeting and was represented by counsel, Mark A. Dresnick. The Board was represented by Deborah Bartholow Loucks, Assistant Attorney General. Having considered the petition, the Board makes the following findings and conclusions:

FINDINGS OF FACT:

1. Petitioner, University of Miami, operates pharmacies in hospitals owned by the University of Miami. These pharmacies are located at the University of Miami Anne Bates

Leach Eye Hospital, 900 NW 17th Street, Miami, Florida (community pharmacy permit number PH 8065) and University of Miami Hospital & Clinics, National Children's Cardiac Hospital Pharmacy, 1475 NW 12th Avenue, Miami, Florida (community pharmacy permit PH 8085).

2. Petitioner employs approximately 800 physicians.

3. The physicians employed by Petitioner frequently request authorized drug manufacturers and drug representatives to provide sample medications which are then dispensed without charge to patients of the University of Miami.

4. Petitioner has determined that it will institute a sample medication policy that will require that all sample medications requested by University of Miami physicians be delivered by the drug manufacturers and representatives directly to the University of Miami pharmacies operated by Petitioner.

5. Petitioner's sample medication policy would require that the sample medications would be dispensed by Petitioner's pharmacists, without any charge to the patients, pursuant to prescriptions issued by Petitioner's practitioners authorized by Florida law to prescribe the drugs.

CONCLUSIONS OF LAW:

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

7. Rule 64B16-27.615, Florida Administrative Code, provides:

- (1) Pharmacies may not be in possession of sample medicinal drugs except:

- (a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May Be Ordered by Pharmacists.
 - (b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.
 - (c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.
- (2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the company of origin in accordance with the requirements of Chapter 499, F.S.

8. Section 499.028(3)(e), Florida Statutes, provides:

(e) Drug samples may only be distributed:

1. To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or
2. At the written request of such practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner's name, address, and professional delegation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.

9. Webster's dictionary defines "possession" as control or occupancy of property without regard to ownership.

10. 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.

11. The Board interprets "possession" within rule 64B16-27.615, Florida Administrative Code, to mean constructive possession so that any practitioner who is part of the University of Miami system may request sample medications be sent directly to the Petitioner's pharmacies and any other practitioner who is part of the University of Miami system who is authorized by law to prescribe medications may write a prescription for a sample medication to be dispensed from Petitioner's pharmacies, even if the prescribing practitioner was not the practitioner who requested that the sample medication be sent to the pharmacy.

12. It is the Board's opinion that sample medicinal drugs that have been requested by an authorized practitioner in compliance with Section 499.028(3)(e), Florida Statutes, may be requested to be delivered directly to a pharmacy under the dominion and control of Petitioner and that any practitioner employed or working under the auspices of Petitioner in whatever capacity who is authorized by law to write prescriptions for medication may write a prescription for a sample medication to be dispensed from Petitioner's pharmacies even if the prescribing practitioner is not the practitioner who requested the sample medication from the drug manufacturer or representative.

13. The Board's response to the Petition is with regard only to the question propounded by Petitioner and only applies to the facts set forth therein. It does not in any way

allow community pharmacies to be in possession of sample medication in contradiction to the exceptions listed in Rule 64B16-27.615, Florida Administrative Code.

DONE AND ORDERED this 15 day of July, 2008.

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: **Mark A. Dresnick, Attorney at Law**, Dresnick & Rodriguez, P.A., One Dattran Center, Suite 1610, 9100 South Dadeland Boulevard, Miami, Florida 33156-7817; by interoffice mail to **Deborah B. Loucks**, Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050 this 17 day of July 2008.

Angel Sanders
5
Deputy Agency Clerk

LAW OFFICES
DRESNICK & RODRIGUEZ, P.A.
ONE DATRAN CENTER • SUITE 1610
9100 SOUTH DADELAND BOULEVARD
MIAMI, FLORIDA 33156-7817

MARK A. DRESNICK
MONICA L. FELDER-RODRIGUEZ*

*BOARD-CERTIFIED IN HEALTH LAW

TELEPHONE (305) 670-9800
FAX (305) 670-9933

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Rachel R*
DATE 3-14-08
OF COUNSEL
PAMELA I. PERRY, P.A.

