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5A

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ *New Pharmacy* or ☐ ***Ownership Change*** *(Provide current license number if making changes:* ***PH____***

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☑ *Partnership - Pages 1,2,5,7*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: AZBDBR, LLC dba AvasaRx Pharmacy

Physical Address: 816 N. 6th Ave.

Mailing Address: 816 N. 6th Ave.

City: Phoenix State: AZ Zip Code: 85003

Telephone: 480-900-7450 Fax: 833 437-2301

Toll Free Number: 844-482-2005 (Required per NAC 639.708)

E-mail: info@avasarx.com Website: AVASARX.COM

Managing Pharmacist: Ronak Modi License Number: S023110

TYPE OF PHARMACY AND SERVICES PROVIDED

Yes/No	TYPE OF PHARMACY	Yes/No	SERVICES PROVIDED
☐	☑ Retail	☐	☑ Off-site Cognitive Services
☐	☑ Hospital (# beds ____)	☐	☑ Parenteral **
☐	☑ Internet	☑	☐ Parenteral (outpatient)
☐	☑ Nuclear	☐	☑ Outpatient/Discharge
☐	☑ Ambulatory Surgery Center	☑	☐ Mail Service
☐	☑ Community	☐	☑ Long Term Care
☑	☐ Other: Independent	☐	☑ Sterile Compounding **
		☐	☑ Non Sterile Compounding
	All boxes must be checked	☐	☑ Mail Service Sterile Compounding **
	For the application to be complete	☑	☐ Other Services: Home Infusion

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

CHAITANYA GADDE
Print Name of Authorized Person

11/1/2018
Date

Board Use Only Date Processed: _____ Amount: 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP General _____ Limited L

Partnership Name: AZBDBR, LLC

Mailing Address: 816 N. 6th Ave.

City: Phoenix State: AZ Zip Code: 85003

Telephone Number: 480-900-7450 Fax Number: 833-437-2301

Contact Person: Ronak Modi

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
Arizona Hemophilia Association	L	51%
Bio Tek reMEDys, Inc.	L	49%

List names of 4 largest partners and percentage of ownership:

Name: Arizona Hemophilia Association %: 51%

Name: Bio Tek reMEDys, Inc. %: 49%

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9:00 am 5:00 pm MST Saturday x am x pm

Sunday x am x pm 24 Hours ON CALL

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: _____

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, CHAITANYA GADDE

Responsible Person of AZBDBR, LLC dba AvasaRx Pharmacy

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

CHAITANYA GADDE
Print Name of Authorized Person

11/1/2018
Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF DELAWARE)
) ss.
NEW CASTLE COUNTY)

I, Chaitanya Gadde, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Authorized Signer for AZBDBR, LLC dba Avasa Rx (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Chaitanya Gadde, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
1st day of November, 2018.

NOTARY PUBLIC

REETA SHARMA
MY COMMISSION
EXPIRES ON
09-25-2020
NOTARY PUBLIC
STATE OF DELAWARE

OWNERS

- AZ Hemophilia Assoc. 826 N. 5th Ave, Phoenix, AZ 85003 602-955-3947
- Bio Tek reMEDys, Inc. 2 Penns Way, Suite #404, New Castle, DE 19720 302-544-5138

	Pharmacist	License #
• Ronak Modi	W. Portland Street, Phoenix, AZ 85003	S023110

	Pharmacy Technician	License #
• Shelomith Adina David	) N. 47th Dr., Phoenix, AZ 85031	10049494

AvasaRX
816 N. 6th Ave. Phoenix, AZ 85003
Tel: 844-482-2005
Fax: 833-437-2301
www.avasarx.com

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 10/02/2018
Receipt Number: 201843721
Receipt Amount $: 240.00

Resident Pharmacy/Limited Service

Retail

	PERMIT NO	EXPIRES
	Y007409	10/31/2019
Issued to :	AZBDBR, LLC 816 N. 6TH AVE. PHOENIX, AZ 85003	AvasaRx Pharmacy 816 N 6TH AVENUE PHOENIX, AZ 85003

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : AZBDBR, LLC
LICENSE NUMBER : Y007409
EXPIRES : 10/31/2019

http://www.azpharmacy.gov

- Your license must be available for inspections during business hours.
- Permit holder(s) must display permit in the location to which it is issued.
- Please note it is your responsibility to keep this license/permit current.

