BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Second Amended Accusation Against:

PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL,

Pharmacy Permit No. HSP 55890,

Sterile Compounding License No. LSC 101129;

LEIGH ANN WITHERSPOON,

Registered Pharmacist License No. RPH 72914;

BLAINE SCOT GUINN,

Registered Pharmacist License No. RPH 42192; and

HENRY MAUHANG CHAN,

Registered Pharmacist License No. RPH 53602,

Respondents.

Agency Case No. 7137

OAH No. 2022100700

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on August 25, 2023.

It is so ORDERED on July 26, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

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PROPOSED DECISION

Administrative Law Judge Karen Reichmann, State of California, Office of Administrative Hearings, heard this matter on May 15 through 19 and 24, 2023, by videoconference.

Deputy Attorney General Susana A. Gonzales represented complainant Anne Sodergren, Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

Attorney Derek S. Davis represented respondent Blaine Scot Guinn, who was present.

All other respondents settled prior to the hearing.

The record closed and the matter was submitted for decision on May 24, 2023.

FACTUAL FINDINGS

Summary

Complainant seeks to discipline respondent based on violations of pharmacy law that took place at a hospital pharmacy where he served as the Area Director of Pharmacy. The alleged violations include improper storage of vaccines and medications, and violations of sterile compounding regulations that occurred while the pharmacy's dedicated compounding room was unusable. Respondent does not dispute that violations occurred, but does not believe license discipline is appropriate because he was not the pharmacist-in-charge and did not directly manage the

hospital's pharmacists. The evidence established cause for discipline, warranting a public reproval of respondent's license.

Jurisdictional Matters

1. Complainant Anne Sodergren filed the Second Amended Accusation solely in her official capacity as the Executive Director of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. Respondent Blaine Scot Guinn has been licensed by the Board as a pharmacist since August 31, 1988. He holds Registered Pharmacist License No. RPH 42192. This license was in full force and effect at all times relevant to this matter and will expire on May 31, 2024, unless renewed. On July 19, 2020, the Board issued Citation No. CI 2019 88576 to respondent and imposed a $400 citation fine for a substantially-related conviction and for using alcohol in a dangerous manner. The citation was based on respondent's 2018 misdemeanor conviction for violating Washoe County (Nevada) Code section 70.390 (reckless driving), following his arrest for driving under the influence with a blood alcohol content of .124 percent. Respondent paid the citation fine.

3. Complainant seeks to revoke respondent's license for acts and omissions pertaining to violations of pharmacy law committed at a pharmacy hospital where he served as a manager. The causes for discipline are aiding and abetting violations of Board regulations governing pharmacy law and inappropriate exercise of respondent's education, training, or experience as a pharmacist.

4. At all times relevant to this matter, respondent was employed by St. Joseph Health of Northern California as an Area Director of Pharmacy, a management position with oversight over four licensed pharmacies, three located in hospitals

(Providence Santa Rosa Memorial Hospital (PSRMH), Queen of the Valley Medical Center (QVMC), and Petaluma Valley Hospital (PVH)) and one located in an outpatient clinic. All four pharmacies also held sterile compounding licenses. Each pharmacy had a pharmacist-in-charge (PIC); respondent was not the PIC for any of the facilities. PIC is a role defined in Business and Professions Code section 4113. Pursuant to this statute, every pharmacy must designate a PIC, subject to Board approval. The PIC "shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." Respondent's managerial position is not similarly mandated or defined by statute. Respondent's employer required that he hold a pharmacist's license. In some organizations, a Director of Pharmacy or Area Manager might not be a licensed pharmacist, especially if the organization has pharmacy locations in multiple states.

5. The allegations in this matter pertain to the improper storage of vaccines and medications and to sterile compounding activities that occurred at PSRMH between November 30 and December 14, 2020. At all times, Leigh Ann Witherspoon, Pharm.D., was the PIC of PSRMH. There were also two other managers supervising day-to-day pharmacy operations at PSRMH.

Sterile Compounding

6. Compounding refers to the process of mixing products for administration to patients. Sterile compounding is the process required for compounding products that will be injected, inhaled, administered intravenously, or placed in the eye. The final product is known as a compounded sterile preparation or CSP. Because of the significant risk of patient harm from administration of a contaminated product, stringent requirements apply to sterile compounding.

7. United States Pharmacopeia (USP) is an organization that advocates for safe medicines, dietary supplements, and foods. USP has developed standards for sterile compounding with the goals of ensuring patients' safety and reducing infection risks. The USP standards for sterile compounding are referred to as USP 797. USP 797 has evolved over time. The current version and version in effect at the time of the allegations was issued in 2018. A revised version will go into effect in November 2023.

8. The Board has adopted regulations governing the practice of sterile compounding, incorporating USP 797. All licensed pharmacists, especially those working in facilities where sterile compounding is performed, are required to be familiar with Board regulations and USP 797.

9. Sterile compounding can be performed in three types of environments: 1) a clean sterile compounding room with an anteroom and a primary engineering control device (PEC) (such as a hood or isolator); 2) a sterile compounding area (SCA) with a PEC; and 3) immediate use compounding, following strict restrictions. In the hospital setting, immediate use compounding sometimes occurs at a patient's bedside, away from the pharmacy.

10. Sterile compounding is categorized as high, medium, or low risk depending upon the risk the final product will have of contamination. An increase in the number of products used and in the number of manipulations of the products increases the risk of contamination. The risk of contamination of a CSP increases with time, because if bacteria are in the product, they can multiply over time. High, medium, and low risk CSPs can be compounded in a clean room environment, but only low risk products can be compounded in a SCA. Low risk compounding is limited to no more than three products and no more than two entries into each package. All CSPs are labeled by the pharmacist with a beyond use date (BUD) which is the time by

which the administration of the product must begin. CSPs can be performed in batches for frequently needed CSPs, or can be custom-compounded for a specific patient.