March 11, 2008

VIA FEDERAL EXPRESS

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

Re: Petition for Declaratory Statement

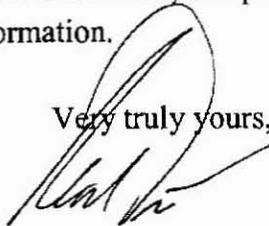
Dear Ms. Poston:

Enclosed please find a Petition for a Declaratory Statement we are submitting to the Florida Board of Pharmacy on behalf of our client, the University of Miami.

We would appreciate it if you would place this Petition on the Board's agenda for the April 8 and 9, 2008 meeting of the Board.

Thank you for your assistance in this matter, and please contact me if you have any questions or need any further information.

Very truly yours,



Mark A. Dresnick

MAD/ts
Enclosure

cc: Maxine Wenzinger, Assistant to Executive Director
of the Florida Board of Pharmacy (w/encl.)
Deborah Loucks, Esq., Assistant Attorney General (w/encl.)
Audra Lazarus, Esq., University of Miami Assistant General Counsel (w/encl.)

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: PETITION FOR DECLARATORY
STATEMENT BEFORE THE FLORIDA
BOARD OF PHARMACY ON BEHALF
OF THE UNIVERSITY OF MIAMI

Petitioner, University of Miami, by its undersigned counsel, pursuant to Section 120.565, Florida Statutes and Rule 28-105.002, Florida Administrative Code petitions the Florida Board of Pharmacy (hereafter referred to as the "Board") for a Declaratory Statement regarding the applicability of Rule 64B16-27.615(1)(b),(c), Florida Administrative Code, regarding the possession of sample medication at pharmacies owned by the University of Miami. The particular set of circumstances pertaining to this Petition are as follows:

1. The primary address for the Petitioner, University of Miami, is 1320 South Dixie Highway, Suite 1250, Coral Gables, FL 33146. For purposes of notifications regarding this proceeding, the Petitioner's address and phone number shall be that of undersigned counsel.

2. Petitioner, University of Miami, operates pharmacies in hospitals owned by the University of Miami. These pharmacies are located at the University of Miami Anne Bates Leach Eye Hospital at 900 NW 17th Street, Miami, FL 33136 (Community Pharmacy License No.: PH8065), and the University of Miami Hospital & Clinics, National Children's Cardiac Hospital Pharmacy at 1475 NW 12th Avenue, Miami, FL 33136-1002 (Community Pharmacy License No: PH8085).

3. The University also employs approximately eight hundred physicians whom practice medicine, teach medical students and residents, and perform medical research.

4. Physicians employed by the University frequently request authorized drug manufacturers and drug representatives to provide sample medications which are then dispensed without charge to patients of the University of Miami.

5. Due to the volume of sample medication requested by University of Miami physicians, the University has determined to institute a sample medication policy to provide safeguards to reduce or eliminate the potential for diversion of sample medications. The University policy will require all sample medications requested by University of Miami faculty members to be delivered by drug manufacturers and representatives directly to the University of Miami pharmacies operated by the University. The sample medications would then be dispensed by the University of Miami pharmacists, without any charge to patients, pursuant to prescriptions issued by University practitioners authorized by Florida law to prescribe the drugs.

6. Federal and state laws specifically authorize the delivery of drug samples to hospital pharmacies, and to pharmacies of other health care entities, at the written request of a practitioner licensed to prescribe the drugs. 21 U.S.C. §353(d)(2),(3),¹ 21 C.F.R. 203.30, 21 C.F.R. 203.31; and Section 499.028(3)(e), Florida Statutes.²

¹ This section is part of the "Prescription Drug Marketing Act" commonly referred to as the PDMA.

² This Florida statute is identical in many respects to 21 U.S.C. §353.

7. The laws regulating this area also recognize that a pharmacy of a hospital or of another health care entity may dispense sample drugs, without charge, at the direction of a practitioner licensed to prescribe the drugs. 21 U.S.C. 353(b)(1),(2); 21 U.S.C. 353(c)(1); 21 U.S.C. 353(d), 21 C.F.R. 203.3(h).

