



**STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH**

**NICOLE ALEXANDER-SCOTT, M.D., M.P.H.,
IN HER CAPACITY AS DIRECTOR OF THE
RHODE ISLAND DEPARTMENT OF HEALTH**

**IN THE MATTER OF:
Michael Souza D.O.
License Number D.O. 00446**

IMMEDIATE COMPLIANCE ORDER

Now comes the Director (the "Director") of the Rhode Island Department of Health ("RIDOH") and, pursuant to RIGL § 23-1-21, after initial investigation of Michael Souza D.O., ("Respondent") pertaining to an inspection of Respondent's business located at 1275 Wampanoag Trail, Riverside, Rhode Island, by the RIDOH Board of Pharmacy ("Board") Inspector on April 15, 2019, makes the following:

FINDINGS OF FACTS

1. Respondent operates I.M. 120 and a "Drip Bar" which utilizes compounded sterile products as treatment for patients. I.M. 120 is located at 1275 Wampanoag Trail, Riverside, Rhode Island.
2. The Board Investigator conducted an initial inspection regarding sterile compounding on April 15th, 2019.
3. Sterile compounding must be done according to USP 797, a federal standard which addresses issues including sterile compounding.
4. Compounding of sterile products must be done in an aseptic manner in order to prevent serious infections in patients receiving any intravenous (I.V.) fluids.
5. The Board Investigator, while conducting the inspection noted Respondent is not following USP 797 standards when making (compounding) these products, which is a violation of the *Rhode Island Rules and Regulations of Pharmacy* 1.7.10-B which requires the pharmacist-in-charge to ensure that activities are accomplished for all sterile compounding as outlined in current USP.
6. Additionally, Respondent is not using a Compounding Aseptic Isolator (CAI) to maintain sterility or minimize introduction of particles. The pharmacy inspector determined this is an immediate threat to the patients who are receiving these products and stated as follows: *"I feel he should be ordered to stop immediately until he can prepare these products according to USP standards"*.

7. The Inspector noted, *Certification procedures such as those outlined in Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.*
8. The certificate on the Compounding Aseptic Isolator (CAI) had expired on 2/28/2018. The previous certification was performed on 8/1/2018. The re-certification is now 45 days past due.
9. The Inspector also noted, *Sterile gloves shall be the last item donned before compounding begins.* The nurse who performs the compounding stated she put the sterile gloves on, then put her hands in the isolator sleeves and her sterile gloves would go inside the blue gloves attached to the isolator sleeves. The blue gloves are not sterile and even if sprayed with sterile 70% isopropyl alcohol (70%IPA) they become sanitized but not sterile. The sterile gloves need to be put on over the blue gloves attached to the sleeves inside the ISO 5 chamber. After the sterile gloves are on top of the blue gloves they may then be disinfected with 70%IPA if deemed necessary.
10. Pharmacy Regulations (216 RICR 40-15-1) require environmental monitoring of the sterile compounding area be performed monthly, and a written plan and schedule for the environmental monitoring procedures for viable microorganisms shall be established and followed. The plan shall be adequate to evaluate the various controlled air environment areas (LAFW, barrier isolators, biological safety cabinets, buffer or clean room, and anteroom) of the designated sterile compounding area(s). For sterile compounding areas used for low- and medium-risk preparations, a minimum monthly evaluation shall be required. For sterile compounding areas used for high-risk preparations, a weekly evaluation shall be required.
11. The last monthly environmental testing was completed on 12/27/2018. There have been no further environmental tests performed. IM 120 stopped using the CAI to make Compounded Sterile Products (CSP) on 1/15/2019.
12. The Inspector also noted, there was no bottle of 70% IPA in the Direct Compounding Area (DCA) of the CAI. A new bottle of 70% IPA should be transferred into the ISO 5 DCA of the CAI using proper disinfecting technique. The bottle should then be opened and left inside the DCA to be used to disinfect gloves and the work surface and to never leave the ISO 5 DCA.
13. The Inspector also noted, all CAI's have a specific isolation time to leave items brought from outside the CAI and placed into the ISO 7 ante-chamber of the CAI. IM 120 should look up the isolation time in the owner's manual and use a digital timer or egg timer to count the time required for isolation in the ISO 7 ante-chamber before items are moved into the ISO 5 DCA.
14. The inspector also noted, *all compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use. Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding.* Although there is a check list stating the compounding employees completed and passed the Gloved Fingertip Test (GFT) and Media Fill Test (MFT) there is no documentation such as the lab results. There needs to be documented evidence (lab results) of three separate GFT of both hands with zero

growth, and one MFT of the most complex compounding, medium risk, before employees may compound.

