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

In the Matter of the Second Amended Accusation Against:

SNP PHARMACY LLC doing business as SKILLED NURSING PHARMACY; BRENDA MANDELBAUM, BENTZION MANDELBAUM, and MICHELLE MANDELBAUM, Owners

Original Pharmacy Permit No. PHY 49974, Sterile Compounding Permit No. LSC 99561,

and

MINA NASR AYAD NASR

Original Pharmacist License No. RPH 78315,

Respondents.

Agency Case No. 6975

OAH No. 2021090385

MODIFIED DECISION AND ORDER

On April 25, 2022, the Board of Pharmacy adopted a Stipulated Settlement and Disciplinary Order in the above referenced case as to SNP Pharmacy LLC dba Skilled Nursing Pharmacy Only (Respondent). On May 9, 2022, the attorneys for the Respondent and the Complainant submitted a Joint Application to correct a typographical error in the Stipulated Settlement. Page 5, line 9 of Stipulated Settlement states that "during the period of probation." In the Joint Application, counsel for both parties stated that the intent of the settlement was for a period of one year. Page 5, line 9 of the attached Stipulated Settlement and Disciplinary Order is amended to read "for a period of one year."

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, with the correction to Page 5, line 9 as described above, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on May 25, 2022.

It is so ORDERED on May 20, 2022.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ву

Seung W. Oh, Pharm.D. Board President

| 10 DEPARTMENT OF CONSUMER AFFAIRS 11 DEPARTMENT OF CONSUMER AFFAIRS 12 STATE OF CALIFORNIA 13 In the Matter of the Second Amended 14 In the Matter of the Second Amended 15 SNP PHARMACY LLC doing business as 16 SKILLED NURSING PHARMACY; 17 BRENDA MANDELBAUM, BENTZION 17 MANDELBAUM, and MICHELLE MANDELBAUM, Owners S1150 Cabot Blvd. 11 Hayward, CA 94545 19 Original Pharmacy Permit No. PHY 49974, 12 and 12 MINA NASR AYAD NASR 5045 Valley Crest Drive, #210 13 Concord, CA 94521 14 Original Pharmacist License No. RPH 78315 15 Respondents. |
|---|
| |
| 28 |
| 1 |
| JOINT APPLICATION TO CORRECT MISTAKE OR CLERICAL ERROR IN DECISION REGARDING RESPONDENT SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY |

| 1 | PARTIES |
|----|---|
| 2 | 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy |
| 3 | (Board). She brought this action solely in her official capacity and is represented in this matter by |
| 4 | Rob Bonta, Attorney General of the State of California, by Aspasia A. Papavassiliou, Deputy |
| 5 | Attorney General. |
| 6 | 2. Respondent SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy |
| 7 | (Respondent) is represented in this proceeding by attorney Stacie K. Neroni of Davis, Wright, |
| 8 | Tremaine LLC, located at 865 South Figueroa Street, Suite 2400, Los Angeles, CA 90017-2566. |
| 9 | 3. On or about April 25, 2022, the Board adopted as its Final Decision and Order a |
| 10 | Stipulated Settlement and Disciplinary Order for Public Reproval as to Respondent. A copy of |
| 11 | the adopted Stipulation and Disciplinary Order for Public Reproval is attached as exhibit A and |
| 12 | incorporated here by reference. |
| 13 | 4. The parties, by and through their counsel, apply to correct a mistake or clerical error |
| 14 | in the Decision and Order pursuant to California Government Code section of 11518.5 subsection |
| 15 | (a), which states: |
| 16 | Within 15 days after service of a copy of the decision on a party, but not later |
| 17 | than the effective date of the decision, the party may apply to the agency for correction of a mistake or clerical error in the decision, stating the specific ground on |
| 18 | which the application is made. Notice of the application shall be given to the other parties to the proceeding. The application is not a prerequisite for seeking judicial |
| 19 | review. |
| 20 | 5. The Stipulated Settlement and Disciplinary Order adopted and served by the Board on |
| 21 | contains a typographical or clerical error on page 5, line 9. The Stipulation erroneously stated, |
| 22 | "Within 30 days, Respondent shall retain, at its own expense, an independent consultant who |
| 23 | shall review the operations of the facility, during the period of probation, on a monthly basis |
| 24 | for compliance of the facility with state and federal laws and regulations governing the practice of |
| 25 | pharmacy, and compliance by respondent." (Emphasis added to erroneous language to be |
| 26 | removed.) |
| 27 | |
| 28 | |
| | 2 |
| | JOINT APPLICATION TO CORRECT MISTAKE OR CLERICAL ERROR IN DECISION REGARDING RESPONDENT SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY |

| 1 | 6. The parties intended to have the stipulation state: | |
|----------|--|--|
| 2 | "Within 30 days, Respondent shall retain, at its own expense, an independent consultant | |
| 3 | who shall review the operations of the facility, for a period of one year, on a monthly basis for | |
| 4 | compliance of the facility with state and federal laws and regulations governing the practice of | |
| 5 | pharmacy, and compliance by respondent." (Emphasis added to intended language to be added.) | |
| 6 | APPLICATION | |
| 7 | The parties, by and through their counsel, jointly request that the Decision and Order be | |
| 8 | corrected to state that Respondent shall retain an independent consultant for a period of one year | |
| 9 | instead of during the period of probation, with all other terms and conditions to remain the same. | |
| 10 | | |
| 11 | DATED: STACY K. NERONI | |
| 12 | Attorney for Respondent | |
| 13 | | |
| 14 | DATED: ROB BONTA Attorney General of California | |
| 15 | DIANN SOKOLOFF Supervising Deputy Attorney General | |
| 16 | | |
| 17 | ACRACIA A DARAMACHIAN | |
| 18 | ASPASIA A. PAPAVASSILIOU Deputy Attorney General Attorney for the Boorde of the State of | |
| 19 20 | Attorneys for the People of the State of California | |
| 21 | OK2020900248 | |
| 22 | | |
| 23 | | |
| 24 | | |
| 25 | | |
| 26 | | |
| 27 | | |
| 28 | | |
| | 3 | |
| | JOINT APPLICATION TO CORRECT MISTAKE OR CLERICAL ERROR IN DECISION REGARDING RESPONDENT SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY | |

| l | * | | |
|----------|--|--|--|
| 1 | 6. The parties intended to have the stipulation state: | | |
| 2 | "Within 30 days, Respondent shall retain, at its own expense, an independent consultant | | |
| 3 | who shall review the operations of the facility, for a period of one year, on a monthly basis for | | |
| 4 | compliance of the facility with state and federal laws and regulations governing the practice of | | |
| 5 | pharmacy, and compliance by respondent." (Emphasis added to intended language to be added.) | | |
| 6 | APPLICATION | | |
| 7 | The parties, by and through their counsel, jointly request that the Decision and Order be | | |
| 8 | corrected to state that Respondent shall retain an independent consultant for a period of one year | | |
| 9 | instead of during the period of probation, with all other terms and conditions to remain the same. | | |
| 10 | X A A | | |
| 11 | DATED: 5-9-22 STACIE K. NERONI | | |
| 12 | Attorney for Respondent | | |
| 13 | | | |
| 14 | DATED: May 9, 2022 ROB BONTA Attorney General of California | | |
| 15 | DIANN SOKOLOFF Supervising Deputy Attorney General | | |
| 16 | Aug Pag | | |
| 17 | ASPASIA A. PAPAVASSILIOU | | |
| 18 | Deputy Attorney General Attorneys for the People of the State of | | |
| 19 20 | California | | |
| 20 | OK2020900248 | | |
| 21 | | | |
| 22 | | | |
| 24 | | | |
| 25 | | | |
| 26 | | | |
| 27 | | | |
| 28 | | | |
| | 3 | | |
| | JOINT APPLICATION TO CORRECT MISTAKE OR CLERICAL ERROR IN DECISION REGARDING RESPONDENT SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY | | |

EXHIBIT A Decision and Order

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

In the Matter of the Second Amended Accusation Against:

SNP PHARMACY LLC doing business as SKILLED NURSING PHARMACY; BRENDA MANDELBAUM, BENTZION MANDELBAUM, and MICHELLE MANDELBAUM, Owners

Original Pharmacy Permit No. PHY 49974, Sterile Compounding Permit No. LSC 99561,

and

MINA NASR AYAD NASR

Original Pharmacist License No. RPH 78315,

Respondents.

Agency Case No. 6975

OAH No. 2021090385

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval 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 May 25, 2022.

It is so ORDERED on April 25, 2022.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Seung W. Oh, Pharm.D. Board President

| 1 | Rob Bonta | |
|----------|--|--|
| 2 | Attorney General of California DIANN SOKOLOFF | |
| 3 | Supervising Deputy Attorney General ASPASIA A. PAPAVASSILIOU | |
| 4 | Deputy Attorney General State Bar No. 196360 | |
| 5 | 1515 Clay Street, 20th Floor P.O. Box 70550 | |
| 6 | Oakland, CA 94612-0550 Telephone: (510) 879-0818 | |
| 7 | Facsimile: (510) 622-2270 E-mail: Aspasia.Papavassiliou@doj.ca.gov | |
| 8 | Attorneys for Complainant | |
| 9 | BEFOR | |
| 10 | BOARD OF P DEPARTMENT OF CO | _ |
| 11 | STATE OF CA | ALIFORNIA |
| 12 | | |
| 13 | In the Matter of the Second Accusation Against: | Case No. 6975 |
| 14 | SNP PHARMACY LLC doing business as | OAH No. 2021090385 |
| 15 16 | SKILLED NURSING PHARMACY; BRENDA MANDELBAUM, BENTZION MANDELBAUM, and MICHELLE | STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL REGARDING SNP |
| 17 | MANDELBAUM, Owners 21150 Cabot Blvd. Hayward, CA 94545 | PHARMACY LLC DBA SKILLED NURSING PHARMACY |
| 18 19 | Original Pharmacy Permit No. PHY 49974, Sterile Compounding Permit No. LSC 99561 | [Bus. & Prof. Code § 495] |
| 20 | and | |
| 21 | MINA NASR AYAD NASR 5045 Valley Crest Drive, #210 | |
| 22 | Concord, CA 94521 Oviginal Pharmasist Lisonge No. DBU 78315 | |
| 23 | Original Pharmacist License No. RPH 78315 Respondents. | |
| 24 25 | Respondents. | |
| 23 26 | | |
| 20 | IT IS HEREBY STIPULATED AND AGR | EED by and between the parties to the above- |
| 28 | entitled proceedings that the following matters are | e true: |
| - | | 1 |
| | | - UBLIC REPROVAL – SNP PHARMACY LLC (6975) |

| 1 | PARTIES | |
|----|---|--|
| 2 | 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy | |
| 3 | (Board). She brought this action solely in her official capacity and is represented in this matter by | |
| 4 | Rob Bonta, Attorney General of the State of California, by Aspasia A. Papavassiliou, Deputy | |
| 5 | Attorney General. | |
| 6 | 2. Respondent SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy | |
| 7 | (Respondent) is represented in this proceeding by attorney Stacie K. Neroni of Davis, Wright, | |
| 8 | Tremaine LLC, located at 865 South Figueroa Street, Suite 2400, Los Angeles, CA 90017-2566. | |
| 9 | JURISDICTION | |
| 10 | 3. On or about December 21, 2009, the Board of Pharmacy issued Original Pharmacy | |
| 11 | Permit Number PHY 49974 and Sterile Compounding Permit Number LSC 99561 to SNP | |
| 12 | Pharmacy Inc., doing business as Skilled Nursing Pharmacy, with Brenda Mandelbaum as 50- | |
| 13 | percent shareholder; Bentzion Mandelbaum as President and 25-percent shareholder, and | |
| 14 | Michelle Mandelbaum as Director and 25-percent shareholder. On April 22, 2019, SNP | |
| 15 | Pharmacy, Inc. changed its corporate name to SNP Pharmacy LLC (Respondent). The Original | |
| 16 | Pharmacy Permit and Sterile Compounding Permit will expire on December 1, 2022, unless | |
| 17 | renewed. | |
| 18 | 4. Second Amended Accusation No. 6975 was filed before the Board of Pharmacy | |
| 19 | (Board), Department of Consumer Affairs and is currently pending against Respondent. The | |
| 20 | Second Amended Accusation and all other statutorily required documents were properly served | |
| 21 | on Respondent on or about January 24, 2022. Respondent had previously timely filed its Notice | |
| 22 | of Defense contesting the Second Amended Accusation. A copy of Second Amended Accusation | |
| 23 | No. 6975 is attached as exhibit A and incorporated by reference. | |
| 24 | ADVISEMENT AND WAIVERS | |
| 25 | 5. Respondent has carefully read, fully discussed with counsel, and understands the | |
| 26 | charges and allegations in Accusation No. 6975. Respondent has also carefully read, fully | |
| 27 | discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary | |
| 28 | Order for Public Reproval. | |
| | 2 | |
| | STIP SETTLEMENT & DISC ORDER FOR PUBLIC REPROVAL – SNP PHARMACY LLC (6975) | |