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.

You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law

In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the Board within 10 business days of move.

Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

5B

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ *New Pharmacy* or ☒ ***Ownership Change*** *(Provide current license number if making changes:* **PH** 03603

Check box below for type of ownership and complete all required forms.

☐ *Publicly Traded Corporation – Pages 1,2,3,7*
☐ *Partnership - Pages 1,2,5,7*
☐ *Non Publicly Traded Corporation – Pages 1,2,4,7*
☐ *Sole Owner – Pages 1,2,6,7*

GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: South Miami Pharmacy II (D/B/A/ SMP Pharmacy Solutions #2)

Physical Address: 7425 SW 42st Miami, FL 33155

Mailing Address: 7425 SW 42st

City: Miami State: FL Zip Code: 33155

Telephone: 305-740-9744 Fax: 866-301-1364

Toll Free Number: 855-255-5005 (Required per NAC 639.708)

E-mail: Dantes@Smppharmacy.com Website: www.smppharmacy.com

Managing Pharmacist: Jenny Lynn Alfonso License Number: PS40236

TYPE OF PHARMACY AND	Yes/No	SERVICES PROVIDED	Yes/No
Retail	☒ ☐	Off-site Cognitive Services	☐ ☒
Hospital (# beds ____)	☐ ☒	Parenteral **	☐ ☒
Internet	☐ ☒	Parenteral (outpatient)	☐ ☒
Nuclear	☐ ☒	Outpatient/Discharge	☐ ☒
Ambulatory Surgery Center	☐ ☒	Mail Service	☒ ☐
Community	☒ ☐	Long Term Care	☐ ☒
Other: _____	☐ ☐	Sterile Compounding **	☒ ☐
		Non Sterile Compounding	☒ ☐
All boxes must be checked		Mail Service Sterile Compounding **	☒ ☐
For the application to be complete		Other Services: _____	☐ ☒

**If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

A. Bardisa

Original Signature of Person Authorized to Submit Application, no copies or stamps

Armando Bardisa, PharmD. 8/20/18

Print Name of Authorized Person Date

Board Use Only	Date Processed:	Amount: $500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Delaware

Parent Company if any: SMP Acquisition Co. Inc.

Mailing Address: 680 Washington Blvd., 10th Floor

City: Stamford State: CT Zip: 06901

Telephone: 203-653-6400 Fax: _____

Contact Person: Philip Borden

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Hours of Operation for the pharmacy:

Monday thru Friday 9 am 7 pm Saturday 10 am 2 pm

Sunday / am / pm 24 Hours /

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: n/a

STATEMENT OF RESPONSIBILITY
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Armando Bandisa

Responsible Person of SMD Pharmacy Solutions #2

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Armando Bandisa

Print Name of Authorized Person

8/20/2018

Date

AFFIDAVIT for Out-of-State Pharmacy License

STATE OF FLORIDA)
) ss.
MIAMI-DADE COUNTY)

I, ARMANDO BANDISA, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PRESIDENT for SOUTH MIAMI PHARMACY II, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, ARMANDO BANDISA, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

A. Bandisa
Name

SUBSCRIBED AND SWORN TO
before me, a notary public this
20th day of AUGUST, 2018.

NOTARY PUBLIC

DANTES ALAN GUTIERREZ
Notary Public - State of Florida
Commission # FF 204557
My Comm. Expires Feb 26, 2019
Bonded through National Notary Assn.

FRIER LEVITT
ATTORNEYS AT LAW

John E. Morrone, Esq.
direct: 973.852.8359
jmorrone@frierlevitt.com

August 30, 2018

Sent via: FEDEX OVERNIGHT MAIL

Nevada Board of Pharmacy
431 W Plumb Ln,
Reno, NV 89509

Re: SMP Pharmacy Solutions #2 (License Number PH03603)
APPLICATION FOR NON-RESIDENT PHARMACY PERMIT
CHANGE OF OWNERSHIP

Dear Sir or Madam:

This firm represents **SMP Pharmacy Solutions II**(with an address at 7425 Southwest 42nd Street, Miami FL 33155, License Number PH03603) (the "Pharmacy") in the above captioned matter. This letter serves as a follow up to our notification letter sent to the Board of Pharmacy ("Board") advising of a proposed change in the ownership structure of each of the aforementioned pharmacy.