11. California Code of Regulations, title 16, section 1751.8, subdivision (e), went into effect in 2017. It provides the following limitations for immediate use compounding:

> Where any sterile compounded drug preparation was compounded either outside of an ISO class 5[1] PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. . . . If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. . . . Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in

[1] ISO class 5 refers to the classification system for cleanrooms.

such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

12. California Code of Regulations, title 16, section 1735.5, subdivision (a)(2), sets forth requirements for compounding logs. These include documentation of name and strength of the CSP; the date the CSP was compounded; the identity of any pharmacy personnel engaged in compounding the CSP; the identity of the pharmacist reviewing the final CSP; the quantity of each ingredient used in compounding the drug preparation; the manufacturer, expiration date and lot number of each component; a pharmacy-assigned unique reference or lot number for the CSP; the beyond use date or beyond use date and time of the final CSP, expressed in the compounding document in a standard date and time format; the final quantity or amount of drug preparation compounded for dispensing; and documentation of quality reviews and required post-compounding process and procedures.

June 2020 Damage to Anteroom

13. Sterile compounding at PSRMH is normally performed in accordance with the most rigorous requirements, in a clean room, which is also referred to as the "buffer room" or the "IV room." There is an adjacent anteroom where individuals performing the compounding (usually pharmacy technicians) garb and wash their hands and perform other required procedures before entering the IV room to prepare CSPs. The CSPs are then verified by licensed pharmacists and logged in a compounding log before being sent to the hospital's departments for administration to patients.

14. On June 11, 2020, a pipe in the ceiling of the anteroom at the PSRMH pharmacy leaked, causing severe damage and rendering the room unusable. Similar damage had occurred in the sterile compounding area three years earlier, prior to respondent's tenure. With the anteroom unusable, the full range of sterile compounding could not be performed in the IV room. Respondent became aware of the situation that same day, when he arrived at the pharmacy and saw water pouring from the ceiling. He helped direct staff in emptying out the room and finding room in the tight pharmacy quarters to store displaced supplies.

15. Later on June 11, 2020, Witherspoon sent an email to all pharmacy staff, including respondent, updating the staff as to the workflow changes in effect as a result of the loss of use of the IV room. The email referenced obtaining approval from the Board to outsource most compounding to PVH and QVMC, and to perform immediate use compounding only at PSRMH. The email included the following:

> We are now limited to compounding that is low-risk, or those that contain 3 products or less, and those intended for immediate use, or are assigned a 1-hr beyond-use-date (BUD). . . . One of the USP updates I wanted to provide clarification on for the group is the definition of products. Below is clarification provided by USP.
>
> "**When compounding sterile CSPs, can more than three individual containers of a sterile product be used?**
>
> The immediate use CSPs provision states that the preparation must not involve more than 3 different sterile products. Two or more of the same sterile product may be

> used as long as there are not more than three different sterile products. For example, two vials of drug are reconstituted using two vials of sterile water for injection and added to an intravenous bag may be considered immediate use as long as the criteria listed in 1.3 Immediate Use CSPs are met. As another example, when the CSP requires combining 4 vials of the same component into a single bag of diluent, only 2 different sterile products are used to prepare the CSP."

The quoted section in Witherspoon's email was not in fact from USP 797 and misstated USP 797's definition of immediate use compounding, which is limited to no more than three products and not more than two entries into any one container or package. The quoted section is from a proposed revision to USP 797. Witherspoon did not direct pharmacy staff to the Board's regulation regarding immediate use compounding's limitations and documentation requirement and did not direct them to review USP 797. There was no evidence, however, that Witherspoon intended to misinform pharmacy staff or intended for them to commit violations of USP 797 or any Board regulations.

16. Higher-risk and batch compounding was immediately outsourced to the hospital's sister facilities, PVH (an approximate 20-minute drive) and QVMC (an approximate 40-minute drive), with regular courier service. Immediate use compounding—as described by Witherspoon in her email—was performed in an office space in the pharmacy that was previously used by the former Area Director Saad Sultan and was referred to as "Saad's old office." The small space was cluttered,

carpeted, had porous ceiling tiles, and a cork bulletin board and computer printer in close proximity to where compounding was performed.

17. On June 12, 2020, Witherspoon sent another email to pharmacy staff, with more detail on workflow changes relating to sterile compounding while the anteroom and IV room were unavailable. She reported that a PEC device would be arriving from a sister facility in Eureka for use while immediate use compounding was performed in Saad's old office. This device was never used.

July 1, 2020, Inspection and Report

18. Board Inspector Scott Huhn performed a partial inspection of the pharmacy on July 1, 2020, after learning that there had been damage to the sterile compounding area. Both Witherspoon and respondent were present. Huhn understood the purpose of the inspection to be to determine whether low risk compounding could be performed in the IV room as a SCA while construction was completed on the damaged anteroom. Huhn toured the area and told Witherspoon and respondent that the IV room could be recertified as a sterile compounding area after thorough cleaning.

19. Huhn testified that he was not made aware during this inspection that immediate use compounding was taking place in Saad's old office, and was under the impression that all compounding was taking place offsite, at the sister facilities. This testimony was credible. Because other credible evidence established that respondent and Witherspoon thought that Huhn understood that immediate use compounding was occurring in Saad's old office, it was not established that Huhn's misunderstanding was the result of any effort by respondent or Witherspoon to deceive or mislead him.

20. At the conclusion of the July 1 inspection, Huhn wrote the following in his inspection report, which was given to Witherspoon and respondent:

> Currently no compounding taking place in the buffer room. Discussed CCR 1751.8(e) regarding "immediate use" compounding for emergencies only. Documentation required if compounding any CSPs in the SCA; include the circumstance and reason for the urgency of the CSP. Currently [QVMC] compounding medium risk CSP's . . . [PVH] providing low risk CSP's.

