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, DO
License No.: DO 00446

IMMEDIATE COMPLIANCE ORDER

Now comes the Director ("Director") of the Rhode Island Department of Health ("RIDOH") and, pursuant to R.I. Gen. Laws § 23-1-21, after initial investigation of Michael Souza, DO ("Respondent"), relative to the May 24, 2021 inspection by a RIDOH Board of Pharmacy Inspector of Respondent's practice located at 1275 Wampanoag Trail, East Providence, Rhode Island, makes the following

FINDINGS OF FACTS

1. Respondent has been a licensed physician in the State of Rhode Island since June 8, 1994. His primary specialty is Family Practice.

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 of Medical Licensure and Discipline ("Board") accepted a "position paper" which indicated that the Board was adopting USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* ("USP 797") as the standard governing "sterile compounding performed by practitioners."

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

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 25, 2019, the Director issued an Immediate Compliance Order ("2019 ICO") against Respondent relative to his compounding of sterile products, pursuant to which Respondent was order 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.*"

7. On June 9, 2020, Respondent entered into a Consent Order to Resolve Immediate Compliance Order and Board of Medical Licens[ure] and Discipline Case No. 190652 ("2020 Consent Order"), pursuant to which the 2019 ICO was vacated and Respondent was permitted to resume sterile compounding after having "*his office compounding program inspected by a Board-approved monitor*" who "*provide[d] 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.*"

8. Pursuant to the 2020 Consent Order, Respondent was further required to "*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 th[e 2020 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 th[e 2020 Consent 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."

9. Additionally, pursuant to the 2020 Consent Order, Respondent was required to pay an administrative fee of $4252.87 within 120 days of ratification of the 2020 Consent Order and send notice of compliance with the condition to DOH.PRCompliance@health.ri.gov within 5 days of submitting payment.

10. The 2020 Consent Order provided that if any term of the 2020 Consent Order was violated after ratification and approval, "the Director shall have the discretion to imposed further disciplinary action."

11. On May 24, 2021, it was determined pursuant to a routine compliance check that notice of compliance with the requirement that Respondent pay the administrative fee had not been sent to DOH.PRCompliance@health.ri.gov within the agreed upon period for compliance. That day, it was also determined that no quarterly reports had been received from a board approved monitor.

12. On June 7, 2021, the Board received notice that a certified bank check had been mailed that day.

13. On May 24, 2021, at the request of the Board, the Board of Pharmacy Investigator conducted an inspection of Respondent's practice. The Board request was predicated upon the above-referenced determination that no quarterly reports had been received from a board approved

monitor.

14. Pursuant to the May 24, 2021 inspection, the Board of Pharmacy Investigator determined that Respondent was and had been engaged in the compounding of sterile products. Upon information and belief, no inspections by a board-approved monitor occurred after June 10, 2020 and, therefore, no reports were prepared or sent to the Board.

15. Additionally, the Board of Pharmacy Investigator identified several deficiencies. He prepared a report and separately opined as follows:

"*The report I provided contained only the items that I could prove as deficient, and those deficiencies were severe. The Compounding Aseptic Isolator Hood being powered down with medications being stored haphazardly in it is a deficiency that cannot be scored on any compliance scale regarding USP <797>. The workflow that was presented to me verbally of running it for 5 minutes before compounding violated the facilities [sic] own SOP (standard operating procedure). Accepted practice is to run for 30 minutes and is validated by the facilities [sic] written policy. The safety of the Isolators [sic] sterile field is determined by the UNINTERUPTED flow of filtered air.*

"*The next concerning item would be the Viable Environmental Monitoring. The facility is conducting its own collection of growth plates. It appears by the reports from the lab that they are doing both air impacted and gravity plates, but I do not see an air sampler or any training/competencies that would determine proficiency with the air collection apparatus. Further concerning me is that they are getting growth on the gravity plates but have 0 cfu's on every sample from the air impacted plates. USP <797> prefers air impaction over gravity and many facilities no longer utilize gravity collection. Results of 0 cfu's for that many consecutive months on air impaction samples is almost impossible to obtain and leads me to question the validity of their results and their sampling methods.*

"*Just looking at these two items I would have great reservations about this facility. It puts*

into question every process that they follow. I cannot say with certainty that they are compliant at any level as these are the basis for everything that USP <797> builds from. This level of compliance failure has led to familiar compounding situations such as New England Compounding. The difference being NECC did ship medications and [Respondent] does not."