15. The Inspector noted, there are specific and detailed standards for cleaning and disinfecting the sterile compounding areas. The IM 120 drip bar does not meet these standards, specifically, "Monthly one-step disinfectant cleaner completed on? The one step EPA registered disinfectant cleaner should be used every day before compounding begins. The daily disinfectant cleaner should be followed by applying s70% IPA which must be allowed to dry before compounding begins. Also, there is a line for the "Monthly Sporidical agent cleaning completed on:". There is no day filled in on any of the cleaning logs.
16. The Inspector also noted according to RICR 40-15-1-1.7-10. E. 5 *When above action level results for viable sampling are discovered, the pharmacy shall keep records of viable sampling reports and remediation actions and have such records readily retrievable for Board inspection for a period of two (2) years.* There was no Corrective Action Plan (CAP) or remediation plan after two separate above action level contaminations were found. The first was on 10/24/2018, 12 CFU of bacteria were found in the DCA. The action level is greater than 3 CFU. There is no recognition by IM Bar 120 there was a problem, no mention if compounding was halted, and no action plan after the problem was discovered such as triple cleaned (antibacterial-sporidical- s70%IPA). There is no mention if the DCA was resampled to verify there was no growth. Again on 12/27/2018 an environmental test came back with above action level contamination in the DCA. This time there was *Aspergillus* which is a mold and is an organism of concern. Again, there was no recognition of the contamination, no mentioned if compounding ceased, no cleaning action plan, and no resampling of the DCA. This was the last environmental sampling test performed. Because there is no CAP, we are left to assume the CAI still has mold in the DCA, compounding continued until 1/11/2019. Compounding then moved outside the CAI until 4/11/2019 when it was moved back into the CAI. There was never a resampling to see if the mold had been remediated.

ALLEGED VIOLATIONS

1. Respondent is in violation of 216 R.I. Code R § 1.7 (B) (1-4)
2. Respondent is in violation of 216 R.I. Code R § 1.7 (E) (4).
3. Respondent is in violation of 216 R.I. Code R § 1.7 (E) (5).
4. Respondent is in violation of RIGL § 5-37-5.1 (24)

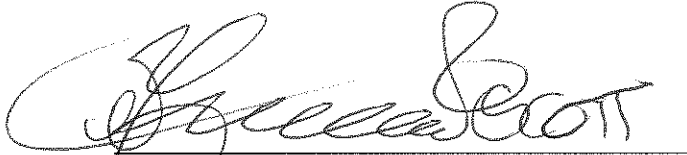
ORDER

Based on the foregoing the Director has determined that the Respondent's conduct as set forth herein constitutes an immediate threat to the health, welfare and safety of the public.

Effective upon service of this Immediate Compliance Order Respondent shall immediately cease preparing and or administering any sterile compounded product.

Failure to strictly comply with this Immediate Compliance Order without written consent from the Director could result in disciplinary action including summary suspension of license.

Entered this 25th day of April 2019

A handwritten signature in black ink, appearing to read "Nicole Alexander-Scott". The signature is written in a cursive style with a horizontal line underneath it.

Nicole Alexander-Scott, M.D., M.P.H.

Director

Rhode Island Department of Health

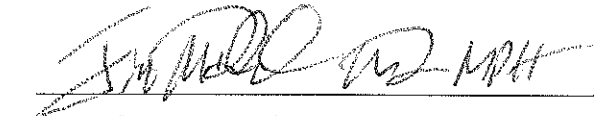
Cannon Building, Room 401

Three Capitol Hill

Providence, RI 02908

CERTIFICATION OF SERVICE

A copy of the within Immediate Compliance Order was delivered to Respondent by email to attorney Dennis Grieco II, DGrieco@grieco-law.com on this 24th day of April 2019.


James V. McDonnell D.D.M.H.

A written request for a hearing may be filed with the Director within ten (10) days of this Immediate Compliance Order.