This report was not provided to the pharmacists working in the pharmacy, and they were not provided with the regulation cited by Huhn or reminded of its requirements.

21. At a date not established, immediate use compounding returned to the buffer room as a SCA. The anteroom was still unusable and construction stalled for months. By November 30, 2020, immediate use compounding returned to Saad's old office due to a resumption of construction in the anteroom.

Complaints to Board and CDPH

22. In early December 2020, a concerned employee of the pharmacy submitted a complaint to both the California Department of Public Health[2] (CDPH) and

[2] The California Department of Public Health also has regulatory authority over hospital pharmacies.

the Board regarding issues at the PSRMH pharmacy. The reporting party[3] wrote that serious regulatory violations and unsafe practices putting patient safety at risk were occurring at the pharmacy. She reported that vaccines and medications were being improperly stored in an unmonitored refrigerator in the employee breakroom; medium risk compounding was occurring under low risk compounding conditions; and that these concerns had been raised by staff to the PIC but were dismissed.

23. CDPH personnel went to the pharmacy on December 14, 2020. They reported their findings to Board personnel, including Supervising Inspector Christine Acosta, and expressed concern about the compounding being performed in Saad's old office. The CPPH personnel reported that the pharmacy was "doing all compounding on countertop as 1 hour BUD," including compounding medium risk products, and had told CDPH inspectors that the Board had authorized this practice.

December 15, 2020, Board Inspection and Investigation

24. Acosta was alarmed by the report from CDPH and assigned Huhn to investigate the pharmacy and the reporting party's complaint. Huhn contacted the reporting party, who sent photographs depicting vaccines and medication stored in a breakroom refrigerator alongside cut watermelon and lunch totes.

25. Huhn made an unannounced visit to the PSRMH pharmacy on the afternoon of December 15, 2020. He met with Witherspoon and respondent to discuss

[3] The individual who submitted the complaints is referred to as the reporting party for confidentiality.

the items in the reporting party's complaint and in the email communications sent to the Board by CDPH.

26. Witherspoon and respondent admitted that vaccines and antibiotics had previously been stored in the breakroom refrigerator, which was not temperature-monitored. Witherspoon explained that they had run out of room to store them in the temperature-controlled refrigerators in the pharmacy.

27. Huhn learned that compounding was taking place in Saad's old office. Huhn was "shocked" when he saw the room, which lacked a PEC and was, in his view, a "blaringly out of compliance" place to compound due to the clutter and porous surfaces.

28. Huhn reviewed the compounding log. He found the logs lacked documentation of the justification for immediate use, and that some products were being compounded that would not in his experience be needed to prevent loss of life or intense suffering. Huhn also observed that the compounding logs lacked documentation of the BUDs and times, final quantities, and quality reviews of the CSPs.

29. Huhn prepared a written notice to the pharmacy identifying the violations he observed. These included at least 593 instances between November 30 and December 14, 2020, in which sterile compounding was performed in circumstances that exceeded the immediate use regulation and incomplete compounding records, based on the compounding log's lack of complete documentation of the BUDs and times, final quantities of drug compounded, and quality reviews and post compounding processes and procedures.

30. Acosta viewed the situation at the PSRMH pharmacy as urgent and presenting a risk to patient safety, and she contacted Witherspoon and respondent to work with them on improving sterile compounding protocols. She met with Witherspoon and respondent on December 16, 2020, by teleconference and sent an email with her concerns. Acosta identified immediate modifications that could be made to Saad's old office to make it safer for compounding, and encouraged them to locate another more appropriate location.

31. As a result of the December inspection and communication with the Board, Witherspoon implemented numerous changes at the pharmacy. Pharmacists were now directed to document the clinical rationale for immediate use compounding, with changes made to the compounding log to include this documentation. By December 18, 2020, respondent reported to Huhn and Acosta that a space had been located in the emergency department of the hospital that was better suited for immediate use compounding.

32. In January 2021, Huhn sent written notices to 18 pharmacists who were involved with sterile compounding at PSRMH between November 30 and December 13, 2020, informing them of his finding that they had committed violations by signing off on CSPs when the circumstances to meet immediate use had been exceeded. Many of the pharmacists responded to the notices, explaining that all medications were urgently needed, that delays could cause harm to the patients, that they were following hospital directives and putting patients' need first, and also detailing the challenges at PSRMH due to the damage to the anteroom and the pandemic. Many wrote that they believed management was working with the Board, and that they trusted management to ensure that the pharmacy was operating in compliance. All 18 pharmacists were subsequently sent letters of admonishment.

Testimony of Christine Acosta

33. Acosta is the Board's expert in sterile compounding and was involved in drafting the sterile compounding regulations. She testified about her role in the investigation and her conclusion that violations occurred at PSRMH, and that respondent should be held accountable for them.

34. Acosta explained that Saad's old office was not an appropriate place for immediate use compounding due to the clutter and porous surfaces, and that the ongoing compounding in this room presented a risk of harm to patients. She identified many things that could easily be removed from the space to reduce the risk of contamination, if a more suitable space could not be found. Acosta explained that the pharmacy management faced competing priorities—compliance with regulations and patient welfare, and that when the anteroom went out of commission, immediate use compounding became the standard of practice for the pharmacy. Nonetheless, the pharmacy management and the individual pharmacists were all individually responsible for complying with the immediate use compounding regulation and USP 797.