16. In his above-referenced report, the Board of Pharmacy Investigator noted several specific deficiencies, including: (1) "*Daily pressure monitoring for the Compound Aseptic Isolator had not been completed for any day in the month of May 2021*," (2) "*Daily Cleaning Log for the CAI had not been completed for any day in the month of May 2021*," (3) "*Medications were inappropriately being stored in CAI. Medications and supplies are to be removed from Direct Compounding Area once procedures are completed*," (4) "*Inspector could find no documentation that a Quality Assurance program was in place. During interview RN Lisa McManaman was unaware of the requirement*," (5) "*Microorganisms identified during viable testing at the facility are listed by cfu's and categorized by 'gram staining techniques and/or colony morphology.' This level of identification is not in compliance with USP<797>. Identification of microorganisms recovered are to be identified down to at least the genus level. This process does not identify the microorganism down to the genus level*," (6) "*There was no documentation and RN Lisa McManaman could not produce written testing for 2020. Last documented written review produced was June 2019*," (7) There was no documentation that personnel had passed a written skills assessment annually, (8) "*There was no documentation found or produced for initial competencies for fingertip testing or media fill for Dr. Michael Souza. USP<797> states that compounding personnel pass fingertip/media fill testing initially and annually*," (9) "*There was no documentation found or produced of competencies for Dr. Michael Souza in Garbing and Gloving. USP<797> states that a visual observation shall be documented and maintained to provide a record of competency*," (10) "*CAI was powered off upon inspector arrival. USP<797> states that Primary Engineering Controls shall be operated continuously during compounding activity*," (11)

"There was no documentation found or produced of SOPS regarding: Start- up of CAI before each compound," and *"Storage of Medications in Direct Compounding Area. USP<797> states that there shall be written approved SOPS."*

ALLEGED VIOLATIONS

1. Respondent is in violation of 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."*

2. Respondent is in violation of R.I. Gen. Laws § 5-37-5.1(24), which defines unprofessional conduct" as including *"[v]iolating any provision or provisions of [R.I. Gen. Laws § 5-37] 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."*

ORDER

1. Based on the foregoing, particularly Respondent's failure to comply with the overall terms of the 2020 Consent Order, and enhanced by Respondent's repeated failure to satisfy the minimum standards of care with respect to the compounding of sterile products, as illustrated by the deficiencies identified by the Board of Pharmacy Investigator, the Director has determined that there exists a violation of law, rule, or regulation within her jurisdiction that requires immediate action to protect the health, welfare, or safety of the public or any member of the public.

2. Accordingly, Respondent shall immediately cease all compounding of sterile products until he receives written approval from the Director. The Director's approval shall be contingent upon a determination that Respondent has achieved compliance with the 2020 Consent Order, specifically with respect to the retention of a Board-approved monitor and the

Board's receipt of a written report from the monitor, following the monitor's inspection of Respondent's office compounding program, attesting to the fact that Respondent's operation to compound sterile products is USP 797 compliant and that, therefore, resuming sterile compounding is appropriate.

3. Additionally, in view of Respondent's repeated failure to satisfy the minimum standards of care with respect to the compounding of sterile products and Respondent's violation of the 2020 Consent Order, to ensure Respondent's continued compliance and to protect the health, welfare, and safety of the public, the monitor shall until further notice conduct announced and unannounced inspections of Respondent's office compounding program at least once every 30 days, the first inspection occurring no later than 7 days from service of this document. Monthly monitoring shall continue until the Director determines, in writing communicated to Respondent, that such measure is no longer necessary to protect the health, welfare, or safety of the public, or until subsequent agreement with the Board. For the avoidance of doubt, the 2020 Consent Order remains in full force and effect.

4. 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 11th day of June 2021

Nicole Alexander-Scott, MD, MPH
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 via his attorney, Dennis Grieco II, Esq., at DGrieco@grieco-law.com, on this ____ day of June 2021.

_____