IN THE MATTER OF:
Michael Souza, MD
License No.: DO 00446
Case Nos.: C19-0652

CONSENT ORDER TO RESOLVE IMMEDIATE COMPLIANCE ORDER AND BOARD OF MEDICAL LICENSE AND DISCIPLINE CASE NO. 190652

Michael Souza, MD ("Respondent") is licensed as a physician in Rhode Island. Respondent has no prior disciplinary action with the Board of Medical Licensure and Discipline ("Board"). The Board makes the following

FINDINGS

1. Respondent has been a licensed physician in the State of Rhode Island since June 8, 1994. His primary specialty is Family Practice. His practice is located at 1278 Wampanoag Trail, Riverside, RI.

2. Respondent's medical practice, East Bay Innovative Medicine, formerly Intellectual Medicine 120 – East Bay ("I.M. 120", is located at 1275 Wampanoag Trail, East Providence, Rhode Island. There, Respondent treats patients for various medical conditions. Per Respondent, in his practice he employs both traditional and integrative approaches to medicine, the latter offering intravenous infusions of compounded sterile products (CSPs), medical weight loss, and other approaches.

3. On May 9, 2012, the Board accepted a "position paper" which indicated the Board was

adopting USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* ("USP 797"), as the standard governing "sterile compounding performed by practitioners." Respondent was unaware the Board had accepted that "position paper," adopting USP 797 and was otherwise unaware that USP 797 applied to him and his office, as USP 797's Introduction states that "[t]he standards in this chapter do not pertain to the clinical administration of [compounded sterile preparations] to patients via application, implantation, infusion, inhalation, injection, insertion, installation and irrigation, which are the routes of administration." .

4. Additionally, the Board recognizes the *Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors* (216-RICR-40-15-1) (hereinafter, the "Pharmacy Regulations") as the applicable standard of care for the compounding sterile products by physicians. However, those Pharmacy Regulations do provide

> In accordance with R.I. Gen. Laws sec. 5-19.1-22, nothing in the Act [defined elsewhere as R.I. Gen. Laws Chapter 5-19.1, the statutory scheme enabling and empowering the Board of Pharmacy] or this Part [the Rhode Island Regulations promulgated by and governing the Board of Pharmacy] shall apply to any practitioner with authority to prescribe who does not maintain an open shop for the retailing, dispensing of medicines and poisons, nor prevent him or her from administering or supplying his patients such articles as he or she may deem fit and proper.

2016-RICR-40-15-1.4.2A. Dr. Souza does not maintain an open shop for the retailing and/or dispensing of medicines and therefore, did not understand that the Rhode Island Pharmacy Regulations applied to him or his office.

5. According to USP 797, preparation of CSPs must be done in an aseptic manner in order to prevent serious infections in patients receiving any I.V. fluids.

6. On April 15, 2019, the Board received a report from the Rhode Island Department of Health ("RIDOH") Board of Pharmacy investigator ("Investigator") relative to the Investigator's April 15, 2019 inspection of Respondent's sterile compounding ("4/15/19 Pharmacy Investigator

Report"). On May 21, 2019, the Board opened its own complaint with respect to that report.

7. The Investigator, who is a licensed pharmacist, noted during his inspection on April 15, 2019 that Respondent was not following USP 797 standards when preparing CSPs, in violation of § 1.7.10(B) of the Pharmacy Regulations, which sets forth the general requirements for all risk levels of sterile compounding, and provides that "[t]*he pharmacist-in-charge shall ensure the following activities are accomplished for all sterile compounding as outlined in current USP standards: . . . All CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter . . . .*"

8. Additionally, the Investigator noted that Respondent had but was not using a Compounding Aseptic Isolator (CAI) to maintain sterility or minimize introduction of particles. The Investigator determined that Respondent's failure to meet these standards represented an immediate threat to the patients receiving compounded products, stating "*I feel he should be ordered to stop immediately until he can prepare these products according to USP standards.*"

9. The Investigator observed that the certificate on Respondent's CAI had expired on February 28, 2019, and was last inspected for certification on August 1, 2018. The Investigator observed, therefore, that more than six months had elapsed since certification of the CAI, in violation of USP 797, which requires that certification procedures be performed "no less than every 6 months."

