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

In the Matter of the First 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 AS TO LEIGH ANN WITHERSPOON ONLY (CASE NO. 7137) PAGE 1

## **DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order 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.

By

It is so ORDERED on July 26, 2023.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

eun

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA	
2	Attorney General of California DIANN SOKOLOFF	
3	Supervising Deputy Attorney General SUSANA A. GONZALES	
4	Deputy Attorney General State Bar No. 253027	
5	1515 Clay Street, 20th Floor P.O. Box 70550	
6	Oakland, CA 94612-0550 Telephone: (510) 879-0266	
7	Facsimile: (510) 622-2270 Attorneys for Complainant	
8		
9	BEFOR BOARD OF F	
10	DEPARTMENT OF CONTROL OF	
11		
12	In the Matter of the First Amended Accusation	
13	Against:	Case No. 7137
14	PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL	OAH No. 2022100700
15	1165 Montgomery Drive Santa Rosa, CA 95405	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO
16	Pharmacy Permit No. HSP 55890	<b>RESPONDENT WITHERSPOON ONLY</b>
17 18	Sterile Compounding License No. LSC 101129	
19	LEIGH ANN WITHERSPOON	
20	1367 Holly Park Way Santa Rosa, CA 95403	
21	Registered Pharmacist License No. RPH 72914	
22	BLAINE SCOT GUINN	
23	2235 Keever Court Reno, NV 89509	
24	Registered Pharmacist License No. RPH	
25	42192	
26		
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	STIPULATED SETTLEN	MENT RESPONDENT WITHERSPOON ONLY (7137)

1 2 3	HENRY MAUHANG CHAN 19 Burlwood Dr. San Francisco, CA 94127		
4	Registered Pharmacist License No. RPH 53602		
5 6 7	Respondents.		
8 9 10 11	IT IS HEREBY STIPULATED AND AGREED by and between the parties listed below that the following matters are true: <u>PARTIES</u> 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Susana A. Gonzales, Deputy Attorney General.		
12 13 14 15			
13 16 17 18	<ol> <li>Respondent Leigh Ann Witherspoon (Respondent Witherspoon) is represented in this proceeding by attorney Kevin T. Dunbar, whose address is: 100 Oceangate, Suite 640, Long Beach, CA 90802-4373.</li> </ol>		
19 20 21	3. 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 in Accusation No. 7137, and will expire on March 31, 2025, unless renewed.		
22	JURISDICTION		
<ul> <li>23</li> <li>24</li> <li>25</li> <li>26</li> <li>27</li> <li>28</li> </ul>	4. First Amended Accusation No. 7137 was filed before the Board, and is currently pending against Respondent Witherspoon. The Accusation and all other statutorily required documents were properly served on Respondent Witherspoon on August 23, 2021. The First Amended Accusation and all other statutorily required documents were served on Respondent		
_~	2 STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)		

1	Witherspoon on June 23, 2022. Respondent timely filed her Notice of Defense contesting the		
2	Accusation.		
3	5. A copy of First Amended Accusation No. 7137 is attached as exhibit A and		
4	incorporated by reference.		
5	ADVISEMENT AND WAIVERS		
6	6. Respondent Witherspoon has carefully read, fully discussed with her counsel, and		
7	understands the charges and allegations in Accusation No. 7137. Respondent Witherspoon has		
8	also carefully read, fully discussed with counsel, and understands the effects of this Stipulated		
9	Settlement and Disciplinary Order.		
10	7. Respondent Witherspoon is fully aware of her legal rights in this matter, including the		
11	right to a hearing on the charges and allegations in the First Amended Accusation; the right to		
12	confront and cross-examine the witnesses against her; the right to present evidence and to testify		
13	on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses		
14	and the production of documents; the right to reconsideration and court review of an adverse		
15	decision; and all other rights accorded by the California Administrative Procedure Act and other		
16	applicable laws.		
17	8. Respondent Witherspoon voluntarily, knowingly, and intelligently waives and gives		
18	up each and every right set forth above.		
19	<u>CULPABILITY</u>		
20	9. Respondent Witherspoon admits the truth of each and every charge and allegation in		
21	Accusation No. 7137.		
22	10. Respondent Witherspoon agrees that her Original Pharmacist License Number RPH		
23	72914 is subject to discipline and she agrees to be bound by the Board's probationary terms as set		
24	forth in the Disciplinary Order below.		
25	<u>CONTINGENCY</u>		
26	11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent		
27	Witherspoon understands and agrees that counsel for Complainant and the staff of the Board of		
28	Pharmacy may communicate directly with the Board regarding this stipulation and settlement,		
	3		
	STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)		

without notice to or participation by Respondent Witherspoon or her counsel. By signing the 1 2 stipulation, Respondent Witherspoon understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. 3 If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and 4 5 Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action 6 7 by having considered this matter.