| 1 | 6. Respondent is fully aware of its legal rights in this matter, including the right to a |
|----|---|
| 2 | hearing on the charges and allegations in the Accusation; the right to be represented by counsel at |
| 3 | its own expense; the right to confront and cross-examine the witnesses against them; the right to |
| 4 | present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel |
| 5 | the attendance of witnesses and the production of documents; the right to reconsideration and |
| 6 | court review of an adverse decision; and all other rights accorded by the California |
| 7 | Administrative Procedure Act and other applicable laws. |
| 8 | 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and |
| 9 | every right set forth above. |
| 10 | <u>CULPABILITY</u> |
| 11 | 8. Respondent understands and agrees that the charges and allegations in Second |
| 12 | Amended Accusation No. 6975, if proven at a hearing, constitute cause for imposing discipline |
| 13 | upon its Original Pharmacy Permit and Sterile Compounding Permit. |
| 14 | 9. For the purpose of resolving the Second Amended Accusation without the expense |
| 15 | and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could |
| 16 | establish a factual basis for the charges in the Second Amended Accusation, and that Respondent |
| 17 | hereby gives up its right to contest those charges. |
| 18 | 10. Respondent further agrees that its Original Pharmacy Permit and Sterile |
| 19 | Compounding Permit are subject to discipline and it agrees to be bound by the Disciplinary Order |
| 20 | below. |
| 21 | 11. In addition, if the Board files an Accusation against Respondent in a future action, |
| 22 | then the charges and allegations in Second Amended Accusation No. 6975 shall be deemed to be |
| 23 | true and correct. |
| 24 | <u>CONTINGENCY</u> |
| 25 | 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent |
| 26 | understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may |
| 27 | communicate directly with the Board regarding this stipulation and settlement, without notice to |
| 28 | or participation by Respondent or its counsel. By signing the stipulation, Respondent understands |
| | 3 |
| | STIP SETTLEMENT & DISC ORDER FOR PUBLIC REPROVAL – SNP PHARMACY LLC (6975) |

and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the 1 2 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall 3 be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action 4 between the parties, and the Board shall not be disqualified from further action by having 5 considered this matter. 6 13. The parties understand and agree that Portable Document Format (PDF) and facsimile 7 8 copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF 9 and facsimile signatures thereto, shall have the same force and effect as the originals. 10 14. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment 11 of their agreement. It supersedes any and all prior or contemporaneous agreements, 12 understandings, discussions, negotiations, and commitments (written or oral). This Stipulated 13

Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,
supplemented, or otherwise changed except by a writing executed by an authorized representative

16 of each of the parties.

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

20

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacy Permit No. PHY 49974 and Sterile Compounding Permit No. LSC 99561 issued to SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy (Respondent) shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of Accusation No. 6975, attached as exhibit A.

26

Cost Recovery

27 Respondent shall pay \$42,075.40 to the Board for its costs associated with the investigation
28 and enforcement of this matter pursuant to Business and Professions Code Section 125.3.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year following the effective date of the decision. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Original Pharmacy Permit and Sterile Compounding Permit until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

7

Consultant Review of Pharmacy Operations

Within 30 days, Respondent shall retain, at its own expense, an independent consultant who 8 9 shall review the operations of the facility, during the period of probation, on a monthly basis for compliance of the facility with state and federal laws and regulations governing the practice of 10 pharmacy, and compliance by respondent. The consultant shall provide the board with an 11 inspection agenda for approval prior to conducting the inspection. Any inspection conducted 12 without prior approval of the inspection agenda shall not be accepted. The consultant shall also 13 14 provide the board with reports documenting the inspection. The reports shall be provided directly to the board, and receive confirmation of receipt from the board, prior to providing to the 15 respondent. Should the board determine that the consultant is not appropriately assessing the 16 operations of respondent, or providing the appropriate written reports, the board shall require 17 respondent to obtain a different consultant through the same process outlined above, by 18 submitting a new name of an expert within sixty (60) days of respondent being notified of the 19 need for a new consultant. The board shall retain discretion to reduce the frequency of the 20consultant's review. 21

Respondent shall submit the name of the proposed consultant for approval within thirty (30) days of the effective date of this decision. The consultant shall be a pharmacist licensed by and not on probation with the board or other professional as appropriate and not on probation with the board, who has been approved by the board to serve in this position. The consultant shall have sufficient education, training, and professional experience to be able to provide guidance to respondent related to the causes for discipline in Case No. 6975. Assumption of any unauthorized

| 1 | supervision responsibilities shall be considered a violation of this condition and cause for further |
|---|--|
| 2 | disciplinary action. |
| 3 | Failure to timely seek approval for, timely retain, or ensure timely reporting by the |

4 consultant shall be considered a violation of this condition and cause for further disciplinary
5 action.

Full Compliance. As a resolution of the charges in Accusation No. 6975, this stipulated
settlement is contingent upon Respondent's full compliance with all conditions of this Order. If
Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for
discipline, including outright revocation, of Respondent's Original Pharmacy Permit No. PHY
49974 and Sterile Compounding Permit No. LSC 99561.

11

18

19

20

21

22

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
Reproval and have fully discussed it with our attorney Stacie K. Neroni. I understand the
stipulation and the effect it will have on our Original Pharmacy Permit and Sterile Compounding
Permit. We enter into this Stipulated Settlement and Disciplinary Order for Public Reproval
voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
Board of Pharmacy.

BRENDA MANDELBAUM for SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY; Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
 Reproval and have fully discussed it with our attorney Stacie K. Neroni. I understand the
 stipulation and the effect it will have on our Original Pharmacy Permit and Sterile Compounding
 Permit. We enter into this Stipulated Settlement and Disciplinary Order for Public Reproval

supervision responsibilities shall be considered a violation of this condition and cause for further disciplinary action.

Failure to timely seek approval for, timely retain, or ensure timely reporting by the
consultant shall be considered a violation of this condition and cause for further disciplinary
action.

Full Compliance: As a resolution of the charges in Accusation No. 6975, this stipulated
settlement is contingent upon Respondent's full compliance with all conditions of this Order. If
Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for
discipline, including outright revocation, of Respondent's Original Pharmacy Permit No. PHY
49974 and Sterile Compounding Permit No. LSC 99561.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public
Reproval and have fully discussed it with our attorney Stacie K. Neroni. I understand the
stipulation and the effect it will have on our Original Pharmacy Permit and Sterile Compounding
Permit. We enter into this Stipulated Settlement and Disciplinary Order for Public Reproval
voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
Board of Pharmacy.