10. The Investigator also noted that "*[t]he 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 Investigator, therefore, identified a violation of USP 797, which requires, "*Sterile gloves shall be the last item donned before compounding begins.*" The Investigator noted, "*The blue gloves are not sterile and even if sprayed*

with sterile 70% isopropyl alcohol (s70%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 s70%IPA if deemed necessary."

11. The Investigator also noted that, according to § 1.7(E)(4) of the Pharmacy Regulations, "*[a] written plan and schedule for the environmental monitoring procedures for viable microorganisms shall be established and followed*" and that "*for sterile compounding areas used for low- and medium-risk preparations, a minimum monthly evaluation shall be required.*" The Investigator identified a violation of the above-referenced Pharmacy Regulation, observing that the last monthly environmental testing was completed on December 27, 2018, more than three months previous, and that Respondent had ceased using the CAI between January 15, 2019 and April 11, 2019, and had not performed any environmental monitoring when use of the CAI resumed.

12. The Investigator also noted that, according to USP 797, "*[a]ll compounding personnel shall successfully complete an initial competency and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use,*" and that "*[m]edia-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.*" The Investigator identified a violation of the foregoing, observing that "*[t]here needs to be documented evidence [lab results] of three separate [gloved fingertip tests] GFT of both hands with zero growth, and one [media-fill test] MFT of the most complex compounding, medium risk, before employees may compound,*" which evidence the Investigator did not see.

13. The Investigator also noted that, according to USP 797, "*cleaning and disinfecting surfaces*

in the . . . CAIs . . . shall be cleaned and disinfected frequently, including at the beginning of each work shift." The Investigator added that "*[t]he one step EPA registered disinfectant cleaner should be used everyday before compounding begins*" and that "*[t]he daily disinfectant cleaner should be followed by applying s70%IPA which must be allowed to dry before compounding begins.*" The Investigator identified a violation of the foregoing, observing that Respondent's cleaning logs are blank relative to completion of monthly one-step disinfectant cleaning and monthly sporicidal cleaning. The Investigator also identified areas of concern relative to adherence to cleaning, disinfecting, and sterilizing procedures, relative to the availability and location of s70%IPA in the direct compounding area and observance and documentation of the "*specific isolation time to leave items brought from outside the CAI and placed into the ISO 7 ante-chamber of the CAI,*" in accordance with USP 797.

14. The Investigator also noted that, according to § 1.7(E)(5) of the Pharmacy Regulations, "*[w]hen 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.*" The Investigator identified a violation of the foregoing, observing that above action level results had been discovered on October 24, 2018 and December 27, 2018, but that Respondent had not implemented a corrective action or remediation plan in either case.

15. Based on the foregoing, the Director of RIDOH ("Director") issued an Immediate Compliance Order ("ICO") on April 25, 2019, ordering Respondent to "*immediately cease preparing and or administering any sterile compounded product,*" warning that "*[f]ailure to strictly comply with this Immediate Compliance Order without written consent from the Director could result in disciplinary action including summary suspension of license.*"

16. In his written response to the Board, Respondent stated that he stopped following USP 797, because he was advised by Dr. Stephen Petteruti, who presented himself to an Investigative Committee of the Board as medical director for I.M. 120, that was not required to do so. Respondent explained in that written response that in early January 2019, Dr. Stephen Petteruti