Effective July 3, 2018, the owner of the Pharmacy, Armando Bardisa ("Bardisa"), has sold the majority of his ownership interest in the Pharmacy, pursuant to a stock sale, to SMP Acquisition Co., Inc. ("Buyer"). The Buyer is a newly formed corporation and an indirect subsidiary of a newly-formed limited liability, SMP Pharmacy Holdings, LLC (the "Holding Company"). Bardisa maintains an ownership interest in the Pharmacy by holding an approximately 33% ownership interest in the Holding Company, which is an indirect parent of the Buyer and the Pharmacy. Approximately 67% of outstanding ownership interest in the Holding Company is held by Galen Partners or its affiliate and other investors.

In furtherance of the change in ownership structure, attached hereto, please find the pharmacy permit application and all subsequent documentation related thereto:

1. Completed Nonresident Pharmacy Permit Application, and application fee in the amount of $500.00 payable to the Nevada Board of Pharmacy
2. Certificate of Good Standing (corporation)
3. Letter of good standing (pharmacy license)
4. Copy of current home state pharmacy permit and Nevada state permit
5. Copy of recent inspection report.
6. Affidavit for out of state pharmacy license

8. DEA Registration

We look forward to your response in this matter. If you have any questions or require any further information, please feel free to contact me.

Very truly yours,

FRIER & LEVITT, LLC

/s/ John E. Morrone, Esq.

John E. Morrone, Esq.

JEM/rss
Enclosures

CC: SMP Pharmacy Solutions #2

AC# 7486456

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/21/2016	PH 24479	92049

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2019**

SOUTH MIAMI PHARMACY II
SMP Pharmacy Solutions #2
7425 SW 42 STREET
MIAMI, FL 33155

QUALIFICATION(S):
COMMUNITY PHARMACY
SCHEDULE II & III
4:1 PHARMACY TECHNICIAN RATIO APPROVED

Rick Scott
GOVERNOR

Celeste M. Philip, M.D., M.P.H.
Surgeon General and Secretary

DISPLAY IF REQUIRED BY LAW

AC# 7486456

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
12/21/2016	PH 24479	92049

The **PHARMACY**
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2019**

SOUTH MIAMI PHARMACY II

LICENSEE SIGNATURE

QUALIFICATION(S):
Community Pharmacy
Schedule II & III
4:1 Pharmacy Technician Ratio Approved

Department of Health

License Verification

Printer Friendly Version

SOUTH MIAMI PHARMACY II SMP Pharmacy Solutions #2

License Number: PH24479

Data As Of 8/17/2018

License Information | Secondary Locations | Discipline/Admin Action | Supervising Practitioners

Profession	Pharmacy
License	PH24479
License Status	CLEAR/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2019
License Original Issue Date	02/23/2010
Address of Record	7425 SW 42 Street MIAMI, FL 33155 UNITED STATES
Discipline on File	No
Public Complaint	No

Back

For instructions on how to request a license certification of your Florida license to be sent to another state from the Florida Department of Health, please visit the License Certifications web page.

Primary Source Verified

SMP Pharmacy Solutions #2
Ownership Information

South Miami Pharmacy II, LLC

- Member/Manager – SMP Acquisition Co., Inc.
- Officers—
  - Armando Bardisa, Pharm.D. (President)
    - DOB:
    - Business Address: 7425 SW 42 St. Miami, FL 33155
    - Home Address:) SW 68 Ct., Miami, FL 33156
    - Business Phone: (305)-740-9744
    - Home Phone:
    - SS #
    - FL Lic#
  - Philip Borden (Treasurer)
    - DOB:
    - Business Address: 680 Washington Blvd, 10th Floor Stamford, CT 06901
    - Home Address: Winthrop Street, Unit 7, Cambridge, MA 02138
    - Business Phone: (203) 653-6400
    - Home Phone: (
    - SS#
  - Zubeen Shroff (Secretary)
    - DOB:
    - Business Address: 680 Washington Blvd, 10th Floor Stamford, CT 06901
    - Home Address: Tarryhill Road, Tarrytown, NY 10591
    - Business Phone: (203) 653-6400
    - Home Phone: (3
    - SS#