DATED: 3-2-22

1

2

11

18

19

20

21

22

23

24

25

26

27

28

BRENDA MANDELBAUM for SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY; Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with our attorney Stacie K. Neroni. I understand the stipulation and the effect it will have on our Original Pharmacy Permit and Sterile Compounding Permit. We enter into this Stipulated Settlement and Disciplinary Order for Public Reproval

STIP SETTLEMENT & DISC ORDER FOR PUBLIC REPROVAL - SNP PHARMACY LLC (6975)

| 1 | voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of th | | |
|----|---|--|--|
| 2 | Board of Pharmacy. | | |
| 3 | | | |
| 4 | DATED: | | |
| 5 | BENTZION MANDELBAUM for SNP PHARMACY LLC DBA | | |
| 6 | SKILLED NURSING PHARMACY; Respondent | | |
| 7 | Кезропиен | | |
| 8 | I have carefully read the above Stipulated Settlement and Disciplinary Order for Public | | |
| 9 | Reproval and have fully discussed it with our attorney Stacie K. Neroni. I understand the stipulation and the effect it will have on our Original Pharmacy Permit and Sterile Compounding | | |
| 10 | | | |
| 11 | Permit. We enter into this Stipulated Settlement and Disciplinary Order for Public Reproval | | |
| 12 | voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the | | |
| 13 | Board of Pharmacy. | | |
| 14 | | | |
| 15 | DATED: | | |
| 16 | MICHELLE MANDELBAUM for SNP PHARMACY LLC DBA | | |
| 17 | SKILLED NURSING PHARMACY; | | |
| 18 | Respondent | | |
| 19 | I have read and fully discussed with the Brenda Mandelbaum, Bentzion Mandelbaum, and | | |
| 20 | Michelle Mandebaum, owners of Respondent SNP Pharmacy LLC doing business as Skilled | | |
| 21 | Nursing Pharmacy, the terms and conditions and other matters contained in the above Stipulated | | |
| 22 | Settlement and Disciplinary Order for Public Reproval. I approve its form and content. | | |
| 23 | Settlement and Disciplinary Order for Fublic Reproval. Tapprove its form and content. | | |
| 24 | | | |
| 25 | DATED: | | |
| 26 | STACIE K. NERONI Attorney for Respondent | | |
| 27 | | | |
| 28 | | | |
| | 7 | | |

voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy. 2 3 3-1-22 DATED: 4 BENTZION MANDELBAUM for 5 SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY; б Respondent 7 8 I have carefully read the above Stipulated Settlement and Disciplinary Order for Public 9 Reproval and have fully discussed it with our attorney Stacie K. Neroni. I understand the 10 stipulation and the effect it will have on our Original Pharmacy Permit and Sterile Compounding Permit. We enter into this Stipulated Settlement and Disciplinary Order for Public Reproval 11 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the 12 13 Board of Pharmacy. 14 15 DATED: MICHELLE MANDELBAUM for 16 SNP PHARMACY LLC DBA SKILLED NURSING PHARMACY; 17 Respondent 18 19 I have read and fully discussed with the Brenda Mandelbaum, Bentzion Mandelbaum, and 20 Michelle Mandebaum, owners of Respondent SNP Pharmacy LLC doing business as Skilled 21 Nursing Pharmacy, the terms and conditions and other matters contained in the above Stipulated 22 Settlement and Disciplinary Order for Public Reproval. I approve its form and content. 23 24 3-2-22 25 RÓNI STA Attorney for Respondent 26 27 28 7 STIP SETTLEMENT & DISC ORDER FOR PUBLIC REPROVAL - SNP PHARMACY LLC (6975)

| 1 | <u> </u> | ENDORSEMENT | |
|----------|---|---|--|
| 2 | The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereb | | |
| 3 | respectfully submitted for consideration | by the Board of Pharmacy of the Department of | |
| 4 | Consumer Affairs. | | |
| 5 | | | |
| 6 | DATED: | Respectfully submitted, | |
| 7 | | ROB BONTA Attorney General of California DIANN SOKOLOFF | |
| 8 | | Supervising Deputy Attorney General | |
| 9 | | | |
| 0 | | ASPASIA A. PAPAVASSILIOU | |
| 1 | | Deputy Attorney General Attorneys for Complainant | |
| 2 | | | |
| 3 | | | |
| 4 | | | |
| 5 | OK2020900248 91470662.docx | | |
| 6 | | | |
| 7 | | | |
| 8 | | | |
| 9 | | | |
| 20 | | | |
| 1 | | | |
| 2 | | | |
| 23 | | | |
| 24 | | | |
| 5 | | | |
| 26 97 | | | |
| 27 28 | | | |
| .0 | | 8 | |

| | EN | DORSEMENT | | |
|--|-------------------------------------|--|---|--|
| | The foregoing Stipulated Settlement | and Disciplinary Order for Public Reproval | is hereby | |
| respectfully submitted for consideration by the Board of Pharmacy of the Department of | | | | |
| | mer Affairs. | | · . | |
| | | | · | |
| DAT | ED: March 3, 2022 | Respectfully submitted, | | |
| | | ROB BONTA Attorney General of California | | |
| | | Attorney General of California DIANN SOKOLOFF | nonal | |
| | | Supervising Deputy Attorney Ger | leral | |
| | | Arre Pres | and the summer of the second se | |
| | • | Aspasia A. Papavassiliou | | |
| | ٠ | Deputy Attorney General Attorneys for Complainant | | |
| | | | | |
| | | | | |
| | · | | | |
| OK2020 | 0900248 91470662.docx | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | • | | · · | |
| | | | | |
| | · . | | | |
| | | | | |
| | • | | | |
| | · | | | |
| | | · · · · · | | |
| · · | | | | |
| 11 . | • | | | |

Exhibit A

Accusation No. 6975

| 1 2 | ROB BONTA Attorney General of California DIANN SOKOLOFF Sumarising Deputy Attorney Concept | |
|--------|---|--|
| 3 | Supervising Deputy Attorney General ASPASIA A. PAPAVASSILIOU | |
| 4 | Deputy Attorney General State Bar No. 196360 | |
| 5 | 1515 Clay Street, 20th Floor P.O. Box 70550 | |
| 6 | Oakland, CA 94612-0550 Telephone: (510) 879-0818 | |
| 7 | Facsimile: (510) 622-2270 E-mail: aspasia.papavassiliou@doj.ca.gov | |
| 8 | Attorneys for Complainant | |
| 9 | BEFOR | ЕТНЕ |
| 10 | BOARD OF P DEPARTMENT OF C | |
| 11 | STATE OF C | |
| 12 | | |
| 13 | In the Matter of the Second Amended Accusation Against: | Case No. 6975 |
| 14 | SNP PHARMACY LLC doing business as | OAH No. 2021090385 |
| 15 | SKILLED NURSING PHARMACY; BRENDA MANDELBAUM, BENTZION | SECOND AMENDED |
| 16 | MANDELBAUM, and MICHELLE MANDELBAUM, Owners | ACCUSATION |
| 17 | 21150 Cabot Blvd. Hayward, CA 94545 | |
| 18 | Original Pharmacy Permit No. PHY 49974, | |
| 19 | Sterile Compounding Permit No. LSC 99561 | |
| 20 | and | |
| 21 | MINA NASR AYAD NASR 5045 Valley Crest Drive, #210 | |
| 22 | Concord, CA 94521 | |
| 23 | Original Pharmacist License No. RPH 78315 | |
| 24 | Respondents. | |
| 25 | PART | TIES |
| 26 | 1. Anne Sodergren (Complainant) brings | s this Second Amended Accusation solely in her |
| 27 | official capacity as the Executive Officer of the B | oard of Pharmacy, Department of Consumer |
| 28 | Affairs. | |
| | | 1 |
| | SNP PHARMACY LLC dba SKILLED NURSING SECOND AMENDE | |