> contacted me and indicated that, based upon his investigation and information he obtained, use of the CAI was not required in my office, and its use was being discontinued at the Intellectual Medicine drip bar in Warwick. After investigating the issue further on my own, I understood that neither chapter 797 of the United States Pharmacopeia ("USP 797"), governing pharmaceutical compounding, nor the Rhode Island statutes and regulations governing pharmacies and compounding applied to or required use of a CAI in physicians' offices. For example, USP 797 states in its Introduction that "[t]he standards in this chapter do not pertain to the clinical administration of [compounded sterile preparations] to patients via application, implantation, infusion, inhalation, injection, insertion, installation and irrigation, which are the routes of administration." Moreover, I am informed that both the Rhode Island statutes and regulations governing pharmaceutical care, including the compounding of medications, expressly state that nothing contained in those statutes or regulations "shall apply to any practitioner with authority to prescribe who does not maintain an open shop for the retailing, dispensing of medications and poisons, nor prevent him or her from administering or supplying to his patients such articles as he or she may deem fit and proper." R.I.Gen.Laws § 5-19.1-22 and 2016 RICR 40-15-1.4.2.A. I do not maintain an open shop for the retailing or dispensing of medications. Further, I am informed that the Rhode Island Board of Pharmacy regulations governing compounding, to which [the Inspector] refers, repeatedly refer to the obligations of the "pharmacist-in-charge" to ensure that "pharmacies" comply with various compounding standards of the United States Pharmacopeia. 2016 RICR 40-15-1.7.B, C and D. My office is not a pharmacy and we have no pharmacist-in-charge.
>
> I also understood that other infusion centers and a multitude of other physicians, such as orthopedists, pain management specialists and dermatologists, have historically aseptically mixed multiple ingredients for injection into patients in their offices without the use of a CAI or otherwise following the requirements of USP 797 or Rhode Island statutes and regulations governing pharmacies and compounding. Like those other physicians, I believed we could aseptically and safely mix IV drips for administration in our office. Moreover, the use of the CAI was time-consuming and cumbersome and often delayed the administration of IV drips to the consternation of patients. As a result of all of this information and in an effort to more efficiently serve our patients, I decided to discontinue the use of the CAI and mid-January, 2019 and commence aseptically mixing ingredients for administration of IV drips in the same manner as other infusion centers and similar to the numerous other physicians that aseptically mix multiple ingredients for

injection into their patients in the office.

17. In addition, on May 9, 2019, the Respondent submitted to the Board and the Investigator a Corrective Action Plan that addressed and resolved all of the Investigator's concerns and noted areas of noncompliance as a result of his April 15, 2019 inspection. That Corrective Action Plan documented that on the day after the inspection, April 16, 2019, the Respondent had Environmental Testing performed on the CAI, which passed all testing and as a result was recertified. The Corrective Action Plan also confirmed that environmental testing of the CAI was scheduled to be performed monthly thereafter. The Corrective Action plan also indicated that as a result of the Investigator's concerns, sterile gloves were placed over the isolator sleeves in the CAI. The Corrective Action Plan also included documentation that on September 4, 2018, before they commenced any compounding, all compounding personnel had successfully completed initial competency and gloved fingertips/thumb sampling testing at least three times. The Corrective Action Plan detailed how the Respondent's office had instituted all the cleaning and sterilization methods and documentation thereof referenced by the Investigator. Lastly, the Corrective Action Plan detailed and documented how the CAI was cleaned and sterilized after each of the two instances when environmental testing showed above action level growth of organisms and that environmental testing thereafter showed no action level growth of organisms, demonstrating that the cleaning and sterilization procedures implemented had been effective

18. On May 16, 2019, the Investigator indicated that he "approve[d] of everything written" in the Corrective Action Plan, and on May 17, 2019 the Corrective Action Plan was accepted.

19. On July 11, 2019, the Investigator conducted a follow-up inspection of Respondent's practice and found no violation of the Corrective Action Plan, any Pharmacy Regulation or USP 797. The Investigator has indicated that he was not aware of any ongoing compounding at that

time. The Board was informed that Respondent and his compounding nurse believed the Investigator was aware that compounding was taking place at the time of the inspection for a number of reasons. First, while the Investigator was performing his inspection, a patient was receiving an IV infusion of a CSP in his plain sight. In addition, during the inspection, when the Respondent's compounding nurse turned on the CAI in the Investigator's presence, he asked her if she was going to compound products for IV infusions. She indicated that she was. At the time, within the CAI were sterile products for to be compounded for IV infusions. The Investigator then asked the Respondent's compounding nurse how long she typically left the CAI on and operational before compounding IV infusions in it, and they discussed the required amount of time that the CAI should be on and operational before compounding was performed inside. Subsequently during that inspection, the Investigator went to the CAI itself and found affixed to it the manufacturer's instructions on the required amount of time the CAI should be on an operational before compounding. The Investigator then showed those instructions to the compounding nurse.

