

**STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

FILED	
Department of Business and Professional Regulation AGENCY CLERK	
CLERK	Ronda L. Bryan
Date	9/23/2016
File #	2016-07337

**In Re: Petition for Declaratory
Statement,**

DS 2016-057

**Sandy Reese, Sevens Management
Company 11 Inc.,
Petitioner.**

FINAL ORDER DENYING PETITION FOR DECLARATORY STATEMENT

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics ("Department" or "Division"), hereby denies the Petition for Declaratory Statement in accordance with Section 120.565, Florida Statutes.

PRELIMINARY STATEMENT

On July 29, 2016, the Division of Drugs, Devices, and Cosmetics received a letter from Sandy Reese, Sevens Management Company 11, Inc., 4361 North State Road 7, Lauderdale Lakes, Florida 33319 "(SMC)". The letter was filed with the agency clerk as a Petition for declaratory Statement ("Petition"), and notice of the Petition was published in the April 20, 2016, edition of the Florida Administrative Register, Volume 42, Number 159.

FINDINGS OF FACT

1. On or about July 29, 2016, the Department received a letter from Sandy Reese of SMC. The letter requested that it be accepted as a Petition for Declaratory Statement.

2. The letter was filed by the Agency Clerk as a Petition for Declaratory Statement.

3. The Petition states in its entirety:

Dear Sir / Madam,

Please accept this as a petition for Declaratory Statement
Is there a special permit or license that is required for this company to supply or distribute the following non-prescription items to pharmacies: Insulin Syringes, Lancets, Glucometers, Test Strips?

What type of entity can distribute all or some of the above supplies and what type of regulatory permits or applications are required to be obtained for Sevens Management Company 11 Inc., to become a distributor of such supplies. What is needed for a company registered in the State of Florida to conduct such business and be a distributor of the above listed supplies.

4. The Petitioner then includes a telephone number, e-mail address, and signature of Sandy Reese.

CONCLUSIONS OF LAW

5. The Department is the state agency charged with the regulation of drugs, devices, and cosmetics, pursuant to Chapter 499, Florida Statutes.

6. The Department has jurisdiction to enter this order pursuant to Section 120.565, Florida Statutes, and Rule 28-105.003, Florida Administrative Code.

7. Section 120.565, Florida Statutes, provides:

120.565 Declaratory statement by agencies.—

(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Register and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

8. Rules 28-105.001 and 28-105.002, Florida Administrative Code,

provide:

28-105.001 Purpose and Use of Declaratory Statement.

A declaratory statement is a means for resolving a controversy or answering questions or doubts concerning the applicability of statutory provisions, rules, or orders over which the agency has authority. A petition for declaratory statement may be used to resolve questions or doubts as to how the statutes, rules, or orders may apply to the petitioner's particular circumstances. A declaratory statement is not the appropriate means for determining the conduct of another person.

28-105.002 The Petition.

A petition seeking a declaratory statement shall be filed with the clerk of the agency that has the authority to interpret the statute, rule, or order at issue and shall provide the following information:

(1) The caption shall read: Petition for Declaratory Statement Before (Name of Agency).

(2) The name, address, any e-mail address, telephone number, and any facsimile number of the petitioner.

(3) The name, address, any e-mail address, telephone number, and any facsimile number of the petitioner's attorney or qualified representative if any.

(4) The statutory provision(s), agency rule(s), or agency order(s) on which the declaratory statement is sought.

(5) A description of how the statutes, rules, or orders may

substantially affect the petitioner in the petitioner's particular set of circumstances.

(6) The signature of the petitioner or of the petitioner's attorney or qualified representative.

(7) The date.

9. The Petition fails to comply with Section 120.565, Florida Statutes, and the administrative rules cited above because the Petitioner fails to state with particularity the Petitioner's set of circumstances, fails to specify the statute, rule, or order that the Petitioner believes may apply to the set of circumstances, and fails to include a description of how the statutes, rules, or orders may substantially affect the Petitioner in the Petitioner's particular set of circumstances.

10. Rather than a request for an explanation of how the Department's statutes, rules or orders affect Petitioner, Petitioner is requesting legal advice as to the licensing requirements for supplying and distributing insulin syringes, lancets, glucometers, and test strips to pharmacies. The Petition fails to meet the requirements for a Petition for Declaratory Statement and must be denied.