35. Acosta's review of the compounding log for December 13 and 14, 2020, revealed that some CSPs compounded as immediate use were for medications that in her experience are not needed to prevent loss of life or intense suffering. Some of the CSPs were for scheduled procedures, such as dialysis, and could have been compounded offsite. Acosta also saw some circumstances where the compounding exceeded low risk (because there were more than three products used or more than two entries into a single container) and therefore were in violation of the limitations of immediate use compounding. She acknowledged that some of the CSPs likely were

necessary to prevent loss of life or intense suffering, but were nonetheless in violation of the law because the justifications were not documented.

36 During her interactions with PSRMH management, Acosta found respondent to be responsive and to act appropriately in response to her suggestions.

37. Acosta makes recommendations regarding discipline, but is not responsible for deciding whether to seek discipline against licensees or what level of discipline to seek. Acosta recommended disciplinary action against the hospital and Witherspoon, but at the hearing she could not recall whether she recommended discipline or a citation and fine against respondent.

38. Acosta explained that non-PIC managers such as respondent are deemed responsible for violations depending on the circumstances. She looks at the culpability of the manager, whether the manager had the opportunity to have stopped the violations, and whether discipline will aid in preventing recurrence. Acosta believes that respondent abetted the sterile compounding violations and failed to appropriately exercise his education, training, and experience as a pharmacist by allowing unsafe compounding to take place at PSRMH. She believes he could have done more to keep abreast of the laws and regulations and to step in and not allow the violations to occur.

Testimony of PSRMH Pharmacists

39. Several pharmacists who received letters of admonishment in connection to the compounding practices at PSRMH testified at the hearing. They reported raising concerns about the safety of compounding in Saad's old office and concerns about whether the compounding log was in compliance at regular staff "huddles" ran by Witherspoon, which respondent often attended. The pharmacists reported that they

were never told that compounding could only be performed to prevent loss of life or intense suffering and that they had to document a justification until after Huhn's inspection in December 2020. All stated, credibly, that they would have changed their practices had they been correctly informed of the requirements for immediate use compounding.

40. These pharmacists reported that they trusted pharmacy management, including Witherspoon and respondent, to ensure that the pharmacy was acting in compliance with the law. Some expressed concern that management had not shared Huhn's July 1, 2020, inspection report with them, as it flagged the importance of adhering to the immediate use compounding regulation. Instead, they were told that as long as the product had a one-hour BUD, it could be compounded onsite.

41. The pharmacists explained that they were doing their best during a stressful and difficult time. Some expressed frustration with the hospital administration for failing to do more to help the pharmacy.

42. The pharmacists described respondent as courteous and professional. None described respondent directly providing any misinformation regarding pharmacy regulations or USP 797.

43. Receiving the written notices of violation and subsequent letters of admonishment was distressing to the pharmacists, who all believed they had been helping patients in need.

44. Several of the pharmacists left the PSRMH pharmacy for other employment.

Respondent's Evidence

RESPONDENT'S BACKGROUND

45. Respondent attended pharmacy school at the University of Southern California and completed a residency in an oncology unit at the City of Hope. He worked as a clinical pharmacist for several years. Respondent was the Director of Pharmacy and the PIC at PSRMH from 1997 through 2005, when he left for a position with a group purchasing company. In 2017, respondent married and moved to Nevada, and obtained licensure there. He worked in a management position for an acute care health services organization.

In 2019, respondent returned to California for the position as Area Director, replacing Saad Sultan. Respondent explained his primary operational duties as fiscal management of the pharmacies, human resources, labor relations, and administering the Medicaid drug purchasing program. He did not manage the pharmacists. He collaborated with pharmacy managers at all four sites. He was regularly onsite at PSRMH and often attended the weekday "huddles."

RESPONDENT'S TESTIMONY REGARDING THE ALLEGATIONS

46. Respondent acknowledged that he was aware that the anteroom at PSRMH had been rendered unusable by the plumbing leak, disrupting normal pharmacy sterile compounding operations. He described this as a catastrophic event, but he denied playing any role in figuring out the course of action and implementing changes to the workflow. Respondent understood generally that the course of action was to have most compounding performed at the sister hospitals' pharmacies, and to set up immediate use compounding at PSRMH. He was not directly involved with setting up the immediate use compounding in Saad's old office. Respondent had no

involvement in creating the compounding logs or directing employees how to document in the logs.

47. Respondent reported his frustration with hospital administration during this crisis. A sister facility in Eureka had a spare PEC device and shipped it to the PSRMH pharmacy. Although use of this device would have made compounding safer, hospital management did not approve its use because it would have required the hospital to arrange for a costly inspection and possible fine by OSHPD (Office of Statewide Health Planning and Development, another state agency). By the time the complaint was filed in December, the hospital was nowhere near completing the repairs to the sterile compounding area. Respondent expressed gratitude to the reporting party for filing the complaint, because as a result, the hospital administration finally took the situation in the pharmacy seriously and provided the needed resources.

48. Respondent testified that he trusted Witherspoon as PIC to comply with sterile compounding regulations because she had specialized training in sterile compounding, and he did not. He believed that the pharmacy was in compliance due to his trust in Witherspoon. Respondent had not been directly involved in compounding since around 2004. There were also other individuals in the organization with specialized training and experience in sterile compounding who were working with Witherspoon, including Henry Chan, pharmacy manager of QVMC, who is board certified in sterile compounding, and Stephen Bryant, a pharmacy technician at a sister facility in Eureka. Respondent had confidence in Witherspoon, whom he viewed and continues to view as highly competent. Respondent believed that Witherspoon was in communication with Board representatives regarding the status of compounding at the hospital. Respondent does not think that Witherspoon intentionally violated Board

regulations. Respondent did not realize that Witherspoon's email to pharmacy staff contained incorrect information about immediate use compounding.

49. Respondent stated that he attended regulatory inspections as an ambassador and a conduit to hospital administration, but that the PIC remained responsible for interfacing with the Board.