8. This Declaratory Statement is being requested by the University of Miami to clarify the applicability of the Florida Board of Pharmacy regulation entitled "Possession of Sample Medicinal Drugs," adopted in 1993. Rule 64B16-27.615 Florida Administrative Code. This regulation states in its entirety as follows:

Possession of Sample Medicinal Drugs

(1) Pharmacies may not be in possession of sample medicinal drugs except:

(a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May be Ordered by Pharmacists.

(b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the

company of origin in accordance with the requirements of Chapter 499, F.S.

9. By its terms, the provisions of this rule pertain to the "possession" of sample drugs by pharmacies, and do not seek to regulate the dispensing of sample drugs. The provisions of Paragraph (1)(b),(c) of this regulation state that pharmacies may possess sample medicinal drugs "upon the written request of the prescribing practitioner." [emphasis supplied]

10. The University of Miami seeks clarification of this rule because the language of the regulation entitled "Possession of Sample Medicinal Drugs" may be interpreted to mean that pharmacies may possess sample medicinal drugs only if the practitioner that requested the delivery of the sample drug to the pharmacy is the exact same practitioner that prescribes the drug to be dispensed (without charge) to a patient. The University of Miami anticipates there will be many circumstances, for example, during which a cardiologist within the Division of Cardiology will request a drug company to provide a blood pressure sample medication to be delivered to the University's pharmacy, but another cardiologist within the Division of Cardiology may be the physician that actually prescribes the medication. The same situation may occur when one urologist in the Department of Urology authorizes the delivery of sample medications to treat a prostate disorder, but another urologist within the Department of Urology may be the physician that actually prescribes the sample medication to a patient.

11. The Petitioner submits that the appropriate interpretation of Rule 64B16-27.615(1)(b),(c), in compliance with all federal and state statutes, would permit a

pharmacy to possess and dispense sample medicinal drugs in situations in which one practitioner requested the drugs be delivered to the pharmacy, and a professional colleague of the practitioner is the prescribing practitioner.

12. Any different interpretation of this provision would require the pharmacies to maintain a separate inventory of sample drugs for each physician that requested the sample medications, and would require that each physician within a University department to separately request their own inventory of sample medication to be delivered to the pharmacy. This would be unwieldy, impractical, and would hinder patients from efficiently obtaining complimentary sample medications. Alternatively, the University would be required to direct its physicians to maintain their own individual stock of sample medications in their individual physician offices which would run contrary to the University's laudable goal of controlling access to sample medications, and substantially reducing the risk of unauthorized diversion and pilferage of drug samples.

13. The University of Miami's intended policy to require all sample medicinal drugs to be delivered to the University's pharmacies and be dispensed by pharmacists (without charge) pursuant to a prescription issued by an authorized practitioner is in compliance with all applicable Florida and federal statutes. This policy is also in the best interest of the public as it substantially reduces the possibility of unauthorized diversion. The medications would be stored in the locked pharmacies instead of being stored in numerous physician offices in various departments at the University which are more vulnerable to unauthorized diversion. This policy is also in the public interest as it

facilitates the efficient and safe dispensing of sample medications without charge to patients.

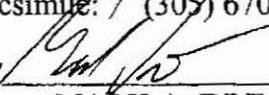
14. The University of Miami wishes to comply with all applicable pharmacy laws and rules and wishes to instruct its pharmacists on the proper manner to dispense sample medicinal drugs delivered to its pharmacies at the request of prescribing practitioners. The Petitioner wishes to advise its pharmacists that: (i) pharmacies at the University may possess sample medicinal drugs delivered to the pharmacies at the request of a prescribing practitioner employed by the University in accordance with the provisions of Section 499.028(3)(e)2, and the Prescription Drug Marketing Act, and (ii) the sample medicinal drugs may be dispensed (without fee) upon the request of a prescribing practitioner authorized to prescribe the drugs. The Petitioner submits that the above statements are in compliance with applicable Federal law and Florida Statutes, and constitutes the proper standard of practice for a Florida pharmacist in conjunction with the dispensing of sample medicinal drugs.