20. In June 2019, the Board was contacted by Harvard Pilgrim Health Care ("Harvard Pilgrim"), a third-party payer, regarding Respondent's compliance with the ICO. Harvard Pilgrim forwarded to the Board a letter sent by Respondent to Harvard Pilgrim, which letter an Investigative Committee of the Board found erroneously stated that Respondent had been "*authorized [by RIDOH] to continue mixing and administering IV fluids.*" On July 25, 2019, the Board's legal counsel informed Respondent's attorney about that finding by the Investigative Committee. The Board's legal counsel was informed orally and in writing that it was Dr. Souza's understanding that the express approval of his Corrective Action Plan authorized him to continue compounding sterile products and administering them intravenously and that understanding was confirmed by the Investigator's July 11, 2019 inspection when sterile products were clearly being

compounded and administered intravenously and the Investigator neither found nor cited Respondent for any violation, as he had during his prior inspection.

21. On August 28, 2019, Respondent appeared before an Investigative Committee of the Board and admitted that he had resumed compounding and had been administering sterile compounded pharmaceuticals to 20-25 patients a week for the past 3 months. Despite not having the written consent of the Director to resume compounding, Respondent represented to the Investigative Committee that he believed he was allowed to resume compounding because the Investigator had accepted his Corrective Action Plan and had performed a subsequent inspection without any violations while sterile products clearly being compounded and administered intravenously.

22. Based on Respondent's letter to Harvard Pilgrim and Respondent's admission to the Investigative Committee to the effect that he has resumed sterile compounding without written authorization of the Director, the Investigative Committee concluded that Respondent violated the terms of the ICO.

23. On May 19, 2020, upon request of the Board, RIDOH Board of Pharmacy inspectors ("Inspectors 2 and 3") conducted a follow up inspection of East Bay Innovative Medicine. On May 28, 2020, Inspector 2 provided a narrative report of the inspection to the Board, which report confirmed that Respondent had resumed the compounding of CSPs and administration of such CSPs to his patients. Inspectors 2 and 3 reported that the compounding was being performed by a registered nurse, employed by Respondent.

24. Inspector 2 noted several observed deficiencies in his report.

25. Noting that § 1.7(A)(6)(a) and (b) of the Pharmacy Regulations require that all CSPs be labeled with the "[c]omplete list of active ingredients" and "assigned beyond-use date ['BUD']", and that § 1.7(C)(4)(e) additionally requires inclusion of the "amounts or concentrations" of all

active ingredients on the label, Inspector 2 reported, "*There were no in-process verification steps to ensure the accuracy of the CSP. Verification that the proper dosages of medications were injected into the IV bag should be done by the responsible licensee, who is a licensed pharmacist or physician, and who assumes responsibility for the completed CSP. Use of Compounded Sterile Product (CSP) that has incorrect active ingredients or concentrations could put the patient at risk for serious adverse health outcomes. [Inspectors 2 and 3] witnessed CSP . . . that was not labeled in accordance with the aforementioned regulation. [Inspectors 2 and 3] viewed a completed CSP IV bag that was labeled with a marker and did not include a BUD (Beyond Use Date aka Expiration Date) or a list of the concentrations of API (active pharmaceutical ingredients/medications) contained in the CSP. The use of a CSP . . . that has passed its BUD . . . increases the risk of bacterial growth in the CSP and puts patient at risk of severe adverse health outcomes.*"

26. Inspector 2 subsequently indicated that neither Respondent nor a licensed pharmacist or physician is required to verify the dosages of the sterile products being compounded. Further, USP 797 has no such requirement and instead, states "[c]ompounding personnel shall visually confirm that ingredients measured in syringes match the written order being compounded. Preferably, a person other than the compounder can verify the correct volumes of correct ingredients were measured to make each CSP."