| 1 | 2. On or about December 21, 2009, the Board of Pharmacy issued Original Pharmacy |
|----|--|
| 2 | Permit Number PHY 49974 and Sterile Compounding Permit Number LSC 99561 to SNP |
| 3 | Pharmacy Inc., doing business as Skilled Nursing Pharmacy, with Brenda Mandelbaum as 50- |
| 4 | percent shareholder; Bentzion Mandelbaum as President and 25-percent shareholder, and |
| 5 | Michelle Mandelbaum as Director and 25-percent shareholder. On April 22, 2019, SNP |
| 6 | Pharmacy, Inc. changed its corporate name to SNP Pharmacy LLP (Respondent SNP). The |
| 7 | Original Pharmacy Permit and Sterile Compounding Permit were in full force and effect at all |
| 8 | times relevant to the charges brought here and will expire on December 1, 2022, unless renewed. |
| 9 | 3. On or about March 27, 2018, the Board of Pharmacy issued Original Pharmacist |
| 10 | License Number RPH 78315 to Mina Nasr Ayad Nasr (Respondent Nasr). The Original |
| 11 | Pharmacist License was in full force and effect at all times relevant to the charges brought here |
| 12 | and will expire on August 31, 2023, unless renewed. |
| 13 | 4. Respondent Nasr has been designated as Respondent SNP's Pharmacist-in-Charge |
| 14 | (PIC) since December 31, 2018. |
| 15 | JURISDICTION |
| 16 | 5. This Second Amended Accusation is brought before the Board of Pharmacy (Board), |
| 17 | Department of Consumer Affairs, under the authority of the following laws. All section |
| 18 | references are to the Business and Professions Code (Code) unless otherwise indicated. |
| 19 | 6. Section 4011 of the Code states, in pertinent part: |
| 20 | The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and |
| 21 | Safety Code). |
| 22 | 7. Section 4300 of the Code states: |
| 23 | (a) Every license issued may be suspended or revoked. |
| 24 | (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found |
| 25 | guilty, by any of the following methods: |
| 26 | (1) Suspending judgment. |
| 27 | (2) Placing him or her upon probation. |
| 28 | (3) Suspending his or her right to practice for a period not exceeding one year. 2 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| 1 | (4) Revoking his or her license. |
|----------|---|
| 2 | (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper. |
| 3 | (c) The board may refuse a license to any applicant guilty of unprofessional |
| 4 | conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all |
| 5 6 | other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following: |
| 7 | (1) Medical or psychiatric evaluation. |
| 8 | (2) Continuing medical or psychiatric treatment. |
| 9 | (3) Restriction of type or circumstances of practice. |
| 10 | (4) Continuing participation in a board-approved rehabilitation program. |
| 11 | (5) Abstention from the use of alcohol or drugs. |
| 12 | (6) Random fluid testing for alcohol or drugs. |
| 13 | (7) Compliance with laws and regulations governing the practice of pharmacy. |
| 14 | (d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of |
| 15 16 | probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions. |
| 17 | (e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and |
| 18 | the board shall have all the powers granted therein. The action shall be final, except that |
| 19 | the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure. |
| 20 | |
| 21 | 8. Section 4300.1 of the Code states: |
| 22 | The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the |
| 23 | placement of a license on a retired status, or the voluntary surrender of a license by a license shall not deprive the board of jurisdiction to commence or proceed with any |
| 23 | investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license. |
| 25 | |
| 26 | 9. Section 4307, subdivision (a), of the Code states: |
| 20 | "Any person who has been denied a license or whose license has been revoked or is under |
| 28 | suspension, or who has failed to renew his or her license while it was under suspension, or who |
| 20 | 3 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| 1 | has been a manager, administrator, owner, member, officer, director, associate, partner, or any |
|----------|---|
| 2 | other person with management or control of any partnership, corporation, trust, firm, or |
| 3 | association whose application for a license has been denied or revoked, is under suspension or has |
| 4 | been placed on probation, and while acting as the manager, administrator, owner, member, |
| 5 | officer, director, associate, partner, or any other person with management or control had |
| 6 | knowledge of or knowingly participated in any conduct for which the license was denied, |
| 7 | revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, |
| 8 | administrator, owner, member, officer, director, associate, partner, or in any other position with |
| 9 | management or control of a licensee as follows: |
| 10 | "(1) Where a probationary license is issued or where an existing license is placed on |
| 11 | probation, this prohibition shall remain in effect for a period not to exceed five years. |
| 12 | "(2) Where the license is denied or revoked, the prohibition shall continue until the license |
| 13 | is issued or reinstated." |
| 14 | STATUTORY PROVISIONS |
| 15 | 10. Section 4113, subdivision (c), of the Code, states, in pertinent part: |
| 16 17 | (c) 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. |
| 18 | 11. Section 4126.8 of the Code states: |
| 19 | The compounding of drug preparations by a pharmacy for furnishing, distribution, or |
| 20 | use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National |
| 21 | Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations. |
| 22 | regulations to impose additional standards for compounding drug preparations. |
| 23 | 12. Section 4301 of the Code states: |
| 24 | The board shall take action against any holder of a license who is guilty of |
| 25 | unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following: |
| 26 | |
| 27 | (o) Violating or attempting to violate, directly or indirectly, or assisting in or |
| 28 | 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, |
| | 4 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR |

| 1 | including regulations established by the board or by any other state or federal |
|----|---|
| 2 | regulatory agency. |
| 3 | 13. Section 4306.5 states, in pertinent part: |
| 4 | Unprofessional conduct for a pharmacist may include any of the following: |
| 5 | (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of |
| 6 | 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, |
| 7 | administration, or operation of a pharmacy or other entity licensed by the board. |
| 8 | (b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with |
| 9 | regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services. |
| 10 | |
| 11 | REGULATORY PROVISIONS |
| 12 | 14. California Code of Regulations, title 16, section 1714, subdivision (b), states: |
| 13 | "Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and |
| 14 | equipment so that drugs are safely and properly prepared, maintained, secured and distributed. |
| 15 | The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice |
| 16 | of pharmacy." |
| 17 | 15. California Code of Regulations, title 16, section 1735.2 states, in pertinent part: |
| 18 | |
| 19 | (e) A drug preparation shall not be compounded until the pharmacy has first prepared |
| 20 | a written master formula document that includes at least the following elements: |
| 21 | (4) Inactive ingredients to be used. |
| 22 | (5) Specific and essential compounding steps used to prepare the drug. |
| 23 | ••• |
| 24 | (g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the |
| 25 | beyond use date indicated on the label, so long as label instructions for storage and handling |
| 26 | are followed after the preparation is dispensed. |
| 27 | |
| 28 | |
| | 5 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| 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 | |
| 4 | (2) A compounding log consisting of a single document containing all of the following: |
| 5 | |
| 6 | |
| 7 | (D) The identity of the pharmacist reviewing the final drug preparation. |
| 8 | 17. California Code of Regulations, title 16, section 1751.7 states, in pertinent part: |
| 9 10 | (b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and esentia area remeties before being allowed to prepare sterile drug |
| 10 | technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used |
| 12 | in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the |
| 13 | individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and |
| 14 | contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials |
| 15 | must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner |
| 16 | consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated. |
| 17 | taken and documented, and the vandation process repeated. |
| 18 | |
| 19 | (3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever: |
| 20 | |
| 21 | (B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a |
| 22 | change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or |
| 23 | when improper aseptic techniques are observed. |
| 24 | <u>COST RECOVERY</u> |
| 25 | 18. Section 125.3 of the Code states, in pertinent part, that the Board may request the |
| 26 | administrative law judge to direct a licentiate found to have committed a violation or violations of |
| 27 | the licensing act to pay a sum not to exceed the reasonable costs of the investigation and |
| 28 | enforcement of the case. |
| | 6 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| 1 | DRUG DEFINITION |
|----|---|
| 2 | 19. Vancomycin is an antibiotic that when taken orally is used to treat bacterial intestinal |
| 3 | infections. It is designated as a dangerous drug under Business and Professions Code section |
| 4 | 4022. |
| 5 | FACTUAL ALLEGATIONS |
| 6 | VANCOMYCIN COMPOUNDING |
| 7 | 20. From December 1, 2018, to February 1, 2019, Respondents reconstituted vancomycin |
| 8 | 5gram vials to compound at least 335 sterile compounded preparations with the incorrect amount |
| 9 | of sterile water. Moreover, the compounding logs lacked documentation of the identity of the |
| 10 | pharmacist who performed the quality review of the final product; the master formula for |
| 11 | vancomycin in sodium chloride 0.9% sterile compounds failed to include the sterile water used |
| 12 | for reconstitution of the vancomycin powder vial used in compounding; and the master formula |
| 13 | failed to include directions for reconstituting the vancomycin vial used in compounding. |
| 14 | Refrigerator Temperature |
| 15 | 21. From January 1, 2020, to October 31, 2020, Respondent SNP's refrigerator |
| 16 | temperature recordings were out of the range of the 36 to 46 degrees Farenheit required for the |
| 17 | proper storage of medications for 239 out of 305 days. |
| 18 | CLEANROOM RENOVATIONS |
| 19 | 22. From April 28, 2021, the date after completion of renovations of Respondent SNP's |
| 20 | cleanroom, including replacement of the floor and work on the ante room ceiling, as well as |
| 21 | replacement of the laminar flow hood, to May 14, 2021, the date when SNP received |
| 22 | environmental sampling results, SNP compounded at least 180 sterile preparations, including at |
| 23 | least 17 total parenteral nutrition (medium risk compounds). Moreover, from April 28, 2021, |
| 24 | after the Primary Engineering Control (PEC) was replaced, to May 20, 2021, the date of the first |
| 25 | results of employee testing to validate aseptic technique in the new PEC, Respondent SNP |
| 26 | compounded at least 200 sterile preparations, of which at least 25 were total parental nutrition |
| 27 | (medium risk compounds). |
| 28 | |
| | 7 SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASK AYAD NASK SECOND AMENDED ACCUSATION |