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The parties understand and agree that Portable Document Format (PDF) and facsimile 12. 9 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals. 10

13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an 11 integrated writing representing the complete, final, and exclusive embodiment of their agreement. 12 It supersedes any and all prior or contemporaneous agreements, understandings, discussions, 13 14 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a 15 writing executed by an authorized representative of each of the parties. 16

14. In consideration of the foregoing admissions and stipulations, the parties agree that 17 the Board may, without further notice or formal proceeding, issue and enter the following 18 Disciplinary Order: 19

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### **DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Original Pharmacist License Number RPH 72914 issued 21 to Respondent Leigh Ann Witherspoon is revoked. However, the revocation is stayed and 22 Respondent Witherspoon is placed on probation for two (2) years on the following terms and 23 24 conditions:

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### **Obey All Laws**

1.

Respondent Witherspoon shall obey all state and federal laws and regulations. Respondent Witherspoon shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

1	• an arrest or issuance of a criminal complaint for violation of any provision of the		
2	Pharmacy Law, state and federal food and drug laws, or state and federal controlled		
3	substances laws		
4	• a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal		
5	criminal proceeding to any criminal complaint, information or indictment		
6	• a conviction of any crime		
7	• the filing of a disciplinary pleading, issuance of a citation, or initiation of another		
8	administrative action filed by any state or federal agency which involves		
9	respondent's license or which is related to the practice of pharmacy or the		
10	manufacturing, obtaining, handling, distributing, billing, or charging for any drug,		
11	device or controlled substance.		
12	Failure to timely report such occurrence shall be considered a violation of probation. 2. <b>Report to the Board</b>		
13	Respondent Witherspoon shall report to the board quarterly, on a schedule as directed by		
14	the board or its designee. The report shall be made either in person or in writing, as directed.		
15	Among other requirements, respondent shall state in each report under penalty of perjury whether		
16	there has been compliance with all the terms and conditions of probation.		
17	Failure to submit timely reports in a form as directed shall be considered a violation of		
18	probation. Any period(s) of delinquency in submission of reports as directed may be added to the		
19 20	total period of probation. Moreover, if the final probation report is not made as directed,		
20	probation shall be automatically extended until such time as the final report is made and accepted		
21 22	by the board. 3. Interview with the Board		
23	Upon receipt of reasonable prior notice, respondent Witherspoon shall appear in person for		
24	interviews with the board or its designee, at such intervals and locations as are determined by the		
25	board or its designee. Failure to appear for any scheduled interview without prior notification to		
26	board staff, or failure to appear for two (2) or more scheduled interviews with the board or its		
27	designee during the period of probation, shall be considered a violation of probation.		
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	STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)		

#### Cooperate with Board Staff 4.

1	4. Cooperate with Board Staff
2	Respondent Witherspoon shall timely cooperate with the board's inspection program and
	with the board's monitoring and investigation of respondent's compliance with the terms and
3	conditions of probation, including but not limited to: timely responses to requests for information
4	by board staff; timely compliance with directives from board staff regarding requirements of any
5	term or condition of probation; and timely completion of documentation pertaining to a term or
6 7	<ul> <li>condition of probation. Failure to timely cooperate shall be considered a violation of probation.</li> <li>5. Continuing Education</li> </ul>
8	Respondent Witherspoon shall provide evidence of efforts to maintain skill and knowledge
9	<ul> <li>as a pharmacist as directed by the board or its designee.</li> <li>6. Reporting of Employment and Notice to Employers</li> </ul>
10	During the period of probation, respondent Witherspoon shall notify all present and
11	prospective employers of the decision in case number 7137 and the terms, conditions and
12	restrictions imposed on respondent by the decision, as follows:
13	Within thirty (30) days of the effective date of this decision, and within ten (10) days of
14	undertaking any new employment, respondent Witherspoon shall report to the board in writing
15	the name, physical address, and mailing address of each of Respondent Witherspoon's
16	employer(s), and the name(s) and telephone number(s) of all of Respondent Witherspoon's direct
17	supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge,
18	responsible manager, or other compliance supervisor(s) and the work schedule, if known.
19	Respondent Witherspoon shall also include the reason(s) for leaving the prior employment.
20	Respondent Witherspoon shall sign and return to the board a written consent authorizing the
21	board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and
22 23	authorizing those employer(s) or supervisor(s) to communicate with the board or its designee,
	concerning respondent's work status, performance, and monitoring. Failure to comply with the
24	requirements or deadlines of this condition shall be considered a violation of probation.
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26	Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
27	respondent undertaking any new employment, respondent shall cause (a) direct supervisor, (b)
28	pharmacist-in-charge, designated representative-in-charge, responsible manager, or other
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compliance supervisor, and (c) the owner or owner representative of her employer, to report to the 1 2 board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7137, and terms and conditions imposed thereby. If one person serves in more than one 3 role described in (a), (b), or (c), the acknowledgment shall so state. It shall be respondent 4 5 Witherspoon's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) 6 during the term of probation, respondent shall cause the person(s) taking over the role(s) to report 7 to the board in writing within fifteen (15) days of the change acknowledging that he or she has 8 9 read the decision in case number 7137, and the terms and conditions imposed thereby.

If respondent Witherspoon works for or is employed by or through an employment service,
respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed
by the board of the decision in case number 7137, and the terms and conditions imposed thereby
in advance of respondent commencing work at such licensed entity. A record of this notification
must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent Witherspoon undertaking any new employment by or through an employment service, respondent Witherspoon shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

25 "Employment" within the meaning of this provision includes any full-time, part-time,
26 temporary, relief, or employment/management service position as a Pharmacist, or any position
27 for which a Pharmacist is a requirement or criterion for employment, whether the respondent is an
28 employee, independent contractor or volunteer.