27. Additionally, Inspector 2 noted that, pursuant to § 1.7(B)(1)(d) of the Pharmacy Regulations, "*Positive sterility test results shall prompt a rapid and systematic investigation of aseptic techniques, environmental controls, and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes*," and that, pursuant to § 1.7(C)(3) of the Pharmacy Regulations, "*Pharmacies that compound CSPs shall implement a*

formal quality assurance program for monitoring, evaluating, correcting, and improving activities, systems and processes that support the preparation of CSPs." Relative to Respondent's compounding operation, Inspector 2 reported, "*The facility does not have a Quality Assurance Program in place to identify sources of contamination, review of aseptic techniques or monitoring of environmental controls. This facility had a positive bacterial result for Coagulase Negative Staphylococcus (4 colony forming units aka CFUs) growth in the [CAI] on 9/2019. The actionable level bacterial growth was detected on the left compounding sleeve that the compounder inserts their hand into and utilizes to manipulate the compounding of sterile products within the Direct Compounding Area (DCA) of the controlled environment of the CAI. There was no subsequent investigation by this facility of the aseptic techniques, disinfection process or environmental controls to determine how bacteria was introduced into the sterile field. This type of investigation is part of a quality assurance program, which there was no documentation of at this facility. Bacterial growth in the [DCA] of the [CAI] is a public health hazard that can lead to serious adverse health risks for the patient up to and including injury or death.*"

28. Subsequent to the Inspection, Respondent provided to the Board, documentation that had been in Respondent's Compounding Binder reviewed by Inspectors 2 and 3 but not seen by them that detailed that on September 12, 2019, the day Respondent received the environmental testing report which showed above action level growth of Staphylococcus on the left compounding sleeve, Respondent's compounding nurse triple cleaned and sterilized the CAI, ordered via overnight delivery two new compounding sleeves, tripled cleaned and sterilized the CAI after installation of those new compounding sleeves and scheduled the CAI for repeat environmental testing on September 30, 2019. Respondent also provided to the Board the results of that September 30, 2019 environmental testing, which demonstrated no bacterial or other organism growth anywhere

within the CAI.

29. Additionally, Inspector 2 noted the requirement, pursuant to § 1.7(B)(2) of the Pharmacy Regulations, that even "*Low Risk CSPs shall have quality assurance practices that shall include, at a minimum, routine disinfections . . . , visual confirmation that personnel are properly garbed; orders reviewed to ensure the correct identity and mount of the ingredients used.*" Inspector 2 reported, "*The SOP (standard operating procedure) for this facility states that an EPA Registered One Step Cleaner is to be utilized each morning followed by 70% IPA (Isopropyl Alcohol). During this inspection, the compounder stated that she cleaned in the morning with only 70% IPA (Isopropyl Alcohol). This is not the appropriate standard for cleaning the CAI and the compounder is not following the SOP for this facility. Improper disinfection can lead to growth of bacteria and mold. This can lead to continued growth of these organisms within the [DCA] of the CAI . . . and can contaminate [CSPs]. These contaminated [CSPs] can cause serious adverse health risks to the patient up to and including injury or death. This facility did not have a compounding log. A compounding log is important to identify the date of when a products was made, the BUD . . . , the API . . . and their NDC and lot numbers) were utilized, the concentration of each ingredient, and the person who compounded the CSP. The compounding log is utilized to identify patients that could have received contaminated products from a non-sterile environment in the CAI . . . , or who could have received a product that was compounded with an API . . . that was part of a manufacturer recall.*"

30. Despite the fact that § 1.7(B)(2) of the Pharmacy Regulations does not contain any requirement for a compounding log with the information described by Inspector 2, subsequent to the inspection, Inspectors 2 and 3 and the Board were informed that the information Inspector 2 indicated should be in a compounding log is in fact entered into and maintained in a patient's

record for each CSP administered intravenously.