50. Respondent testified that he believed that Huhn was aware that immediate use compounding was being performed in Saad's old office following the July 1, 2020, inspection. Respondent did not realize Saad's old office was inappropriate for immediate use compounding.

51. Respondent acknowledged that he did not research and review laws and regulations regarding sterile compounding. He acknowledged attending numerous pharmacy "huddles" where compounding protocols were discussed, but never perceived that the pharmacists had safety concerns. Respondent denied making any representations to staff that the Board had given its approval to the immediate use protocols implemented in the pharmacy.

52. Respondent discovered vaccines and medication in the breakroom refrigerator in September 2020. He immediately texted the pharmacy managers and directed them to act. He raised the issue at the next staff huddle, reminding staff that it was inappropriate.

53. Respondent described the many other challenges the hospital organization and pharmacies under his management were facing in 2020, during the COVID-19 pandemic, including loss of revenue at the onset of the pandemic when patients delayed medical procedures, persistent staff shortages, severe wildfires, supply shortages, an increase in hospitalizations when COVID-19 cases surged,

implementation of new therapies as COVID-19 treatment practices evolved, and preparation for arrival of the COVID-19 vaccines.

54. Respondent resigned his employment as Area Director in March 2021. He is now living in Nevada and again working for a group purchasing organization. In this role, respondent is not directly involved in practicing pharmacy and does not supervise any pharmacists.

RESPONDENT'S EXPERT, RAFFI SIMONIAN, PHARM.D.

55. Respondent retained Raffi Simonian, Pharm.D., as an expert witness. Simonian reviewed the investigation report and other documents, wrote a letter with his findings, and testified at the hearing. Prior to being hired by respondent, Simonian was retained by Witherspoon in connection to the allegations against her and had conversations with her.

56. Simonian has been a licensed pharmacist since 1979. His long and distinguished career includes academic positions at University of California, San Diego and UCSF. He performed clinical work throughout his career, including sterile compounding. He served as Director of Pharmacy with PIC responsibilities for multiple pharmacies. Simonian served on the Board from 1991 to 1998, including one year as president.

Simonian is now a consultant. He assists pharmacy clients with compliance and serves as an expert witness in civil cases and discipline matters. He serves as practice monitor for a client on Board probation.

57. Simonian does not believe that respondent violated any pharmacy laws or regulations. He explained that the PIC is the individual responsible by statute for

compliance, and that the individual pharmacists are also responsible for compliance regarding their own actions. Simonian believes that a manager such as respondent, if not actively engaged in compounding and not actively managing pharmacy staff, is not expected to have detailed knowledge of USP and regulations.

Simonian believes respondent appropriately used his training, education, and experience by delegating authority over the response to the leak to the PIC and not undermining her authority. Simonian views respondent's role as supporting the PIC and helping when requested. He does not believe respondent had an obligation to intervene, and was not even required to attend Board inspections.

58. Simonian agreed that Saad's old office was not a desirable location for sterile compounding, but might have been the only option. The pharmacy was obligated to perform immediate use compounding to serve the needs of the patients, and if there was no other space available, it would have been appropriate to use Saad's old office. Simonian acknowledged that there were items that could have been easily removed to improve the space, and that it would have been a good idea to require pharmacy technicians to garb and sterilize surfaces when using that space for compounding.

Ultimate Findings

59. Clear and convincing evidence established that numerous violations of the Board's regulations regarding sterile compounding took place at PSRMH over an extended period of time while respondent served as Area Director. From November 30 through December 14, 2020, sterile compounding was performed in circumstances that exceeded the immediate use regulation and incomplete compounding logs were maintained.

60. Respondent was aware that the normal sterile compounding room was unusable for many months following a leak in June, and that immediate use compounding was being performed in a small office space. He was frequently onsite and attended staff huddles where concerns were raised by the pharmacists. Respondent did not research the law or reach out to the Board to confirm that the immediate use compounding practices implemented by Witherspoon were lawful, instead relying on her to ensure compliance.

61. The opinions of the Board's inspectors that, under these circumstances, respondent had an obligation to confirm that the pharmacy and its pharmacists were adhering to the law and that his failure to do more to prevent the violations from occurring assisted and abetted their occurrence and constituted an inappropriate exercise of his education, training, and experience were more persuasive than the opinions of Dr. Simonian that he had no such obligation and appropriately exercised his education, training, and experience.

62. Accordingly, clear and convincing evidence established that respondent assisted and abetted violations of pharmacy law and inappropriately exercised his education, training, and experience in connection to the sterile compounding performed at the PSRMH pharmacy.

63. The evidence established that respondent acted quickly when he discovered that vaccines and medications were improperly stored. Respondent did not aid or assist violations of pharmacy law or inappropriately exercise his education, training, and experience in connection to the improper storage of vaccines and medications at the PSRMH pharmacy.

Costs

64. Complainant submitted declarations certifying $57,247.75 in costs for the investigation and enforcement of this matter as to all four respondents. The parties agreed that it is appropriate to attribute approximately 20 percent of the total costs towards respondent. Accordingly, complainant is seeking a cost recovery award of $11,373.60 against respondent, and the parties stipulate that this is a reasonable sum.

LEGAL CONCLUSIONS

1. It is complainant's burden to demonstrate the truth of the allegations by "clear and convincing evidence to a reasonable certainty," and that the allegations constitute cause for discipline of respondent's license. (*Sternberg v. California State Board of Pharmacy* (2015) 239 Cal.App.4th 1159, 1171; *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.)

Sixth Cause for Discipline[4]

2. Business and Professions Code section 4301, subdivision (o), provides that the Board may discipline a licensee for unprofessional conduct, including assisting in or abetting the violation of federal and state laws and regulations governing pharmacy. Cause for discipline was established, in light of the matters set forth in Factual Finding 62.