CERTIFICATE *of* ACCREDITATION

ACCREDITATION COMMISSION FOR HEALTH CARE CERTIFIES THAT:

South Miami Pharmacy II
d/b/a SMP Pharmacy Solutions #2
MIAMI, FLORIDA

HAS DEMONSTRATED A COMMITMENT TO PROVIDING QUALITY CARE AND SERVICES TO CONSUMERS THROUGH COMPLIANCE WITH ACHC'S NATIONALLY-RECOGNIZED STANDARDS FOR ACCREDITATION AND IS THEREFORE GRANTED ACCREDITATION FOR THE FOLLOWING:

PHARMACY

PCAB ACCREDITATION
For patient specific prescription compounding of
Non-Sterile Compounding, Ref. USP <795>
Sterile Compounding, Ref. USP <797>

FROM *May 17, 2016* THROUGH *May 16, 2019*

CHIEF EXECUTIVE OFFICER

CHAIRMAN OF THE BOARD OF COMMISSIONERS

ACHC ACCREDITED · ACHC ACCREDITED · ACHC ACCREDITED · ACHC ACCREDITED · ACHC

ACCREDITATION COMMISSION *for* HEALTH CARE

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

www.FloridaHealth.gov

File # 17021
Insp # 141787

NAME	PERMIT NUMBER	DATE OF INSPECTION
SOUTH MIAMI PHARMACY II	24479	04/24/2018
DOING BUSINESS AS		
SMP PHARMACY SOLUTIONS #2		
STREET ADDRESS	**TELEPHONE #**	**EXT**
7425 SW 42 Street		
CITY	**COUNTY**	**STATE/ZIP**
MIAMI	MIAMI-DADE	FL/33155

Additional Information

Business Operation Hours

Monday Y	Monday Hours 09:00 AM TO 07:00 PM
Tuesday Y	Tuesday Hours 09:00 AM TO 07:00 PM
Wednesday Y	Wednesday Hours 09:00 AM TO 07:00 PM
Thursday Y	Thursday Hours 09:00 AM TO 07:00 PM
Friday Y	Friday Hours 09:00 AM TO 07:00 PM
Saturday Y	Saturday Hours 10:00 AM TO 02:00 PM

Registered Pharmacist / Intern / Tech

License # PS 40236	Licensee Name Jenny L. Alfonso
License Type Registered Pharmacists	
License # RPT 17130	Licensee Name Gerald D Henriquez
License Type Pharmacy Tech	
License # RPT 37290	Licensee Name Danielle L. Guldris
License Type Pharmacy Tech	
License # RPT 34262	Licensee Name Katherin Gastelbondo
License Type Pharmacy Tech	
License # PS 37955	Licensee Name Eduardo Lopez III
License Type Registered Pharmacists	
License # RPT 37568	Licensee Name Rashma Seepersaud
License Type Pharmacy Tech	
License # RPT 31144	Licensee Name Adrilen Orduno
License Type Pharmacy Tech	
License # RPT 37387	Licensee Name Miguel Jose Feria
License Type Pharmacy Tech	
License # PS 54466	Licensee Name Yeney Montano
License Type Registered Pharmacists	
License # PS 55665	Licensee Name Stephanie A. Perez
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FS1854151	