31. Additionally, Inspector 2 noted the requirement pursuant to § 1.7.1 of the Pharmacy Regulations that "*[w]ritten procedures outlining . . . monitoring for proper function . . . shall be established and followed for all equipment, apparatus, and devices used in the preparation of CSPs,*" and the requirement set forth in USP 797, relative to "*Establishing and Maintaining Pressure Differentials,*" that "*[t]he qualitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring.*" Inspector 2 reported, "*The CAI . . . at this facility was found to not be monitored for pressure differential readings and no record or log is maintained. Pressure differentials are utilized to maintain the sterility of the CAI . . . environment as well as control the particle counts to the correct ISO 5 Level (amount of particles per unit of air). Failure to monitor pressure differentials increases the likelihood of the introduction of particles carrying bacteria or fungus into the sterile compounding environment. The compounder (who is the lead compounder) was unaware of the gauges on the CAI . . . and was unsure what the values represented or how to determine proper functioning of the CAI. This lack of knowledge puts the integrity of the CSP at risk of bacterial or fungal infiltration. This is a public health hazard that can lead to serious adverse health risks for the patient up to and including injury or death.*"

32. USP 797 requires a "pressure gauge or velocity meter [to] be installed 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 shall be reviewed and documented on a log at least every work shift . . . or by a continuous recording device." However, Respondent's CAI is a type for which USP 797 does not require either a buffer area or an ante-area as those terms are defined. For this reason and because the prior Rhode Island Board of Pharmacy

Investigator had never raised an issue concerning or cited Respondent for anything to do with pressure differentials, Respondent did not believe that any record or log of pressure differentials was required and instead, understood that the pressure gauges and abnormal pressure alarm on the CAI could be relied upon for appropriate pressure differentials to maintain the required ISO Class 5 environment.

33. Based on the foregoing, an Investigative Committee of the Board found Respondent violated R.I. Gen. Laws § 5-37-5.1(19), which defines "unprofessional conduct" as including, "*[i]ncompetent, negligent, or willful misconduct in the practice of medicine which includes the rendering of medically unnecessary services, and any departure from, or the failure to conform to, the minimal standards of acceptable and prevailing medical practice in his or her area of expertise as is determined by the board,*" and R.I. Gen. Laws § 5-37-5.1(24), which defines "unprofessional conduct" as including, "*[v]iolating any provision or provisions of this chapter or the rules and regulations of the board or any rules or regulations promulgated by the director or of an action, stipulation, or agreement of the board.*"

Based on the foregoing, the RIDOH, the Director, the Board and Respondent agree as follows:

1. Respondent admits to and agrees to remain under the jurisdiction of the Board.

2. Respondent has agreed to this Consent Order and understands that it is subject to final approval of the both the Director and the Board and is not binding on Respondent until final ratification by both.

3. If ratified by the Director and the Board, Respondent hereby acknowledges and waives with respect to the matters this Consent Order resolves:

a. The right to appear personally or by counsel or both before the Board;

b. The right to produce witnesses and evidence on his behalf at a hearing;

c. The right to cross examine witnesses;

d. The right to have subpoenas issued by the Board;

e. The right to further procedural steps except for those specifically contained herein;

f. Any and all rights of appeal of this Consent Order;

g. Any objection to the fact that this Consent Order will be presented to the Director and the Board for consideration and review; and

h. Any objection that this Consent Order will be reported to the National Practitioner Date Bank and Federation of State Medical Boards and posted to the RIDOH public website.

4. Respondent agrees to pay, within 120 days of the ratification of this Consent Order, an administrative fee of $ 4252.87.00 for costs associated with the investigating the above-referenced complaint. Such payment shall be made by certified check, made payable to the "**Rhode Island General Treasurer,**" and sent to Rhode Island Department of Health, 3 Capitol Hill, Room 205, Providence, RI 02908, Attn: Lauren Lasso. Respondent will send notice of compliance with this condition to DOH.PRCompliance@health.ri.gov within 5 days of submitting the above-referenced payment.