[4] The first five causes for discipline in the second amended accusation relate to the other respondents, as do the eighth and ninth causes for discipline.

Seventh Cause for Discipline

3. Business and Professions Code sections 4301, subdivision (o), and 4306.5, subdivision (a), provide that the Board may discipline a licensee for unprofessional conduct due to acts or omissions by the licensee that involve an inappropriate exercise of the licensee's education, training, or experience as a pharmacist, including acts and omissions that arise in the management, administration, or operation of a pharmacy. Cause for discipline was established, in light of the matters set forth in Factual Finding 62.

Determination of Discipline

4. Business and Professions Code section 4001.1 provides that in exercising its disciplinary function, protection of the public is the Board's highest priority.

5. To aid in the determination of discipline, the Board has issued a manual of disciplinary guidelines. The factors relevant to this matter are: 1) actual or potential harm to the public; 2) actual or potential harm to any consumer; 3) prior disciplinary record; 4) prior warnings (including citations, letters of admonishment, and correction notices); 5) number and/or variety of current violations; 6) nature and severity of the acts under consideration; 7) aggravating evidence; 8) mitigating evidence; 9) rehabilitation evidence; 10) time passed since the acts; 11) whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct; and 12) financial benefit to the respondent from the misconduct.

6. This case involves repeated violations of sterile compounding regulations taking place in late 2020. The practices at the PSRMH pharmacy presented a potential

risk of serious harm to patients, although fortunately there is no evidence of actual harm. There was no evidence that respondent intended for the violations to occur or knowingly participated in them. Respondent did not benefit financially from the violations. Respondent has been a licensed pharmacist for more than 30 years. He received one citation (for conduct unrelated to these allegations), which has been paid, and no prior Board discipline.

In mitigation, respondent credibly testified as to the significant operational challenges he faced as Area Director of Pharmacy during the time in question and his reliance on others with more experience in sterile compounding. Under these circumstances, a public reproval of respondent's license will suffice to protect the public.

7. Business and Professions Code section 125.3 authorizes the Board to recover its reasonable costs of investigation and enforcement from a licensee who has been found to have violated the licensing law. In *Zuckerman v. Board of Chiropractic Examiners* (2002) 29 Cal.4th 32, the California Supreme Court set forth standards by which a licensing board must exercise its discretion to reduce or eliminate cost awards to ensure that licensees with potentially meritorious claims are not deterred from exercising their right to an administrative hearing. Those standards include whether the licensee has been successful at hearing in getting the charges dismissed or reduced, the licensee's good faith belief in the merits of his or her position, whether the licensee has raised a colorable challenge to the proposed discipline, the financial ability of the licensee to pay, and whether the scope of the investigation was appropriate to the alleged misconduct. Respondent had a good faith belief in the merits of his position and successfully reduced the discipline imposed from

complainant's request for license revocation. Accordingly, a significant reduction in costs is warranted. Respondent will be ordered to pay costs in the amount of $2,000.

ORDER

1. It is hereby ordered that a public reproval be issued against licensee Blaine Scot Guinn, Registered Pharmacist License No. RPH 42192. Respondent is required to report this reproval as a disciplinary action.

2. Respondent shall pay to the Board its costs of investigation and prosecution in the amount of $2,000.

DATE: 06/21/2023

Karen Reichmann

KAREN REICHMANN
Administrative Law Judge
Office of Administrative Hearings

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Second Amended Accusation Against: **PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL** **1165 Montgomery Drive** **Santa Rosa, CA 95405** **Pharmacy Permit No. HSP 55890** **Sterile Compounding License No. LSC 101129** **LEIGH ANN WITHERSPOON** **1367 Holly Park Way** **Santa Rosa, CA 95403** **Registered Pharmacist License No. RPH 72914** **BLAINE SCOT GUINN** **2235 Keever Court** **Reno, NV 89509** **Registered Pharmacist License No. RPH 42192**	Case No. 7137 **SECOND AMENDED ACCUSATION** **(AS TO RESPONDENT GUINN ONLY)**

HENRY MAUHANG CHAN
19 Burlwood Dr.
San Francisco, CA 94127

Registered Pharmacist License No. RPH 53602

Respondents.

PARTIES

1. Anne Sodergren (Complainant) brings this Second Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about August 31, 1988, the Board of Pharmacy issued Original Pharmacist License Number RPH 42192 to Blaine Scot Guinn (Respondent Guinn). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and will expire on May 31, 2024, unless renewed.

3. On or about April 1, 2018, the Board of Pharmacy issued Original Permit Number HSP 55890 to Providence Santa Rosa Memorial Hospital (Respondent Providence). The Original Permit was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and will expire on April 1, 2022, unless renewed.

4. On or about August 14, 2015, the Board of Pharmacy issued Original Pharmacist License Number RPH 72914 to Leigh Ann Witherspoon (Respondent Witherspoon). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and will expire on March 31, 2023, unless renewed.

5. On or about August 23, 2002, the Board of Pharmacy issued Registered Pharmacist License Number RPH 53602 to Henry Mauhang Chan (Respondent Chan). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought in this Second Amended Accusation and will expire on September 30, 2022, unless renewed.[1]

[1] All parties with the exception of Respondent Guinn reached a settlement agreement with the Board prior to the filing of this Second Amended Accusation.

JURISDICTION

6. This Second Amended Accusation as to Respondent Guinn only is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

7. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

8. Section 4300, subdivision (a), of the Code provides that every license issued by the Board may be suspended or revoked.

9. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

10. Section 4342 of the Code states in relevant part:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

STATUTORY PROVISIONS

11. Section 4301 of the Code states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:
>
> . . .

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs

. . .