1	7. Notification of Change(s) in Name, Address(es), or Phone Number(s)		
2	Respondent Witherspoon shall further notify the board in writing within ten (10) days of		
	any change in name, residence address, mailing address, e-mail address or phone number.		
3	Failure to timely notify the board of any change in employer, name, address, or phone		
4 5	number shall be considered a violation of probation. 8. <b>Restrictions on Supervision and Oversight of Licensed Facilities</b>		
6	During the period of probation, respondent Witherspoon shall not supervise any intern		
7	pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible		
8	manager or other compliance supervisor of any entity licensed by the board, nor serve as a		
9	consultant. Assumption of any such unauthorized supervision responsibilities shall be considered		
10	a violation of probation. 9. <b>Reimbursement of Board Costs</b>		
11	As a condition precedent to successful completion of probation, respondent Witherspoon		
12	shall pay to the board its costs of investigation and prosecution in the amount of \$2,564.27.		
13	Respondent Witherspoon shall make said payments as follows:		
14	There shall be no deviation from this schedule absent prior written approval by the board or		
15	its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of		
16	probation.		
17	Respondent Witherspoon shall be permitted to pay these costs in a payment plan approved		
18	by the board or its designee, so long as full payment is completed no later than one (1) year prior		
19	to the end date of probation.		
20	10. Probation Monitoring Costs		
21	Respondent Witherspoon shall pay any costs associated with probation monitoring as		
22	determined by the board each and every year of probation. Such costs shall be payable to the		
23	board on a schedule as directed by the board or its designee. Failure to pay such costs by the		
24	deadline(s) as directed shall be considered a violation of probation.		
25	11. Status of License Respondent Witherspeen shall at all times while on probation maintain an active surrent		
26	Respondent Witherspoon shall, at all times while on probation, maintain an active, current		
27	Registered Pharmacist License with the board, including any period during which suspension or		
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	STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)		

probation is tolled. Failure to maintain an active, current Registered Pharmacist License shall be 2 considered a violation of probation.

If respondent Witherspoon's Registered Pharmacist License expires or is cancelled by 3 operation of law or otherwise at any time during the period of probation, including any extensions 4 5 thereof due to tolling or otherwise, upon renewal or reapplication respondent Witherspoon's license shall be subject to all terms and conditions of this probation not previously satisfied. 6 12. **License Surrender While on Probation/Suspension** 

Following the effective date of this decision, should respondent Witherspoon cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent Witherspoon may relinquish her Registered Pharmacist License, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

16 Upon acceptance of the surrender, respondent Witherspoon shall relinquish her Registered 17 Pharmacist pocket and/or wall license, including any indicia of licensure not previously provided 18 to the board within ten (10) days of notification by the board that the surrender is accepted if not 19 already provided. Respondent Witherspoon may not reapply for any license from the board for 20 three (3) years from the effective date of the surrender. Respondent Witherspoon shall meet all 21 requirements applicable to the license sought as of the date the application for that license is 22 submitted to the board, including any outstanding costs.

#### **Practice Requirement** 13.

24 Except during periods of suspension, respondent Witherspoon shall, at all times while on probation, be employed as a Pharmacist in California for a minimum of 100 hours per calendar 25 month. Any month during which this minimum is not met shall extend the period of probation by 26 one month. During any such period of insufficient employment, respondent Witherspoon must 27

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nonetheless comply with all terms and conditions of probation, unless respondent receives a waiver in writing from the board or its designee.

3	If respondent Witherspoon does not practice as a Pharmacist in California for the minimum	
4	number of hours in any calendar month, for any reason (including vacation), respondent shall	
5	notify the board in writing within ten (10) days of the conclusion of that calendar month. This	
6	notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s)	
7	for the interruption or reduction in practice; and the anticipated date(s) on which respondent will	
8	resume practice at the required level. Respondent Witherspoon shall further notify the board in	
9	writing within ten (10) days following the next calendar month during which respondent practices	
10	as a Pharmacist in California for the minimum of hours. Any failure to timely provide such	
11	notification(s) shall be considered a violation of probation.	

It is a violation of probation for respondent Witherspoon's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and nonconsecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

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### Violation of Probation

If respondent Witherspoon has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and the board shall provide notice to respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If respondent Witherspoon violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing

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1	jurisdiction and the period of probation shall be automatically extended until the petition to	
2	revoke probation or accusation is heard and decided. 15. <b>Completion of Probation</b>	
	3 Upon written notice by the board or its designee indicating successful completion of	
4 5	probation, respondent Witherspoon's Registered Pharmacist license will be fully restored. 16. <b>Remedial Education</b>	
6	Within 90 days of the effective date of this decision, respondent shall submit to the board or	
7	its designee, for prior approval, an appropriate program of remedial education related to USP 797.	
8	The program of remedial education shall consist of at least 10 hours, which shall be completed	
9	within 6 months at respondent's own expense, 50% of which must be live webinar or in-person	
10	instruction. All remedial education shall be in addition to, and shall not be credited toward,	
11	continuing education (CE) courses used for license renewal purposes for pharmacists.	
12	Failure to timely submit for approval or complete the approved remedial education shall be	
13	considered a violation of probation. The period of probation will be automatically extended until	
14	such remedial education is successfully completed and written proof, in a form acceptable to the	
15	board, is provided to the board or its designee.	
16	Following the completion of each course, the board or its designee may require the	
17	respondent, at respondent's own expense, to take an approved examination to test the	
18	respondent's knowledge of the course. If the respondent does not achieve a passing score on the	
19	examination that course shall not count towards satisfaction of this term. Respondent shall take	
20	another course approved by the board in the same subject area. 17. Ethics Course	
21	Within sixty (60) calendar days of the effective date of this decision, respondent	
22	Witherspoon shall enroll in a course in ethics, at her expense, approved in advance by the Board	
23	or its designee that complies with Title 16 California Code of Regulations section 1773.5.	
24	Respondent Witherspoon shall provide proof of enrollment upon request. Within five (5) days of	
25 26	completion, respondent Witherspoon shall submit a copy of the certificate of completion to the	
26 27	Board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course	
27 28	during the first year of probation, to successfully complete it before the end of the second year of	
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	STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)	

1	probation, or to timely submit proof of completion to the board or its designee, shall be		
2	considered a violation of probation. 18. <b>No Ownership or Management of Licensed Premises</b>		
<ul> <li>Respondent shall not own, have any legal or beneficial interest in, nor serve as a ma</li> <li>administrator, member, officer, director, trustee, associate, or partner of any business, firm</li> </ul>			
6	or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90)		
7	days following the effective date of this decision and shall immediately thereafter provide written		
8	proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide		
9	documentation thereof shall be considered a violation of probation.		
10	ACCEPTANCE		
11	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully		
12	discussed it with my attorney, Kevin T. Dunbar. I understand the stipulation and the effect it will		
13	have on my Registered Pharmacist License. I enter into this Stipulated Settlement and		
14	Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the		
15	Decision and Order of the Board of Pharmacy.		
16			
17	DATED:		
18	LEIGH ANN WITHERSPOON		
19	Respondent Witherspoon		
20	I have read and fully discussed with Respondent Leigh Ann Witherspoon the terms and		
21	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.		
22	I approve its form and content.		
23			
24	DATED:		
25	KEVIN T. DUNBAR Attorney for Respondent Witherspoon		
26	Thomey for Respondent Hunderspoon		
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	STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)		

probation, or to timely submit proof of completion to the board or its designee, shall be ١ 2 considered a violation of probation. No Ownership or Management of Licensed Premises 18. 3 Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, 4 administrator, member, officer, director, trustee, associate, or partner of any business, firm, 5 partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell 6 or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) 7 days following the effective date of this decision and shall immediately thereafter provide written 8 proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide 9 documentation thereof shall be considered a violation of probation. 10 ACCEPTANCE 11 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 12 discussed it with my attorney, Kevin T. Dunbar. I understand the stipulation and the effect it will 13 have on my Registered Pharmacist License. I enter into this Stipulated Settlement and 14 Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the 15 Decision and Order of the Board of Pharmacy. 16 17 DATED: 3/23/2 18 ndent Witherspoon 19 20 I have read and fully discussed with Respondent Leigh Ann Witherspoon the terms and 21 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. 22 I approve its form and content. 23 DATED: 3/23/2013 24 DUNBAR 25 KEVIN T. Attorney for Respondent Witherspoon 26 27 28 12 STIPULATED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)

1	<u>ENDORSEMENT</u>	
2	2 The foregoing Stipulated Settlement and Discip	plinary Order is hereby respectfully
3	3 submitted for consideration by the Board of Pharmac	y.
4	4 DATED:	Respectfully submitted,
5	5 DATED.	Rob Bonta
6 7		Attorney General of California DIANN SOKOLOFF
8		Supervising Deputy Attorney General
° 9		
9 10		SUSANA A. GONZALES Deputy Attorney General
10		Deputy Attorney General Attorneys for Complainant
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	STIPULATED SETTLEMEN	T RESPONDENT WITHERSPOON ONLY (7137)

1	<b>ENDORSEMENT</b>	
2	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully	
3	submitted for consideration by the Bo	pard of Pharmacy.
4	DATED: 3/23/2023	Respectfully submitted,
5		- Rob Bonta
6		Attorney General of California DIANN SOKOLOFF
7		Supervising Deputy Attorney General
8		Susana A. Jonzales
9		SUSANA A. GONZALES
10		Deputy Attorney General Attorneys for Complainant
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	STIPULAT	ED SETTLEMENT RESPONDENT WITHERSPOON ONLY (7137)