11. Based on the foregoing, the Department declines to issue a declaratory statement, and the Petition is DENIED.


12. Notwithstanding the denial of the Petition, Petitioner may submit a Petition that complies with the requirements of Section 120.595, Florida Statutes, and Rule 28-105, Florida Administrative Code.

Done and ordered this 22nd day of September, 2016, at

Tallahassee, Leon County, Florida.

KEN LAWSON, SECRETARY
Department of Business & Professional
Regulation

BY:


Reginald D. Dixon, ~~Division Director~~
Division of Drugs, Devices and
Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047
Telephone: (850) 717-1800
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Electronic mail to Sandy Reese, Sevens Management Company 11, Inc., 4361 North State Road 7, Lauderdale Lakes, Florida 33319 (sandy@icadrx.com), this 23rd day of September 2016.


Agency Clerk

Copies furnished to:

Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney

NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 2601 BLAIR STONE ROAD TALLAHASSEE, FLORIDA 32399-1047, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.

Sevens Management Company 11 Inc.
4361 N State Rd 7
Lauderdale Lakes, FL 33319

FILED	
<small>Department of Business and Professional Regulation</small>	
<small>Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	7/29/2016
File #	

July 26, 2016

Division of Drugs, Devices and Cosmetics,
1940 N. Monroe Street Suite 26A
Tallahassee, FL 32309-1047

DS 2016-057

Dear Sir/Madam,

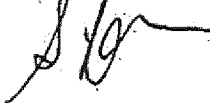
Please accept this as a petition for a Declaratory Statement

Is there a special permit or license that is required for this company to supply or distribute the following non-prescription items to pharmacies: Insulin Syringes, Lancets, Glucometers, Test Strips?

What type of entity can distribute all or some of the above supplies and what type of regulatory permits or applications are required to be obtained for Sevens Management Company 11 Inc. to become a distributor of such supplies. What is needed for a company registered in the state of Florida to conduct such business and to be a distributor of the above listed supplies.

I can be reached at 954 662 7378 or via email at sandy@icadrx.com

Regards,



Sandy Recse



DECLARATORY STATEMENTS

A Declaratory Statement is the sole means for obtaining a binding interpretation or opinion from the Division of Drugs, Devices and Cosmetics concerning the applicability of statutory provisions, rules or orders over which the Division has authority (Chapters 499, Florida Statutes, and Chapter 61N-1, Florida Administrative Code). A Petition for a Declaratory Statement may only be used to resolve questions or doubts as to how the statutes, rules or orders may apply to the petitioner's particular circumstances.

Please note, the Legislature, not the Division, which is entitled to set and ultimately define the scope of practice for any profession.

With regard to any questions concerning authorization to conduct a particular activity, the Division needs to be provided specific information detailing the particular activity, the relationships between any corporate entities (contractual, parent/subsidiary/sister) that will be participating in the activity, and the roles, responsibilities, and obligations of the entities that will be participating in the activity. Please note the Florida Legislature is the only entity authorized to set the scope of activities authorized by permits issued by the Division. The Division is tasked with interpreting and implementing the statutory provisions in a manner consistent with the intent of the Florida Legislature. Any Petition for Declaratory Statement that meets the requirements for Division consideration must be publicly noticed in the Florida Administrative Weekly. Upon reaching a decision, the Division will issue an Order setting forth its findings of fact and conclusions of law.

Refer to **Section 120.565, Florida Statutes**, and **Chapter 28-105, Florida Administrative Code**, which sets out the requirements for a Petition for Declaratory Statement. Such a petition is an individual request by a substantially affected person to an agency to give its opinion as to the effect of a particular statute or rule upon the petitioner in his or her circumstances. For instance, a licensee may request for the Division to issue an opinion on whether a certain practice or procedure in which the licensee wishes to engage in is permitted within the scope of practice. The Division of Drugs, Devices and Cosmetics is limited to addressing its opinions to **Chapter 499 Florida Statutes**, and **Florida Administrative Code 61N-1**. It has no authority to render formal opinions concerning any other state statutes or federal laws and regulations.

Submit questions to:

Division of Drugs, Devices and Cosmetics
1940 N. Monroe Street Suite 26A
Tallahassee, FL 32399-1047
Phone 850.717.1800
Fax to: 850.414.8240