15. Petitioner, University of Miami, is substantially affected by the issue presented in this Declaratory Statement as the pharmacists and practitioners it employs, and the pharmacies it operates, want to ensure that they are abiding by the proper standards of practice in conjunction with the possession and dispensing of sample medicinal drugs. Furthermore, the University of Miami has a substantial interest in making sample medicinal drugs available without cost to its patients to further its goal of providing high quality health care to its patients, as well as ensuring that any medication kept at the University is properly stored and dispensed.

WHEREFORE, Petitioner, University of Miami, respectfully requests that the Board of Pharmacy grant this Petition for Declaratory Statement, and/or provide any other guidance regarding this issue which is appropriate under the circumstances.

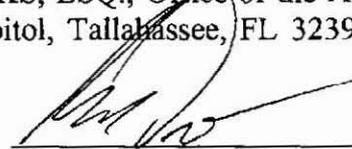
Respectfully submitted, this 11th day of March, 2008.

DRESNICK & RODRIGUEZ, P.A.
Attorneys for University of Miami
9100 South Dadeland Boulevard
One Datan Center, Suite 1610
Miami, FL 33156-7817
Telephone: (305) 670-9800
Facsimile: (305) 670-9933

By 
MARK A. DRESNICK
Florida Bar No. 229008

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by overnight mail to: REBECCA POSTON, Executive Director, Florida Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3252; and by U.S. Mail to DEBORAH LOUCKS, ESQ., Office of the Attorney General, Department of Legal Affairs, PL01 The Capitol, Tallahassee, FL 32399-1050, this 11 day of March, 2008.


MARK A. DRESNICK

Final Order No. DOH-08-1645-^{JS}MOA
FILED DATE - 7-17-08
Department of Health
By: Racquel
Deputy Agency Clerk

**STATE OF FLORIDA
BOARD OF PHARMACY**

IN RE: PETITION FOR DECLARATORY STATEMENT
UNIVERSITY OF MIAMI

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 April 8, 2008, in Orlando, Florida, for consideration of the Petition for Declaratory Statement of UNIVERSITY OF MIAMI (hereinafter "the Petitioner").

The inquiry posed by the declaratory statement is: under Rule 64B16-27.615, Florida Administrative Code, does the term "possession" mean that pharmacies may possess sample medications only if the practitioner who requested the delivery of the sample medication to the pharmacy is the same practitioner that prescribes the drug to be dispensed (without charge) to a patient?

Petitioner was present at the meeting and was represented by counsel, Mark A. Dresnick. The Board was represented by Deborah Bartholow Loucks, Assistant Attorney General. Having considered the petition, the Board makes the following findings and conclusions:

FINDINGS OF FACT:

1. Petitioner, University of Miami, operates pharmacies in hospitals owned by the University of Miami. These pharmacies are located at the University of Miami Anne Bates

Leach Eye Hospital, 900 NW 17th Street, Miami, Florida (community pharmacy permit number PH 8065) and University of Miami Hospital & Clinics, National Children's Cardiac Hospital Pharmacy, 1475 NW 12th Avenue, Miami, Florida (community pharmacy permit PH 8085).

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4. Petitioner has determined that it will institute a sample medication policy that will require that all sample medications requested by University of Miami physicians be delivered by the drug manufacturers and representatives directly to the University of Miami pharmacies operated by Petitioner.

5. Petitioner's sample medication policy would require that the sample medications would be dispensed by Petitioner's pharmacists, without any charge to the patients, pursuant to prescriptions issued by Petitioner's practitioners authorized by Florida law to prescribe the drugs.

CONCLUSIONS OF LAW:

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

7. Rule 64B16-27.615, Florida Administrative Code, provides:

(1) Pharmacies may not be in possession of sample medicinal drugs except:

- (a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May Be Ordered by Pharmacists.
- (b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.
- (c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.
- (2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the company of origin in accordance with the requirements of Chapter 499, F.S.

8. Section 499.028(3)(e), Florida Statutes, provides:

(e) Drug samples may only be distributed:

1. To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or
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11. The Board interprets "possession" within rule 64B16-27.615, Florida Administrative Code, to mean constructive possession so that any practitioner who is part of the University of Miami system may request sample medications be sent directly to the Petitioner's pharmacies and any other practitioner who is part of the University of Miami system who is authorized by law to prescribe medications may write a prescription for a sample medication to be dispensed from Petitioner's pharmacies, even if the prescribing practitioner was not the practitioner who requested that the sample medication be sent to the pharmacy.