## Exhibit A

First Amended Accusation No. 7137

1 2 3 4 5 6 7 8 9	ROB BONTA Attorney General of California DIANN SOKOLOFF Supervising Deputy Attorney General SUSANA A. GONZALES Deputy Attorney General State Bar No. 253027 1515 Clay Street, 20th Floor P.O. Box 70550 Oakland, CA 94612-0550 Telephone: (510) 879-0266 Facsimile: (510) 622-2270 Attorneys for Complainant BEFOR BOARD OF HEDEPARTMENT OF COMP	PHARMACY ONSUMER AFFAIRS
11	STATE OF C.	ALIFORNIA
11		
12	In the Matter of the First Amended Accusation Against:	Case No. 7137
14	PROVIDENCE SANTA ROSA	
15	MEMORIAL HOSPITAL 1165 Montgomery Drive Santa Rosa, CA 95405	FIRST AMENDED ACCUSATION
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21	Registered Pharmacist License No. RPH 72914	
22	BLAINE SCOT GUINN	
23	2235 Keever Court Reno, NV 89509	
24 25	Registered Pharmacist License No. RPH 42192	
26 27		
28		1
	(PROVIDENCE SANTA ROSA MEMORI	AL HOSPITAL, BLAINE SCOT GUINN, LEIGH ANN IAUHANG CHAN) FIRST AMENDED ACCUSATION

1 2 3	HENRY MAUHANG CHAN 19 Burlwood Dr. San Francisco, CA 94127			
	Registered Pharmacist License No. RPH			
4	53602			
5	Respondents.			
6				
7	PARTIES			
8	1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her			
9	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer			
10	Affairs.			
11	2. On or about April 4, 2018, the Board of Pharmacy issued Sterile Compounding			
12	License Number LSC 101129 to Providence Santa Rosa Memorial Hospital (Respondents). The Sterile Compounding License expired on October 1, 2020, and has not been renewed.			
13				
14	3. On or about April 1, 2018, the Board of Pharmacy issued Original Permit Number			
15	HSP 55890 to Providence Santa Rosa Memorial Hospital (Respondents). The Original Permit			
16	was in full force and effect at all times relevant to the charges brought in this First Amended			
17	Accusation and will expire on April 1, 2022, unless renewed.			
18	4. On or about August 31, 1988, the Board of Pharmacy issued Original Pharmacist			
19 20	License Number RPH 42192 to Blaine Scot Guinn (Respondents). The Original Pharmacist			
20	License was in full force and effect at all times relevant to the charges brought brought in this			
21	First Amended Accusation and will expire on May 31, 2022, unless renewed.			
22	5. On or about August 14, 2015, the Board of Pharmacy issued Original Pharmacist			
23	License Number RPH 72914 to Leigh Ann Witherspoon (Respondents). The Original Pharmacist			
24	License was in full force and effect at all times relevant to the charges brought brought in this			
25	First Amended Accusation and will expire on March 31, 2023, unless renewed.			
26	6. On or about August 23, 2002, the Board of Pharmacy issued Registered Pharmacist			
<ul> <li>27</li> <li>28</li> <li>28</li> <li>2</li> <li>2</li> </ul>				
			(PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL, BLAINE SCOT GUINN, LEIGH ANN WITHERSPOON, and HENRY MAUHANG CHAN) FIRST AMENDED ACCUSATION	

License was in full force and effect at all times relevant to the charges brought brought in this 1 2 First Amended Accusation and will expire on September 30, 2022, unless renewed. JURISDICTION 3 7. This First Amended Accusation is brought before the Board of Pharmacy (Board), 4 5 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. 6 8. Section 4011 of the Code provides that the Board shall administer and enforce both 7 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances 8 9 Act [Health & Safety Code, § 11000 et seq.]. 9. Section 4300, subdivision (a), of the Code provides that every license issued by the 10 Board may be suspended or revoked. 11 10. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or 12 suspension of a Board-issued license, the placement of a license on a retired status, or the 13 14 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 15 licensee or to render a decision suspending or revoking the license. 16 11. Section 4342 of the Code states in relevant part: 17 "(a) The board may institute any action or actions as may be provided by law and that, in its 18 discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not 19 conform to the standard and tests as to quality and strength, provided in the latest edition of the 20 21 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 22 104 of the Health and Safety Code)." 23 24 /// /// 25 /// 26 /// 27 28 /// 3 (PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL, BLAINE SCOT GUINN, LEIGH ANN