| 1 | CAUSES FOR DISCIPLINE AGAINST RESPONDENT SNP |
|----------|--|
| 2 | FIRST CAUSE FOR DISCIPLINE - SNP |
| 3 | (Incorrect Reconstitution of Compounded Drug Preparation) (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (g)) |
| 4 | 23. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are |
| 5 | subject to disciplinary action because Respondent SNP compounded at least 335 vancomycin |
| 6 | sterile preparations with vancomycin 5gram vials which were reconstituted with 50mls of sterile |
| 7 | water rather than the manufacturer's FDA approved package insert instructions of 100mls of |
| 8 | sterile water. The circumstances are set forth in paragraph 20, above. (Bus. & Prof. Code, \S |
| 9 | 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subd. (g).) |
| 10 11 | SECOND CAUSE FOR DISCIPLINE - SNP (Incomplete Compounding Records) (Bus. & Prof. Code, § 4301, subd. (0); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D)) |
| 12 | 24. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are |
| 13 | subject to disciplinary action because Respondent SNP failed to keep complete compounding |
| 14 | records, as set forth in paragraph 20, above. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code |
| 15 | Regs., tit. 16, § 1735.3, subd. (a)(2)(D).) |
| 16 | |
| 17 18 | THIRD CAUSE FOR DISCIPLINE - SNP (Incomplete Master Formula) (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.2, subds. (e)(4) and (e)(5)) |
| 19 | 25. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are |
| 20 | subject to disciplinary action because Respondent SNP failed to prepare a written master formula |
| 21 | document that includes inactive ingredients to be used, and specific and essential compounding |
| 22 | steps used to prepare the drug, before compounding a drug preparation, as set forth in paragraph |
| 23 | 20, above. (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subds. (e)(4) |
| 24 | and (e)(5).) |
| 25 26 | FOURTH CAUSE FOR DISCIPLINE - SNP (Failure to Maintain Operational Standards and Security) (Bus. & Prof. Code, § 4301, subd. (0); Cal. Code Regs., tit. 16, § 1714, subd. (b)) |
| 27 | 26. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are |
| 28 | subject to disciplinary action because Respondent SNP failed to maintain operational standards |
| | 8 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| ĺ | |
|----------|---|
| 1 | and security. (Bus. & Prof. Code, §§ 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., |
| 2 | tit. 16, § 1714, subd. (b).) The circumstances are set forth in paragraph 21, above. |
| 3 4 | FIFTH CAUSE FOR DISCIPLINE - SNP (Compounding after Renovation without Environmental Sampling) (Bug & Brof, Code SS 4301, subd. (a), and 4126 8) |
| 4 5 | (Bus. & Prof. Code, §§ 4301, subd. (o), and 4126.8) 27. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are |
| 6 | subject to disciplinary action because it engaged compounding sterile preparations after |
| | compounding room renovations without waiting for environmental sampling results as required |
| 7 | |
| 8 | by United States Pharmacopeia-National Formulary (USP), which states that environmental |
| 9 | sampling shall occur as part of a comprehensive quality management program and shall occur |
| 10 | minimally under any of the following conditions: as part of the commissioning and certification |
| 11 | of new facilities and equipment and following any servicing of facilities and equipment. (Bus. & |
| 12 | Prof. Code, §§ 4301, subd. (o), and 4126.8.) The circumstances are described in paragraph 22, |
| 13 | above |
| 14 15 | SIXTH CAUSE FOR DISCIPLINE - SNP (Compounding after PEC Change without Validation of Compounding Personnel) (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B)) |
| 16 | 28. Respondent SNP's Original Pharmacy Permit and Sterile Compounding Permit are |
| 17 | subject to disciplinary action because it engaged in compounding of sterile preparations after a |
| 18 | change in the Primary Engineering Control or compounding environment without first ensuring |
| 19 | that compounding personnel demonstrated competency on aseptic technique and aseptic area |
| 20 | practices. The circumstances are described in paragraph 22, above. (Bus. & Prof. Code, § 4301, |
| 21 | subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B).) |
| 22 | CAUSES FOR DISCIPLINE AGAINST RESPONDENT NASR |
| 23 | |
| 24 | FIRST CAUSE FOR DISCIPLINE - NASR (Incorrect Reconstitution of Compounded Drug Preparation) |
| 25 | (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.2, subd. (g)) |
| 26 | 29. Respondent Nasr's Original Pharmacist License is subject to disciplinary action |
| 27 | because between December 31, 2018 and February 1, 2019, while Respondent Nasr was PIC, |
| 28 | Respondent SNP compounded at least 149 vancomycin sterile preparations with vancomycin |
| | 9 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| 1 | 5gram vials which were reconstituted with 50mls of sterile water rather than the manufacturer's |
|----------|---|
| 2 | instructions of 100mls of sterile water. The circumstances are set forth in paragraph 20, above. |
| 3 | (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code |
| 4 | Regs., tit. 16, § 1735.2, subd. (g).) |
| 5 | |
| 6 7 | SECOND CAUSE FOR DISCIPLINE - NASR (Incomplete Compounding Records) (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D)) |
| 8 | 30. Respondent Nasr's Original Pharmacist License is subject to disciplinary action |
| 9 | because between December 31, 2018, and February 1, 2019, while Respondent Nasr was PIC, |
| 10 | Respondent SNP failed to keep complete compounding records, as set forth in paragraph 20, |
| 11 | above. (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. |
| 12 | Code Regs., tit. 16, § 1735.3, subd. (a)(2)(D).) |
| 13 | |
| 14 15 | THIRD CAUSE FOR DISCIPLINE - NASR (Incomplete Master Formula) (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.2, subds. (e)(4) and (e)(5)) |
| 16 | 31. Respondent Nasr's Original Pharmacist License is subject to disciplinary action |
| 17 | because between December 31, 2018 and February 1, 2019, while Respondent Nasr was PIC, |
| 18 | Respondent SNP failed to prepare a written master formula document that includes inactive |
| 19 | ingredients to be used, and specific and essential compounding steps used to prepare the drug, |
| 20 | before compounding a drug preparation, as set forth in paragraph 20, above. (Bus. & Prof. Code, |
| 21 | §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1735.2, |
| 22 | subds. (e)(4) and (e)(5).) |
| 23 | |
| 24 | FOURTH CAUSE FOR DISCIPLINE - NASR (Failure to Maintain Operational Standards and Security) |
| 25 | (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code Regs., tit. 16, § 1714, subd. (b)) |
| 26 | 32. Respondent Nasr's Original Pharmacist License is subject to disciplinary action |
| 27 | because he failed to maintain operational standards and security while as PIC of Respondent SNP. |
| 28 | (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), 4306.5, subds. (a) and (b); Cal. Code |
| | 10 |
| | SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

| 1 | Regs., tit. 16, § 1714, subd. (b).) The circumstances are set forth in paragraph 21, above. |
|----------|---|
| 2 | FIFTH CAUSE FOR DISCIPLINE - NASR |
| 3 | (Compounding after Renovation without Environmental Sampling) (Bus. & Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), and 4126.8) |
| 4 | 33. Respondent Nasr's Original Pharmacist License is subject to disciplinary action |
| 5 | because as PIC of Respondent SNP he authorized compounding sterile preparations after |
| 6 | compounding room renovations without waiting for environmental sampling results as required |
| 7 | by United States Pharmacopeia-National Formulary (USP), which states that environmental |
| 8 | sampling shall occur as part of a comprehensive quality management program and shall occur |
| 9 | minimally under any of the following conditions: as part of the commissioning and certification |
| 10 | of new facilities and equipment and following any servicing of facilities and equipment. (Bus. & |
| 11 | Prof. Code, §§ 4113, subd. (c), 4301, subd. (o), and 4126.8.) The circumstances are described in |
| 12 | paragraph 22, above. |
| 13 | |
| 14 15 | SIXTH CAUSE FOR DISCIPLINE - NASR (Compounding after PEC Change without Validation of Compounding Personnel) (Bus. & Prof. Code, §§ 4113, subd. (c), and 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B)) |
| 16 | 34. Respondent Nasr's Original Pharmacist License is subject to disciplinary action |
| 17 | because as PIC of Respondent PIC he authorized compounding of sterile preparations after a |
| 18 | change in the Primary Engineering Control or compounding environment without first ensuring |
| 19 | that compounding personnel demonstrated competency on aseptic technique and aseptic area |
| 20 | practices. The circumstances are described in paragraph 22, above. (Bus. & Prof. Code, §§ 4113, |
| 21 | subd. (c), 4301, subd. (o); Cal. Code Regs., tit. 16, § 1751.7, subd. (b)(3)(B).) |
| 22 | DISCIPLINE CONSIDERATIONS |
| 23 | To determine the degree of discipline to be imposed on Respondents, Complainant |
| 24 | further alleges that the Board issued Respondents the below-listed citations, which are now final. |
| 25 | Respondent SNP Only |
| 26 | 35. On or about August 16, 2017, Respondent SNP was issued Citation No. CI 2017 |
| 27 | 75997 for its pharmacy permit and Citation No. CI 2016 7286 for its sterile compounding permit |
| 28 | for the following violations, discovered during an inspection on or about November 2, 2016: |
| | 11 SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR |
| | SECOND AMENDED ACCUSATION |