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

12. Code section 4306.5, subdivision (a), states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

. . .

13. Section 4113, subdivision (c) of the Code states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

14. Code section 4307 states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

REGULATORY PROVISIONS

15. California Code of Regulations, title 16, section 1714 states:

(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and Professions Code section 4029 which solely or predominantly furnish drugs to inpatients of the hospital) shall contain an area which is suitable for confidential patient counseling.

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

(e) The pharmacy owner, the building owner or manager, or a family member of a pharmacist owner (but not more than one of the aforementioned) may possess a key to the pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that the pharmacist may readily determine whether the key has been removed from the container.

(f) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.

16. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.
(2) A compounding log consisting of a single document containing all of the following:
(A) Name and Strength of the compounded drug preparation.
(B) The date the drug preparation was compounded.
(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.
(D) The identity of the pharmacist reviewing the final drug preparation.
(E) The quantity of each ingredient used in compounding the drug preparation.
(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

17. California Code of Regulations, title 16, section 1751.8 states, in pertinent part:

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and
(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation 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 compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

COST RECOVERY

18. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTUAL ALLEGATIONS

19. At all times relevant to the charges brought in this Second Amended Accusation with respect to Respondent Guinn, Respondent Guinn served as the Pharmacy Director at Providence.

July 2020 Inspection

20. On July 1, 2020, Board inspector SH conducted an inspection at Respondent Providence. The inspection was pursuant to a recent plumbing leak in the ante room of the pharmacy on June 11, 2020. SH was assisted by Respondent Guinn and Pharmacist-in-Charge (PIC) Respondent Witherspoon. During the inspection, SH discussed California Code of Regulations, section 1751.8, subdivision (e), regarding "immediate use" compounding for

emergencies only with Respondent Witherspoon and Respondent Guinn. SH explained that documentation is required if compounding any compounded sterile preparation in the sterile compounding area, and that the documentation must include the circumstance and reason for the urgency of the compounded sterile preparation.

December 2020 Inspection

21. On December 3, 2020, the Board received a complaint against Respondent Providence alleging that there were serious regulatory violations and unsafe practices occurring at Respondent Providence for the past several months. According to the complainant, staff at Respondent Providence voiced their concerns to Respondent Witherspoon, but she dismissed the concerns. The complainant later submitted photographs of a staff break room refrigerator where vaccines and antibiotics were improperly stored.

22. On December 15, 2020, the Board received an email from DD, a pharmacist and pharmaceutical consultant for the California Department of Public Health (CDPH). DD reported that she was at Respondent Providence on December 14, 2020, and she found the IV room blocked off for construction. IV rooms, often used in hospital and pharmacy applications, are a place for the sterile preparation of medications. DD observed a pharmacy technician preparing immediate use compounded sterile products (CSP) for first doses and emergency doses on a countertop in a room within the pharmacy. A one-hour beyond-use date (BUD) was hand-written on the prescription label, and a green auxiliary sticker was affixed to the medication indicating to hang the product within one hour. DD was told that this immediate use room was set-up on November 30, 2020, and that the Board had approved the set-up.

23. On December 15, 2020, Board inspector SH went to Respondent Providence to conduct a routine partial inspection. SH was assisted by Respondent Witherspoon and Respondent Guinn. The inspector observed and took pictures of various parts of the pharmacy, including the part of the pharmacy intended as the Segregated Compounding Area (SCA). The SCA was a carpeted office room adjacent to the pharmacy. A cork bulletin board was above the compounding tray, printers which generated labels were near the compounding tray, non-sterile

gloves were available, CSP's were placed on a non-sterile pad, and the ceiling tiles were made of a porous material.

24. During the inspection, SH also reviewed CSP compounding records from November 30, 2020, to December 15, 2020. SH reminded Respondents Witherspoon and Guinn of a conversation they had during the inspection on July 1, 2020, regarding the Board regulation concerning any sterile compounded drug preparation compounded either outside of an ISO class 5 Primary Engineering Control, or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d) of California Code of Regulations, title 16, section 1751.8. An ISO 5 is a cleanroom classification. Pursuant to California Code of Regulations, title 16, section 1735.1, subdivision (ab), "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators. SH found that Respondent Providence's compounding records lacked detailed documentation to support immediate use compounding in at least 593 instances between November 30, 2020, and December 13, 2020.

November 2021 Inspection

25. On November 17, 2021, Board inspector SH conducted a partial inspection at Respondent Providence after the Board received an anonymous complaint that Respondent Providence was compounding batches of non-patient specific epidural syringes. Respondent Providence had a segregated compounding area/room where it was capable of compounding low risk compounded sterile products and a maximum 12 hour beyond use date. Pharmacist-in-Charge, Respondent Chan, assisted inspector SH as he inspected the area. Respondent Chan explained that the hospital could no longer buy fentanyl/bupivacaine from its former supplier, thus staff were instructed to compound three syringes of fentanyl/bupivacaine/sodium chloride syringes for epidural injection twice daily for the Labor and Delivery (L&D) department. The Board's inspection revealed that Respondent Providence was anticipatorily compounding and

then storing the epidural syringes, which were non-patient specific, in the pharmacy refrigerator. The pharmacy would transport the syringes to the L&D floor within fifteen minutes of a request for one by the L&D department. Before a syringe was transported to L&D, the pharmacy staff would create a patient-specific label and affix it to the syringe. The pharmacy wasted the syringes that were not used after 12 hours of being compounded.

FIRST CAUSE FOR DISCIPLINE

(Immediate Use Compounding Not Used in Limited Situations)

26. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1751.8. "Immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment, and where failure to administer could result in loss of life or intense suffering. Specifically, between November 30, 2020, and December 13, 2020, Respondent Providence compounded at least 593 "immediate use" sterile preparations outside of an ISO Class 5 PEC without meeting the circumstances to justify an immediate need in these 593 instances. The circumstances are set forth in further detail in paragraphs 19 through 24, above.