1	STATUTORY PROVISIONS		
2	12. Section 4301 of the Code states, in pertinent part:		
3 4	The board shall take action against any holder of a license who is guilty of		
4 5	unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:		
6			
7	(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		
8			
9 10	(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.		
11	13. Section 4113, subdivision (c) of the Code states:		
12 13	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	14. Section 4307 states:		
15	(a) Any person who has been denied a license or whose license has been revoked or is		
16	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,		
17	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		
18 19	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		
20	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		
21	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:		
22	10110 W 3.		
23	(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.		
24	(2) Where the license is denied or revoked, the prohibition shall continue until the		
25	license is issued or reinstated.		
26	(b) "Manager, administrator, owner, member, officer, director, associate, partner, or		
27	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		
28	in or for a licensee.		
	4		
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1	(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to		
2	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		
3	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		
4	Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed		
5	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.		
6	REGULATORY PROVISIONS		
7	15. California Code of Regulations, title 16, section 1714 states:		
8	(a) All pharmacies (except hospital inpatient pharmacies as defined by Business and		
9	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.		
10	(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures,		
11	and equipment so that drugs are safely and properly prepared, maintained, secured and		
12	distributed. The pharmacy shall be of sufficient size and unobstructed area to accommod the safe practice of pharmacy.		
13	(c) The pharmacy and fixtures and equipment shall be maintained in a clean and		
14 15	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 corrunning water for pharmaceutical purposes.		
16			
17	(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		
18 19	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		
20 21	pharmacist owner (but not more than one of the aforementioned) may possess a key to the		
21 22	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		
22	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		
23	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		
25 26	license to certify that it meets the requirements of this section at the time of licensure or renewal.		
20 27	(g) A pharmacy shall maintain a readily accessible restroom. The restroom shall		
28	contain a toilet and washbasin supplied with running water.		
20	5		
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1	16. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:		
2	(a) For each compounded drug preparation, pharmacy records shall include:		
3	(1) The master formula document.		
4	(2) A compounding log consisting of a single document containing all of the following:		
5	(A) Name and Strength of the compounded drug preparation.		
6	<ul><li>(B) The date the drug preparation was compounded.</li><li>(C) The identity of any pharmacy personnel engaged in compounding the drug</li></ul>		
7	preparation. (D) The identity of the pharmacist reviewing the final drug preparation.		
8	<ul><li>(E) The quantity of each ingredient used in compounding the drug preparation.</li><li>(F) The manufacturer, expiration date and lot number of each component. If the</li></ul>		
9	manufacturer name is demonstrably unavailable, the name of the supplier may be		
10	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		
11	limitations of section 1735.2, subdivision (l) shall apply.		
12	(i) Exempt from the requirements in this paragraph $(1735.3(a)(2)(F))$ are sterile		
13	and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd		
14			
15 16	Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.		
17	(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.		
18	(H) The beyond use date or beyond use date and time of the final compounded drug		
19	preparation, expressed in the compounding document in a standard date and time format.		
20	(I) The final quantity or amount of drug preparation compounded for dispensing.		
21	(J) Documentation of quality reviews and required post-compounding process and procedures.		
22	procedures.		
23	(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in		
24	compounding.		
25	(c) Active ingredients shall be obtained from a supplier registered with the Food and		
26	Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-		
27	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		
28	drug products used in compounding. Certificates of purity or analysis are not required for		
	6		
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I				
1	drug products received			
2				
3	(d) Pharmacies shall maintain and retain all records required by this article in the			
4	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			
5	Professions Code section 4070 subsection (c).			
6	17. California Code of Regulations, title 16, section 1751.8 states, in pertinent part:			
7	In conformity with and in addition to the requirements and limitations of section			
8	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			
9	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			
10 11	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),			
12	hereby incorporated by reference, that would justify an extended beyond use date, conforms			
13	to the following limitations:			
14 15	(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			
16	days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:			
17	(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an			
18	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			
19				
20	(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile			
21	preparations and not more than two entries into any one sterile container or package of			
22	sterile preparations or administration containers/devices to prepare the drug preparation; and			
23	(3) Compounding manipulations are limited to aseptically opening ampules,			
24	penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer			
25	devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.			
26	(b) The beyond use date shall specify that storage and exposure periods cannot			
27	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			
28	compounded solely with aseptic manipulations and all of the following apply:			
	7			
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1	(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an
2	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
3	sterile preparations combined or pooled to prepare a compounded sterile preparation that
4	will be administered either to multiple patients or to one patient on multiple occasions; and
5	(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
6	(3) The compounding process requires unusually long duration such as that required
7	to complete dissolution or homogenous mixing.
8	(c) The beyond use date shall specify that storage and exposure periods cannot exceed
9 10	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:
11	(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an
12	ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which
13	meets the requirements in $1751.4(f)(1)-(3)$ .
14 15	(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:
16 17 18	(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
19	(2) The compounding process involves simple transfer of not more than three
20	commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and
21	(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.
22	(3) The compounding process involves not more than two entries into any one
23	container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.
24	container/device.
25	(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
26	of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled
27	"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
28	immediately and completely administered by the person who prepared it or immediate and
	8
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1 2 3 4 5 6 7	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 interse suffering. Any such compounding shall be only in such			
8	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.			
9	COST RECOVERY			
10	18. Section 125.3 of the Code states, in pertinent part, that the Board may request the			
11	administrative law judge to direct a licentiate found to have committed a violation or violations of			
12	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and			
13	enforcement of the case.			
14	FACTUAL ALLEGATIONS			
15	December 2020 Inspection			
16	19. On December 3, 2020, the Board received a complaint against Respondent			
17	Providence alleging that there were serious regulatory violations and unsafe practices occurring at			
18	Respondent Providence for the past several months. According to the complainant, staff at			
19	Respondent Providence voiced their concerns to Pharmacist-in-Charge (PIC) Respondent			
20	Witherspoon, but she dismissed the concerns. The complainant later submitted photographs of a			
21	staff break room refrigerator where vaccines and antibiotics were improperly stored.			
22	20. On December 15, 2020, the Board received an email from DD, a pharmacist and			
23	pharmaceutical consultant for the California Department of Public Health (CDPH). DD reported			
24	that she was at Respondent Providence on December 14, 2020, and she found the IV room			
25	blocked off for construction. IV rooms, often used in hospital and pharmacy applications, are a			
26	place for the sterile preparation of medications. DD observed a pharmacy technician preparing			
27	immediate use compounded sterile products (CSP) for first doses and emergency doses on a			
28	countertop in a room within the pharmacy. A one-hour beyond-use date (BUD) was hand-written 9			
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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.