| 1 | • The annual review of compounding policies and procedures had not been documented |
|----|---|
| 2 | as reviewed by the Pharmacist in Charge, in violation of California Code of |
| 3 | Regulations, title 16, section 1735.5, subdivision (b); |
| 4 | • The weekly cleaning of the walls, ceilings, floors, shelves, tables and stools had not |
| 5 | been documented from March 2016 to October 2016, in violation of California Code |
| 6 | of Regulations, title 16, section 1751.4(d); |
| 7 | • The refrigerator temperatures were outside the stated acceptable temperature range |
| 8 | approximately 38 times between March 2016 and October 2016, in violation of |
| 9 | California Code of Regulations, title, section 1714, subdivision (b); |
| 10 | • Prescription number 7235121 failed to list the inactive ingredient and amount used to |
| 11 | reconstitute the active ingredient, in violation of the California Code of Regulations, |
| 12 | title 16, section 1735.3(a)(5); and |
| 13 | • Prescription number 7235121 failed to list the inactive ingredient manufacturer, lot |
| 14 | number and expiration date used to reconstitute the active ingredient, in violation of |
| 15 | California Code of Regulations, title 16, section 1735.3(a)(6). |
| 16 | 36. On or about May 14, 2020, Respondent SNP was issued Citation No. CI 2018 82624 |
| 17 | regarding its pharmacy permit for failing to review a patient's drug therapy and medication |
| 18 | record, in violation of California Code of Regulations, title 16, section 1707.3, and for failing to |
| 19 | verify an uncertain or erroneous prescription, in violation of California Code of Regulations, title |
| 20 | 16, section 1761. Specifically, on July 11, 2018, SNP pharmacist CN failed to screen for severe |
| 21 | potential drug therapy problems while reviewing RX# 7958076 and dispensing the prescription to |
| 22 | ME without contacting the prescriber to validate the uncertain direction of daily dosing of |
| 23 | methotrexate for the treatment of rheumatoid arthritis; and on July 24, 2018, SNP pharmacist AD |
| 24 | failed to screen for severe potential drug therapy problems while reviewing RX# 7973015 and |
| 25 | dispensing the prescription to ME without contacting the prescriber to validate the uncertain |
| 26 | direction of daily dosing of methotrexate for the treatment of rheumatoid arthritis. ME was |
| 27 | dispensed methotrexate 2.5 mg with directions to take one tablet daily instead of four tablets |
| 28 | weekly, and subsequently suffered from methotrexate toxicity, ultimately resulting in patient |
| | 12 SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR SECOND AMENDED ACCUSATION |

death. Additionally, RX# 7958076 and RX# 7973015 were dispensed pursuant to faxed discharge 1 2 instructions, and not a valid chart order or telephone order from the facility. Furthermore, the dispensing pharmacist failed to contact the prescriber to obtain an oral order or to verify the 3 uncertain order prior to dispensing the prescription. 4

5

RESPONDENTS SNP AND NASR

37. On or about May 21, 2020, Respondent SNP was issued Citation No. CI 2019 87894 6 for its pharmacy permit and Citation No. CI 2019 86128 its sterile compounding permit, and 7 Respondent Nasr was issued Citation No. CI 2019 87893. The basis for the citations was that on 8 9 or about October 30, 2019, Respondents failed to ensure that all equipment used in the designated area or cleanroom was made of a material that could be easily cleaned and disinfected (Cal. Code 10 Regs., tit. 16, § 1751.4, subds. (c) and (e)); and Respondents failed to ensure adequate training of 11 sterile injectable compounding staff (Cal. Code Regs., tit. 16, § 1751.6, subd. (e)(1)). 12 Specifically, a technician failed to properly demonstrate the cleaning of the laminar air flow 13 14 workbench (LAFW) and did not know the cleaning agents required and their dwell times for use. In addition, the technician failed to clean the ceiling and back wall of the LAFW and there was no 15 ceiling panel covering the light fixture allowing staff to clean the ceiling. Furthermore, the 16 pharmacy also had a hole in the ceiling making the ISO 7 buffer room exposed to outside air and 17 a rolling stool with a plastic bag covering the seat making these areas not cleanable surfaces. 18 Finally, the pharmacy failed to have complete training records for all their compounding staff. 19 **OTHER MATTERS** 20

38. Pursuant to section 4307 of the Code, if discipline is imposed on Original Pharmacy 21 Permit Number PHY 49974, issued to SNP Pharmacy LLC., doing business as Skilled Nursing 22 Pharmacy with Brenda Mandelbaum as 50-percent shareholder, Bentzion Mandelbaum as 23 24 President and 25-percent shareholder, and Michelle Mandelbaum as Director and 25-percent shareholder, while Brenda Mandelbaum, Bentzion Mandelbaum, and Michelle Mandelbaum were 25 shareholders of Skilled Nursing Pharmacy and had knowledge of or knowingly participated in 26 any conduct for which Original Pharmacy Permit Number PHY 49974 was disciplined, Brenda 27 Mandelbaum, Bentzion Mandelbaum, and Michelle Mandelbaum shall be prohibited from serving 28 13

| 1 | as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee |
|----|--|
| 2 | for five years if Original Pharmacy Permit Number PHY 49974 is placed on probation or until |
| 3 | Original Permit Number PHY 49974 is reinstated if it is revoked. |
| 4 | PRAYER |
| 5 | WHEREFORE, Complainant requests that a hearing be held on the matters here alleged, |
| 6 | and that following the hearing, the Board of Pharmacy issue a decision: |
| 7 | 1. Revoking or suspending Original Pharmacy Permit Number PHY 49974, issued to |
| 8 | SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy; |
| 9 | 2. Revoking or suspending Sterile Compounding Permit Number LSC 99561, issued to |
| 10 | SNP Pharmacy LLC doing business as Skilled Nursing Pharmacy; |
| 11 | 3. Revoking or suspending Original Pharmacist License Number RPH 78315, issued to |
| 12 | Mina Nasr Ayad Nasr; |
| 13 | 4. Prohibiting Brenda Mandelbaum, Bentzion Mandelbaum, and Michelle Mandelbaum |
| 14 | from serving as a manager, administrator, owner, member, officer, director, associate, or partner |
| 15 | of a licensee for five years if Original Pharmacy Permit Number PHY 49974 is placed on |
| 16 | probation or until Original Pharmacy Permit Number PHY 49974 is reinstated if Original |
| 17 | Pharmacy Permit Number 49974 issued to SNP Pharmacy LLC doing business as Skilled Nursing |
| 18 | Pharmacy, is revoked; |
| 19 | 5. Ordering SNP Pharmacy LLC and Mina Nasr Ayad Nasr to pay the Board of |
| 20 | Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to |
| 21 | Business and Professions Code section 125.3; and, |
| 22 | 6. Taking such other and further action as deemed necessary and proper. |
| 23 | |
| 24 | DATED: 1/24/2022 Signature on File |
| 25 | ANNE SODERGREN Executive Officer |
| 26 | Board of Pharmacy Department of Consumer Affairs |
| 27 | State of California Complainant |
| 28 | OK2020900248 91440354.docx |
| | 14 SNP PHARMACY LLC dba SKILLED NURSING PHARMACY; and MINA NASR AYAD NASR |
| | SECOND AMENDED ACCUSATION |