License Relations

Pharmacy Affiliate

INV359 - Community Requirements

Insp # 141787

SOUTH MIAMI PHARMACY II

File # 17021

BARDISA, ARMANDO	License #

Pharmacy Corporate Entity/Affil/Pharm

SOUTH MIAMI PHARMACY	License #

RX DPT MGR/COR/POR

ALFONSO, JENNY LYNN	License # 40236

Special Sterile Compounding

SOUTH MIAMI PHARMACY II	License # 29770

INV 359 - Community Requirements

Community Requirements General Section

Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, no other personnel remain in the department, and a sign not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating "Prescription Department Closed". [64B16-28.109 F.A.C.]	N/A
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (3) &(4) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.] ;[64B16-26.400(4) F.A.C.][64B16-27.420 F.A.C.].	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Pharmacists, interns and technicians have proof of current licensure [465.014 F.S.], [465.015(2)(b)	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Generic equivalent sign posted. [465.025(7), FS]	Yes
A sign has been prominently posted indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that the pharmacist is available for consultation upon request during the meal break. [64B16-27.1001 F.A.C.]	N/A
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; 64B16-28.108 F.A.C.]; [893.04(1)(e)F.S.] [21CFR1306.24];[21CFR1306 14]	Yes
Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.], [766.101(1)(a)(I) F.S.]	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	Yes
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	Yes
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	Yes
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12)(a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12)(b) F.S.] [64B16-28.140 F.A.C.]	Yes
Controlled substance prescriptions have the date dispensed and dispensing pharmacist. [893.04(1) F.S.]; [21CFR1306.22(c)]; [64B16-28.140(3) F.A.C.]	Yes
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) &(e) F.A.C]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11)(b) F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.]	Yes
Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	N/A
Compounding records properly maintained. [64B16-28.140(4), F.A.C.]	N/A
All prepacking is done in accordance with procedures set up by the PDM and Records of returns of unit dose medications are properly maintained. [465.016(1) F.S.]; 64B16-28.118 F.A.C.]; [64B16-28.120(3)]	N/A

Insp # 141787

INV359 - Community Requirements

SOUTH MIAMI PHARMACY II

File # 17021

The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
Central Fill and originating pharmacy shall each be identified on the prescription container label.	
The word "central fill" appears on the face of the original prescription and the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Remarks:

Controlled Substance Biennial Inventory conducted on 12/30/2017, in addition this pharmacy maintains a perpetual inventory.
Wholesaler: Cardinal Health.
Las CQI meeting conducted on 02/16/2018.
Pharmacy is clean/safe and has met all inspection requirements.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

BARREIROS, DANAY

Date:4/24/2018

Representative:

Danles A Gutierrez Compliance Coordinator

Date:4/24/2018

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797-Sterile Compounding

File # 23306
Insp # 148595

NAME	PERMIT NUMBER	DATE OF INSPECTION
SOUTH MIAMI PHARMACY II	29770	05/31/2018
DOING BUSINESS AS SMP PHARMACY SOLUTIONS #2		
STREET ADDRESS 7425 SW 42 Street	**TELEPHONE #**	**EXT**
CITY MIAMI	**COUNTY** MIAMI-DADE	**STATE/ZIP** FL/33155

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 am to 7pm
Monday N	Tuesday N
Wednesday N	Thursday N
Friday N	Saturday N
Sunday N	

Registered Pharmacist / Intern / Tech

License # PS44230	Licensee Name RICHARD MAYAN
License Type Registered Pharmacists	
License # RPT11596	Licensee Name CARLOS GOMEZ
License Type Pharmacy Tech	
License # 32965	Licensee Name Armando Bardisa
License Type Pharmacy Tech	
License # 48129	Licensee Name Agnelica Londono
License Type Pharmacy Tech	
License # PS40236	Licensee Name Jenny Lynn Alfonso
License Type Registered Pharmacists	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FS1854151	

License Relations

Pharmacy Affiliate

BARDISA, ARMANDO	License #

RX DPT MGR/COR/POR

ALFONSO, JENNY LYNN	License # 40236

Special Sterile Compounding

SOUTH MIAMI PHARMACY II	License # 24479

INV797 - Sterile Compounding

LOW RISK

1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	
3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs]	

MEDIUM RISK

4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes
5. Medium Risk CSP's, In absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs]	Yes