- 21. On December 15, 2020, Board inspector SH went to Respondent Providence to 4 5 conduct a routine partial inspection. SH was assisted by PIC Respondent Witherspoon and Pharmacy Director, Respondent Guinn. The inspector observed and took pictures of various parts 6 7 of the pharmacy, including the part of the pharmacy intended as the Segregated Compounding 8 Area (SCA). The SCA was a carpeted office room adjacent to the pharmacy. A cork bulletin 9 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 10 the ceiling tiles were made of a porous material. 11
- 22. During the inspection, SH also reviewed CSP compounding records from November 12 30, 2020, to December 15, 2020. SH reminded Respondent Witherspoon of a conversation they 13 14 had during an previous inspection on July 1, 2020, regarding the Board regulation concerning any sterile compounded drug preparation compounded either outside of an ISO class 5 Primary 15 Engineering Control, or under conditions that do not meet all of the requirements for any of 16 subdivisions (a) through (d) of California Code of Regulations, title 16, section 1751.8. An ISO 5 17 is a cleanroom classification. Pursuant to California Code of Regulations, title 16, section 1735.1, 18 subdivision (ab), "Primary Engineering Control (PEC)" means a device that provides an ISO 19 Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first 20air for compounding sterile preparations. Examples of PEC devices include, but are not limited 21 to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated 22 robots, compounding aseptic isolators, and compounding aseptic containment isolators. SH 23 24 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 25 December 13, 2020. 26 /// 27 28 ///

1	FIRST CAUSE FOR DISCIPLINE		
2	(Immediate Use Compounding Not Used in Limited Situations)		
3	23. Respondent Providence has subjected its Original Permit and its Sterile Compounding		
4	License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist		
5	License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113,		
6	subdivision (c), in that Respondent Providence compounded drugs in violation of California Code		
7	of Regulations, title 16, section 1751.8. "Immediate use" preparations shall be compounded only		
8	in those limited situations where there is a need for immediate administration of a sterile		
9	preparation compounded outside of an ISO class 5 environment, and where failure to administer		
10	could result in loss of life or intense suffering. Specifically, between November 30, 2020, and		
11	December 13, 2020, Respondent Providence compounded at least 593 "immediate use" sterile		
12	preparations outside of an ISO Class 5 PEC without meeting the circumstances to justify an		
13	immediate need in these 593 instances. The circumstances are set forth in further detail in		
14	paragraphs 18 through 21, above.		
15	SECOND CAUSE FOR DISCIPLINE		
16	(Incomplete Compounding Log Documentation)		
17	24. Respondent Providence has subjected its Original Permit and its Sterile Compounding		
18	License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist		
19	License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113,		
20	subdivision (c), in that Respondent Providence compounded drugs in violation of California Code		
21	of Regulations, title 16, section 1735.3, subdivision (a)(2)(H). Specifically, between November		
22	30, 2020, and December 13, 2020, at least 593 of Respondent Providence's compounding logs		
23	lacked complete documentation of the beyond use date and time of the final compounded drug		
24	preparation. The circumstances are set forth in further detail in paragraphs 18 through 21, above.		
25	THIRD CAUSE FOR DISCIPLINE		
26	(Final Quantity of Drug Not Present)		
27	25. Respondent Providence has subjected its Original Permit and its Sterile Compounding		
28	License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist		
	11 (PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL, BLAINE SCOT GUINN, LEIGH ANN		
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License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, 1 2 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 3 November 30, 2020, and December 13, 2020, compounding logs for at least 593 drug 4 5 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 6 7 through 22, above. FOURTH CAUSE FOR DISCIPLINE 8 9 (Incomplete Compounding Log Documentation) Respondent Providence has subjected its Original Permit and its Sterile Compounding 10 26. License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist 11 License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, 12 subdivision (c), in that Respondent Providence compounded drugs in violation of California Code 13 14 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 15 drug preparations lacked documentation of quality reviews and post-compounding process and 16 procedures. The circumstances are set forth in further detail in paragraphs 19 through 22, above. 17 FIFTH CAUSE FOR DISCIPLINE 18 19 (Operational Standards and Security) 27. Respondent Providence has subjected its Original Permit and its Sterile Compounding 20 License to disciplinary action and Respondent Witherspoon has subjected her Original Pharmacist 21 License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113, 22 subdivision (c), in that Respondent Providence failed to maintain its facilities, space, fixtures, and 23 24 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). 25 Specifically, between at least September 21, 2020, and November 1, 2020, Respondent 26 Providence was not properly monitoring medication storage refrigerator temperatures 27 28 appropriately. The refrigerator also contained improperly stored food items with medications 12 (PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL, BLAINE SCOT GUINN, LEIGH ANN

during this time period. The circumstances are set forth in further detail in paragraphs 19 through 22, above.