SECOND CAUSE FOR DISCIPLINE

(Incomplete Compounding Log Documentation)

27. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(H). Specifically, between November 30, 2020, and December 13, 2020, at least 593 of Respondent Providence's compounding logs

lacked complete documentation of the beyond use date and time of the final compounded drug preparation. The circumstances are set forth in further detail in paragraphs 19 through 24, above.

THIRD CAUSE FOR DISCIPLINE

(Final Quantity of Drug Not Present)

28. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(I). Specifically, between at least November 30, 2020, and December 13, 2020, compounding logs for at least 593 drug preparations lacked documentation of the final quantity or amount of drug preparation compounded for dispensing. The circumstances are set forth in further detail in paragraphs 19 through 24, above.

FOURTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Log Documentation)

29. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(J). Specifically, between at least November 30, 2020, and December 13, 2020, compounding logs for at least 593 compounded drug preparations lacked documentation of quality reviews and post-compounding process and procedures. The circumstances are set forth in further detail in paragraphs 19 through 24, above.

FIFTH CAUSE FOR DISCIPLINE

(Operational Standards and Security)

30. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113,

subdivision (c), in that Respondent Providence failed to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured, and distributed in accordance with California Code of Regulations, title 16, section 1714, subdivision (b). Specifically, between at least September 21, 2020, and November 1, 2020, Respondent Providence was not properly monitoring medication storage refrigerator temperatures appropriately. The refrigerator also contained improperly stored food items with medications during this time period. The circumstances are set forth in further detail in paragraphs 19 through 24, above.

SIXTH CAUSE FOR DISCIPLINE

(Aiding and Abetting Violations of Pharmacy Law)

31. Respondent Witherspoon and Respondent Guinn have subjected their Original Pharmacist Licenses to discipline under Code section 4301, subdivision (o), in that they aided and abetted the violation of the Board's regulations governing pharmacy law. Specifically, between at least November 30, 2020, and December 13, 2020, Respondent Witherspoon, as Pharmacist-in-Charge, and Respondent Guinn, as pharmacy director of Respondent Providence, aided and abetted Respondent Providence and several of the pharmacists employed at Respondent Providence in violating California Code of Regulations, title 16, sections 1751.8, subdivision (e), 1714, subdivision (b), and 1735.3, subdivisions (a)(2)(H), (I), and (J), as more fully set forth in paragraphs 19 through 30, above.

SEVENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education, Training, or Experience as a Pharmacist)

32. Respondent Guinn has subjected his Pharmacist License to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivision (a), by his inappropriate exercise of his pharmacist education, training, or experience, as set forth in paragraphs 19 through 30, above.

EIGHTH CAUSE FOR DISCIPLINE

(Sterile Compounded Drug Preparations)

33. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Chan has subjected his Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1751.8, subdivision (d)(1)-(3). Specifically, on November 17, 2021, Respondent Providence compounded fentanyl/bupivacaine/sodium chloride syringes for epidural injection. This compounded sterile product required three entries to the administration syringe. Pharmacy law does not allow more than two entries into any one container or package of sterile infusion solution or administration container or device. These allegations are fully set forth in paragraph 25, above.

NINTH CAUSE FOR DISCIPLINE

(Incomplete Compounding Log)

34. Respondent Providence has subjected its Original Permit and its Sterile Compounding License to disciplinary action and Respondent Chan has subjected his Original Pharmacist License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, subdivision (c), in that Respondent Providence compounded drugs in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(G). Specifically, on November 14, 2021, and November 15, 2021, Respondent Providence compounded non-patient specific fentanyl/bupivacaine/sodium chloride syringes for epidural injection and used the date as the reference number rather than a pharmacy-assigned unique reference or lot number. These allegations are fully set forth in paragraph 25, above.

OTHER MATTERS

35. Pursuant to section 4307 of the Code, if discipline is imposed on Original Permit Number HSP 55890 or on Sterile Compounding License Number LSC 101129, then any person who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or

association which received this discipline or denial, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control, had knowledge of or knowingly participated in any conduct leading to discipline or denial, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for: five years if Original Permit Number HSP 55890 or Sterile Compounding License Number LSC 101129 is placed on probation or until any license revoked or denied is issued or reinstated.

36. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacist License Number RPH 72914, issued to Leigh Ann Witherspoon, Original Pharmacist License Number RPH 42192, issued to Blaine Scot Guinn, or Original Pharmacist License Number RPH 53602, issued to Henry Mauhang Chan, then the licensee so disciplined shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for: five years if the license is placed on probation; or if the license is revoked, until it is reinstated or reissued.

DISCIPLINARY CONSIDERATIONS

37. To determine the degree of discipline, if any, to be imposed on Respondent Guinn, Complainant alleges that on July 3, 2020, the Board issued Citation No. CI 2019 88576 to Respondent Guinn based upon his conviction of a crime substantially related to the practice of pharmacy (Bus. & Prof. Code, § 4301, subd. (l)), and his self-administration of a dangerous drug, controlled substance, or alcohol in a manner injurious to himself. (Bus. & Prof. Code, § 4301, subd. (h).) The citation assessed a civil penalty of $400.00. That Citation is incorporated by reference and is now final.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Second Amended Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Pharmacist License Number RPH 42192, issued to Blaine Scot Guinn;

2. Ordering Blaine Scott Guinn to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

3. Taking such other and further action as deemed necessary and proper.

DATED: 4/16/2023

Sodergren, Anne@DCA Digitally signed by Sodergren, Anne@DCA Date: 2023.04.16 20:21:12 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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