HIGH RISK

6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	Yes
7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *Alprostadil stock solution Lot: 180416E compounded on , assigned a day BUD and is used in batched tri mix Lot 180416F with no sterility tests.*	No
9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]	Yes
10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]	Yes
11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] *High risk alprostadil stock soln lot 180222O is used in final CSP products without sterilization.*	No
12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]	Yes
13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *Progesterone is sterilized through dry heat appropriately.*	Yes
14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] *Oven mapping was conducted on 2/7/17 that included a cycle for depyrogenation and a cycle for sterilization of progesterone. Depyrogenation validation cycle was run empty only. Not all spots in oven were tested (8 thermocouples) for cold spots.*	No
15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat] *Dry heat depyrogenation cycle was run without glassware. Last ECV test conducted on 8/23/17. Firm rinses glassware with distilled water from an inhouse water system, not sterile water.*	No
16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] *alprostadil sub batch compounding used for final trimix CSP's is not being tested for sterility.*	No

USP <71> STERILITY TESTING (Outsourced)

17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>]	Yes
18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	Yes
20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	Yes
21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	Yes

USP <71> STERILITY TESTING

22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing]	
24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	

25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested]	
26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi]	
27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]	
28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures]	
30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	
31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS]	

ENDOTOXIN TESTING

32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	Yes
33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>]	Yes
34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]	Yes

IMMEDIATE USE COMPOUNDING

35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs. 2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour. 3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces. 4. Administration begins not later than 1 hour following the start of the preparation of the CSP. 5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time. 6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs]	N/A

SINGLE/MULTIPLE DOSE CONTAINER BUD

36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A
39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS]	N/A

HAZARDOUS DRUGS

40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs]	Yes
41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]	Yes
42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs]	N/A
43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs]	Yes
44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]	Yes
45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]	Yes
46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs]	Yes
47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs]	Yes
48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]	Yes
49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]	Yes
50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs]	Yes

FACILITY DESIGN AND CERTIFICATION

51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program] *Certified by Medrep March 8, 2018. ISO 7 Buffer room, Chemo room, Supply room, pass through #1. ISO 8 Anteroom. PEC's primarily in use in chemo room Class II A2 BSC (Baker) classified as ISO5, Air Science Vertifcal Laminar Flow clean bench in non-HD positive pressure room classified as ISO 5.*	Yes
52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes

ISOLATORS

55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	
57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	

FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)

58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring]	Yes
59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] *ACPH as noted from March 8, 2018 by medrep for non-HD buffer room was 55.14.*	Yes
60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]	Yes
67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]	Yes

QUALITY AND CONTROL

68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan] *Yes, but please include in your Environmental Monitoring policy 3.03 method of collection.*	Yes
69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] *Medrep*	Yes
70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media]	Yes
71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]	N/A
72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period] *Trended by Medrep*	Yes

73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment] *Monthly per policy*	Yes
74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]	Yes
75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] *3/15/18 Medrep recovered actionable Micrococcus in chemo room. Subsequent retesting on 4/2/18-no growth.*	Yes
76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

QUALITY AND CONTROL (Secondary Engineering Controls)

83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes

PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION

86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]	Yes
93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] *No medium risk media fill for employees.*	No
94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] *RPh JA has signed a few componding worksheets for sterile compounding for Leuprolide Acetate 5mg/ml and Progesterone 50mg/ml Ethyl Oleate released to patients in May 2018, however there is no high risk Media fill completed for this PIC.*	No
95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *No documentation of hand hygeine, garbing and aseptic technique observations for JA, RPh, PIC who signs off on sterile HD compounds..*	No
96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A

97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]	N/A
98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] *Cleaning observations not provided for PIC JA who signs off on sterile HD CSP's.*	No
99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling] *PIC, JA who signs off on compounded high risk CSP's has not completed gloved fingertip sampling.*	No
100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]	Yes

VERIFICATION

101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] *Progesterone 100mg/ml rx #8708086 label indicates "Prog 100mg/ml ehyl oleate (smp)", no total quantity in units (10? ml? each?); smp may be misconstrued as an ingredient in your compound. Names of CSP's on labels do not indicate dosage form.; your trimix labels lack inclusion of all ingredients rx #'s 8704510 and #8697966 read "alprostadil 10mcg/papaverine H"*	No
102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] *Firm does not send alprostadil stock solution for sterility tests (two sub batches: 1st batch alprostadil w/ ethyl alcohol lot # 180222O assigned 180 days. 2nd batch contains lot 180222O plus WFI lot 180416E assigned 14 day BUD) both used in tri mix lot 180416F without sterility tests. Final CSP lot 180416F assigned a 60 day BUD. Trimix lot # 180205Q assigned 60 day BUD, with active ingredients that expire before the assigned BUD - phentolamine expired 2/6/18 and alprostadil 100mcg / WFI (lot 180130L) expires on 2/13/18.*	No
103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures]	Yes
104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates] *Trimix 10/30/1 lot 180416F is assigned a 60 day BUD, no potency over time available, rx 8704510 and 8697966 were dispensed. Trimix 20/30/2 lot 180418O assigned 60 day BUD, no potency, rx # 8708808 dispensed.*	No
105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems]	N/A