5. Respondent hereby agrees to this reprimand on his physician license.

6. Respondent has stopped compounding all sterile products while the terms of this Consent Order were being addressed. Prior to resuming sterile compounding, Respondent shall have his office compounding program inspected by a Board-approved monitor. Respondent may resume compounding sterile products when that monitor provides a written report to the Board opining that Respondent's operation to compound sterile products is USP 797 compliant and that therefore, resuming sterile compounding is appropriate. Respondent also shall retain, at his own expense, a

Board-approved monitor, which monitor shall no less than quarterly, for a period of three years from the ratification of this Consent Order, inspect and review Respondent's practice to ensure compliance with applicable laws, regulations, guidelines, and the overall standard of care, with respect to the compounding of sterile products. The first inspection shall occur within 90 days of ratification of this order. If all reports are favorable for the first 2 years, Respondent may request the third year of monitoring be waived. Respondent shall ensure that the monitor prepares a report relative to Respondent's compliance pursuant to each inspection. Such reports are to be sent directly to the Board at DOH.PRCompliance@health.ri.gov by the fifteenth day of the month following the applicable quarter.

7. The Immediate Compliance Order referenced above, dated April 25, 2019, is hereby vacated and of no force and effect.

8. The Board Case No. C19-0652 is hereby finally concluded and closed. In addition, the Board, the Director, and the RIDOH, including any of its boards, departments, agencies or subparts, stipulate and agree that this Consent Order resolves and precludes any or all of them from taking or pursuing any action of any kind, including but not limited to regulatory, licensure, disciplinary, adjudicatory, prosecutorial and/or the filing of any legal action in any Court or other body, relating in any way to compounding or any action connected with or related to compounding, which occurred prior to the date this Consent Order is ratified and executed by the undersigned, by Respondent, Respondent's medical practice, and/or any person or entity for whom Respondent could be deemed responsible. The purpose of this paragraph is to permanently and finally resolve for Respondent any and all compounding issues, violations or actions of any kind that occurred any time prior to the date hereof.

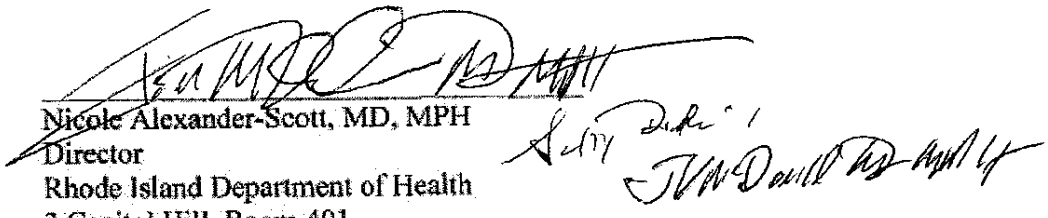
9. In the event that any term of this Consent Order in paragraphs 1-8 immediately above is violated, after ratified and approved, the Director shall have the discretion to impose further disciplinary action pursuant to R.I. Gen. Laws §§ 5-37-5.1 through 5-37-6.3, including immediate suspension of his medical license pursuant to and as permitted by R.I.Gen.Laws §§ 5-37-8 and 42-35-14(c). If the Director imposes further disciplinary action, Respondent shall be given notice and shall have the right to have an administrative hearing within twenty (20) days of the suspension and/or further discipline or any lesser time period permitted by law or regulation. The Director shall also have the discretion to request an administrative hearing after notice to Respondent of a violation of any term of this Consent Order. The Board may suspend Respondent's license or impose further discipline as described above if any alleged violation is proven by a preponderance of evidence. Any administrative hearings, whether initiated by the Director or the Respondent, shall be conducted in accordance with R.I.Gen.Laws §§ 5-37-5.1 through5-37-6.3 or R.I.Gen.Laws §§ 5-37-8 and 42-35-14(c) , the Rules and Regulations for the Licensure and Discipline of Physicians (216-RICR-40-05-1), the Rules and Regulations for Practices and Procedures Before the Rhode Island Department of Health (216-RICR-10-05-4), and applicable provisions of R.I. Gen. Laws Chapter 42-35 and § 42-35-9 through 42-35-13. Any discipline ultimately imposed pursuant to this paragraph is appealable pursuant to Rhode Island Gen. Laws §§ 5-37-37 et seq. and 42-35-15 et seq.

[SIGNATURE PAGE FOLLOWS]

Signed this 9th day of June, 2020.

Michael Souza D.O.

Ratified by the Rhode Island Department of Health and the Board of Medical Licensure and Discipline on the 10th day of June, 2020.



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