12. It is the Board's opinion that sample medicinal drugs that have been requested by an authorized practitioner in compliance with Section 499.028(3)(e), Florida Statutes, may be requested to be delivered directly to a pharmacy under the dominion and control of Petitioner and that any practitioner employed or working under the auspices of Petitioner in whatever capacity who is authorized by law to write prescriptions for medication may write a prescription for a sample medication to be dispensed from Petitioner's pharmacies even if the prescribing practitioner is not the practitioner who requested the sample medication from the drug manufacturer or representative.

13. The Board's response to the Petition is with regard only to the question propounded by Petitioner and only applies to the facts set forth therein. It does not in any way

allow community pharmacies to be in possession of sample medication in contradiction to the exceptions listed in Rule 64B16-27.615, Florida Administrative Code.

DONE AND ORDERED this 15 day of July, 2008.

BOARD OF PHARMACY

Rebecca R. Poston

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

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Angel Sanders
5
Deputy Agency Clerk

LAW OFFICES
DRESNICK & RODRIGUEZ, P.A.

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9100 SOUTH DADELAND BOULEVARD
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MARK A. DRESNICK
MONICA L. FELDER-RODRIGUEZ*

*BOARD-CERTIFIED IN HEALTH LAW

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Rachel R*
DATE 3.14.08
OF COUNSEL
PAMELA I. PERRY, P.A.

March 11, 2008

VIA FEDERAL EXPRESS

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

Re: Petition for Declaratory Statement

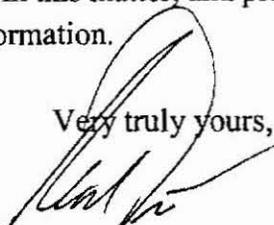
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Thank you for your assistance in this matter, and please contact me if you have any questions or need any further information.

Very truly yours,



Mark A. Dresnick

MAD/ts
Enclosure

cc: Maxine Wenzinger, Assistant to Executive Director
of the Florida Board of Pharmacy (w/encl.)
Deborah Loucks, Esq., Assistant Attorney General (w/encl.)
Audra Lazarus, Esq., University of Miami Assistant General Counsel (w/encl.)

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¹ This section is part of the "Prescription Drug Marketing Act" commonly referred to as the PDMA.

² This Florida statute is identical in many respects to 21 U.S.C. §353.

7. The laws regulating this area also recognize that a pharmacy of a hospital or of another health care entity may dispense sample drugs, without charge, at the direction of a practitioner licensed to prescribe the drugs. 21 U.S.C. 353(b)(1),(2); 21 U.S.C. 353(c)(1); 21 U.S.C. 353(d), 21 C.F.R. 203.3(h).

8. This Declaratory Statement is being requested by the University of Miami to clarify the applicability of the Florida Board of Pharmacy regulation entitled "Possession of Sample Medicinal Drugs," adopted in 1993. Rule 64B16-27.615 Florida Administrative Code. This regulation states in its entirety as follows:

Possession of Sample Medicinal Drugs

(1) Pharmacies may not be in possession of sample medicinal drugs except:

(a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May be Ordered by Pharmacists.

(b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the

company of origin in accordance with the requirements of Chapter 499, F.S.

9. By its terms, the provisions of this rule pertain to the "possession" of sample drugs by pharmacies, and do not seek to regulate the dispensing of sample drugs. The provisions of Paragraph (1)(b),(c) of this regulation state that pharmacies may possess sample medicinal drugs "upon the written request of the prescribing practitioner." [emphasis supplied]

10. The University of Miami seeks clarification of this rule because the language of the regulation entitled "Possession of Sample Medicinal Drugs" may be interpreted to mean that pharmacies may possess sample medicinal drugs only if the practitioner that requested the delivery of the sample drug to the pharmacy is the exact same practitioner that prescribes the drug to be dispensed (without charge) to a patient. The University of Miami anticipates there will be many circumstances, for example, during which a cardiologist within the Division of Cardiology will request a drug company to provide a blood pressure sample medication to be delivered to the University's pharmacy, but another cardiologist within the Division of Cardiology may be the physician that actually prescribes the medication. The same situation may occur when one urologist in the Department of Urology authorizes the delivery of sample medications to treat a prostate disorder, but another urologist within the Department of Urology may be the physician that actually prescribes the sample medication to a patient.