### SIXTH CAUSE FOR DISCIPLINE

(Aiding and Abetting Violations of Pharmacy Law)

28. Respondent Witherspoon and Respondent Guinn have subjected their Original 5 Pharmacist Licenses to discipline under Code section 4301, subdivision (o), in that they aided and 6 abetted the violation of the Board's regulations governing pharmacy law. Specifically, between 7 8 at least November 30, 2020, and December 13, 2020, Respondent Witherspoon, as Pharmacist-in-9 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), 11 1714, subdivision (b), and 1735.3, subdivisions (a)(2)(H), (I), and (J), as more fully set forth in 12 paragraphs 19 through 27, above. 13

14 15

### FACTUAL ALLEGATIONS

### **November 2021 Inspection**

29. On November 17, 2021, Board inspector SH conducted a partial inspection at 16 Respondent Providence after the Board received an anonymous complaint that Respondent 17 Providence was compounding batches of non-patient specific epidural syringes. Respondent 18 19 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. During this 20inspection, SH was assisted by Pharmacist-in-Charge Respondent Chan. Respondent Chan 21 explained that the hospital could no longer buy fentanyl/bupivacaine from its former supplier, 22 thus staff were instructed to compound three syringes of fentanyl/bupivacaine/sodium chloride 23 24 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 25 then storing the epidural syringes, which were non-patient specific, in the pharmacy refrigerator. 26 The pharmacy would transport the syringes to the L&D floor within fifteen minutes of a request 27 for one by the L&D department. Before a syringe was transported to L&D, the pharmacy staff 28 13

ĺ			
1	would create a patient-specific label and affix it to the syringe. The pharmacy wasted the syringes		
2	that were not used after 12 hours of being compounded.		
3	SEVENTH CAUSE FOR DISCIPLINE		
4	(Sterile Compounded Drug Preparations)		
5	30. Respondent Providence has subjected its Original Permit and its Sterile Compounding		
6	License to disciplinary action and Respondent Chan has subjected his Original Pharmacist		
7	License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113,		
8	subdivision (c), in that Respondent Providence compounded drugs in violation of California Code		
9	of Regulations, title 16, section 1751.8, subdivision (d)(1)-(3). Specifically, on November 17,		
10	2021, Respondent Providence compounded fentanyl/bupivacaine/sodium chloride syringes for		
11	epidural injection. This compounded sterile product required three entries to the administration		
12	syringe. Pharmacy law does not allow more than two entries into any one container or package of		
13	sterile infusion solution or administration container or device.		
14	EIGHTH CAUSE FOR DISCIPLINE		
15	(Incomplete Compounding Log)		
16	31. Respondent Providence has subjected its Original Permit and its Sterile Compounding		
17	License to disciplinary action and Respondent Chan has subjected his Original Pharmacist		
18	License to discipline under Code section 4301, subdivisions (j) and (o), and/or Code section 4113,		
19	subdivision (c), in that Respondent Providence compounded drugs in violation of California Code		
20	of Regulations, title 16, section 1735.3, subdivision (a)(2)(G). Specifically, on November 14,		
21	2021, and November 15, 2021, Respondent Providence compounded non-patient specific		
22	fentanyl/bupivacaine/sodium chloride syringes for epidural injection and used the date as the		
23	reference number rather than a pharmacy-assigned unique reference or lot number.		
24	OTHER MATTERS		
25	32. Pursuant to section 4307 of the Code, if discipline is imposed on Original Permit		
26	Number HSP 55890 or on Sterile Compounding License Number LSC 101129, then any person		
27			
27	who has been a manager, administrator, owner, member, officer, director, associate, partner, or		
27 28	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.

33. 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.

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### **DISCIPLINE CONSIDERATIONS**

34. 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.

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### <u>PRAYER</u>

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

Revoking or suspending Sterile Compounding License Number LSC 101129, issued
 to Providence Santa Rosa Memorial Hospital;

1	2.	. Revoking or suspending Original Permit Number HSP 55890, issued to Providence		
2	Santa Rosa	Santa Rosa Memorial Hospital;		
3	3.	Revoking or suspending	Original Pharmacist License Number RPH 42192, issued to	
4	Blaine Sco	Blaine Scot Guinn;		
5	4.	. Revoking or suspending Original Pharmacist License Number RPH 72914, issued to		
6	Leigh Ann Witherspoon;			
7	5.	5. Revoking or suspending Registered Pharmacist License Number RPH 53602, issued		
8	to Henry Mauhang Chan;			
9	6. Ordering Respondent Providence, Respondent Witherspoon, Respondent Guinn, and			
10	Respondent Chan to pay the Board of Pharmacy the reasonable costs of the investigation and			
11	enforcement of this case, pursuant to Business and Professions Code section 125.3 to pay the			
12	Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,			
13	pursuant to Business and Professions Code section 125.3; and,			
14	7.	Taking such other and fu	orther action as deemed necessary and proper.	
15				
16				
17	DATED:	6/12/2022	Signature on File	
18			ANNE SODERGREN Executive Officer	
19			Board of Pharmacy Department of Consumer Affairs	
20			State of California Complainant	
21			1	
22	OK2021900	121		
23	Edited FAA			
24				
25				
26				
27				
28	16			
	(PROVIDENCE SANTA ROSA MEMORIAL HOSPITAL, BLAINE SCOT GUINN, LEIGH ANN WITHERSPOON, and HENRY MAUHANG CHAN) FIRST AMENDED ACCUSATION			