DISPENSING/DISTRIBUTION

106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs :]	Yes
107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]	Yes

POLICY/PROCEDURE

109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]	Yes
111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]	Yes
112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs]	Yes
113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]	N/A

RADIOPHARMACEUTICALS

114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs]	
115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs]	
116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs]	

MISCELLANEOUS

117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g]	N/A
118. Compounding records are properly maintained. [FAC 64B16-28.140(4)] *Please add storage conditions on your compounding worksheets.*	No

119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas]	N/A

SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	
121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	
122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	
123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	
124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	
125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	
126. All controlled substance prescriptions contain information required. [893.04, F.S.]	
127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	
129. DEA 222 order forms properly completed. [893.07, F.S.]	
130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	
131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	
132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	
133. Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	
134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14)	

Remarks:

Routine SSCP inspection conducted with Richard Mayan Rph, Dantes Gutierrez RPT and Carlos Gomez RPT. Please send inspector a corrective action plan for all deficiencies on or before July 2, 2018.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature:

Date:5/31/2018

Representative:

Richard Mayan

Date:5/31/2018

SMP PHARMACY SOLUTIONS

7425 SW 42nd ST, MIAMI, FL 33155
T: (305) 740-9744 | F: (866) 301-1364

June 25, 2018

Florida Department of Health
Board of Pharmacy
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399-3258
Ph: 954-267-4530
Fx: 954-202-3254

Re: Non-Resident Pharmacy Renewal – Corrective Action Plan

To Whom It May Concern:

In an effort to ensure compliance with the Department of Health, South Miami Pharmacy II, Inc (d/b/a: SMP Pharmacy Solutions #2) has finalized items that were incomplete at the time of our sterile inspection.

- #8: Standards Operating Procedure (SOP) has been updated to reflect all sub-formulas for Compounded Sterile Products (CSPs) undergo the proper sterile testing. Also, the Tri-Mix formula has been discontinued and will no longer be compounded.
- #11: SOP has been updated to reflect all sub-formulas for CSPs undergo the proper sterile testing. Also, the Tri-Mix formula has been discontinued and will no longer be compounded.
- #14: Thermo-mapping for the oven completed on June 21, 2018 with the correct amount of themocouples.
- #15. SOP has been updated to reflect glassware that is depyrogenated be rinsed with sterile water instead of filtered water/alcohol combo.
- #16: SOP has been updated to reflect all sub-formulas for CSPs undergo the proper sterile testing. Also, the Tri-Mix formula has been discontinued and will no longer be compounded.
- #93: Medium Risk Media Fills have been performed.
- #94: The Pharmacist-in-Charge (PIC) has done proper module training and competency testing.
- #95: The PIC has done proper module training and competency testing.
- #98: The PIC has done proper module training and competency testing.
- #99: The PIC has done proper module training and competency testing.
- #101: Recommended label adjustments have been made.
- #102: SOP has been updated to reflect all sub-formulas for CSPs undergo the proper sterile testing. Also, the Tri-Mix formula has been discontinued and will no longer be compounded.

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- #104: SOP has been updated to reflect all sub-formulas for CSPs undergo the proper sterile testing. Also, the Tri-Mix formula has been discontinued and will no longer be compounded.
- #118: "Room Temperature" storage condition has been documented on compounded worksheets

Should you require any additional information, please contact me directly.

Sincerely,

Dantes Gutiérrez, CPhT.
Data & Compliance Coordinator

South Miami Pharmacy
Ph #: 305.740.9696 ext.526
Fx #: 888.615.6637
dantes@smppharmacy.com