11. The Petitioner submits that the appropriate interpretation of Rule 64B16-27.615(1)(b),(c), in compliance with all federal and state statutes, would permit a

pharmacy to possess and dispense sample medicinal drugs in situations in which one practitioner requested the drugs be delivered to the pharmacy, and a professional colleague of the practitioner is the prescribing practitioner.

12. Any different interpretation of this provision would require the pharmacies to maintain a separate inventory of sample drugs for each physician that requested the sample medications, and would require that each physician within a University department to separately request their own inventory of sample medication to be delivered to the pharmacy. This would be unwieldy, impractical, and would hinder patients from efficiently obtaining complimentary sample medications. Alternatively, the University would be required to direct its physicians to maintain their own individual stock of sample medications in their individual physician offices which would run contrary to the University's laudable goal of controlling access to sample medications, and substantially reducing the risk of unauthorized diversion and pilferage of drug samples.

13. The University of Miami's intended policy to require all sample medicinal drugs to be delivered to the University's pharmacies and be dispensed by pharmacists (without charge) pursuant to a prescription issued by an authorized practitioner is in compliance with all applicable Florida and federal statutes. This policy is also in the best interest of the public as it substantially reduces the possibility of unauthorized diversion. The medications would be stored in the locked pharmacies instead of being stored in numerous physician offices in various departments at the University which are more vulnerable to unauthorized diversion. This policy is also in the public interest as it

facilitates the efficient and safe dispensing of sample medications without charge to patients.

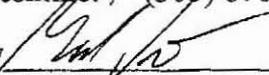
14. The University of Miami wishes to comply with all applicable pharmacy laws and rules and wishes to instruct its pharmacists on the proper manner to dispense sample medicinal drugs delivered to its pharmacies at the request of prescribing practitioners. The Petitioner wishes to advise its pharmacists that: (i) pharmacies at the University may possess sample medicinal drugs delivered to the pharmacies at the request of a prescribing practitioner employed by the University in accordance with the provisions of Section 499.028(3)(e)2, and the Prescription Drug Marketing Act, and (ii) the sample medicinal drugs may be dispensed (without fee) upon the request of a prescribing practitioner authorized to prescribe the drugs. The Petitioner submits that the above statements are in compliance with applicable Federal law and Florida Statutes, and constitutes the proper standard of practice for a Florida pharmacist in conjunction with the dispensing of sample medicinal drugs.

15. Petitioner, University of Miami, is substantially affected by the issue presented in this Declaratory Statement as the pharmacists and practitioners it employs, and the pharmacies it operates, want to ensure that they are abiding by the proper standards of practice in conjunction with the possession and dispensing of sample medicinal drugs. Furthermore, the University of Miami has a substantial interest in making sample medicinal drugs available without cost to its patients to further its goal of providing high quality health care to its patients, as well as ensuring that any medication kept at the University is properly stored and dispensed.

WHEREFORE, Petitioner, University of Miami, respectfully requests that the Board of Pharmacy grant this Petition for Declaratory Statement, and/or provide any other guidance regarding this issue which is appropriate under the circumstances.

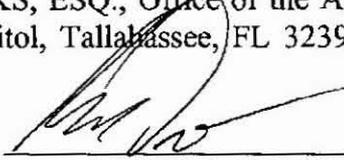
Respectfully submitted, this 11th day of March, 2008.

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By 
MARK A. DRESNICK
Florida Bar No. 229008

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by overnight mail to: REBECCA POSTON, Executive Director, Florida Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3252; and by U.S. Mail to DEBORAH LOUCKS, ESQ., Office of the Attorney General, Department of Legal Affairs, PL01 The Capitol, Tallahassee, FL 32399-1050, this 11 day of March, 2008.


MARK A. DRESNICK