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

In the Matter of the First Accusation Against: Brenda Laurie Manfredi, M.D. Physician's and Surgeon's Certificate No. G 129943 Respondent.	Case No. 800-2021-074525

DECISION

The attached Stipulated Surrender of License and Disciplinary Order is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on December 16, 2024. IT IS SO ORDERED December 9, 2024.

MEDICAL BOARD OF CALIFORNIA

Reji Varghese
Executive Director

ROB BONTA
Attorney General of California
ALEXANDRA M. ALVAREZ
Supervising Deputy Attorney General
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Attorneys for Complainant

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

In the Matter of the First Amended Accusation Against: **BRENDA LAURIE MANFREDI, M.D.** **6408 Peppermill Dr.** **Oak Ridge, NC 27310-9803** **Physician's and Surgeon's Certificate No. G 129943** Respondent.	Case No. 800-2021-074525 OAH No. 2024040755 **STIPULATED SURRENDER OF LICENSE AND DISCIPLINARY ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Reji Varghese (Complainant) is the Executive Director of the Medical Board of California (Board). He brought this action solely in his official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Karolyn M. Westfall, Deputy Attorney General.

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2. Brenda Laurie Manfredi, M.D. (Respondent) is represented in this proceeding by attorney Ian A. Scharg, Esq., whose address is: 400 University Avenue, Sacramento, CA 95825-6502.

3. On or about April 25, 2014, the Medical Board issued Physician's and Surgeon's Certificate No. G 129943 to Respondent. The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 800-2021-074525. The Physician's and Surgeon's Certificate expired on July 31, 2021, and has not been renewed.

JURISDICTION

4. First Amended Accusation No. 800-2021-074525, which superseded the Accusation filed on January 4, 2024, was filed before the Board and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on March 5, 2024. Respondent timely filed her Notice of Defense contesting the Accusation. A copy of First Amended Accusation No. 800-2021-074525 is attached hereto as Exhibit A and is incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 800-2021-074525. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Disciplinary Order.

6. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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7. Having the benefit of counsel, Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent understands that the charges and allegations in First Amended Accusation No. 800-2021-074525, if proven at a hearing, constitute cause for imposing discipline upon her Physician's and Surgeon's Certificate.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the First Amended Accusation and that those charges constitute cause for discipline. Respondent denies the allegations contained in First Amended Accusation 800-2021-074525; however, Respondent hereby gives up her right to contest that cause for discipline exists based on those charges.

10. Respondent understands that by signing this stipulation she enables the Board to issue an order accepting the surrender of her Physician's and Surgeon's Certificate without further process.

11. Respondent further understands that if she should ever apply or reapply for a new license or certification, or petition for reinstatement of her license, all of the charges and allegations contained in First Amended Accusation No. 800-2021-074525 shall be deemed to be true, correct, and fully admitted by Respondent for the purposes of any such proceeding.

CONTINGENCY

12. Business and Professions Code section 2224, subdivision (b), provides, in pertinent part, that the Medical Board "shall delegate to its executive director the authority to adopt a ... stipulation for surrender of a license."

13. Respondent understands that, by signing this stipulation, she enables the Executive Director of the Board to issue an order, on behalf of the Board, accepting the surrender of her Physician's and Surgeon's Certificate No. G 129943 without further notice to, or opportunity to be heard by, Respondent.

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14. This Stipulated Surrender of License and Disciplinary Order shall be subject to the approval of the Executive Director on behalf of the Board. The parties agree that this Stipulated Surrender of License and Disciplinary Order shall be submitted to the Executive Director for his consideration in the above-entitled matter and, further, that the Executive Director shall have a reasonable period of time in which to consider and act on this Stipulated Surrender of License and Disciplinary Order after receiving it. By signing this stipulation, Respondent fully understands and agrees that she may not withdraw her agreement or seek to rescind this stipulation prior to the time the Executive Director, on behalf of the Medical Board, considers and acts upon it.

15. The parties agree that this Stipulated Surrender of License and Disciplinary Order shall be null and void and not binding upon the parties unless approved and adopted by the Executive Director on behalf of the Board, except for this paragraph, which shall remain in full force and effect. Respondent fully understands and agrees that in deciding whether or not to approve and adopt this Stipulated Surrender of License and Disciplinary Order, the Executive Director and/or the Board may receive oral and written communications from its staff and/or the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the Executive Director, the Board, any member thereof, and/or any other person from future participation in this or any other matter affecting or involving respondent. In the event that the Executive Director on behalf of the Board does not, in his discretion, approve and adopt this Stipulated Surrender of License and Disciplinary Order, with the exception of this paragraph, it shall not become effective, shall be of no evidentiary value whatsoever, and shall not be relied upon or introduced in any disciplinary action by either party hereto. Respondent further agrees that should this Stipulated Surrender of License and Disciplinary Order be rejected for any reason by the Executive Director on behalf of the Board, Respondent will assert no claim that the Executive Director, the Board, or any member thereof, was prejudiced by its/his/her review, discussion and/or consideration of this Stipulated Surrender of License and Disciplinary Order or of any matter or matters related hereto.

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ADDITIONAL PROVISIONS

16. This Stipulated Surrender of License and Disciplinary Order is intended by the parties herein to be an integrated writing representing the complete, final and exclusive embodiment of the agreements of the parties in the above-entitled matter.

17. The parties agree that copies of this Stipulated Surrender of License and Disciplinary Order, including copies of the signatures of the parties, may be used in lieu of original documents and signatures and, further, that such copies shall have the same force and effect as originals.

18. In consideration of the foregoing admissions and stipulations, the parties agree the Executive Director of the Board may, without further notice to or opportunity to be heard by Respondent, issue and enter the following Disciplinary Order on behalf of the Board:

ORDER

IT IS HEREBY ORDERED that Physician's and Surgeon's Certificate No. G 129943, issued to Respondent Brenda Laurie Manfredi, is surrendered and accepted by the Board.

1. The surrender of Respondent's Physician's and Surgeon's Certificate and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

2. Respondent shall lose all rights and privileges as a physician and surgeon in California as of the effective date of the Board's Decision and Order.

3. Respondent shall cause to be delivered to the Board her pocket license and, if one was issued, her wall certificate on or before the effective date of the Decision and Order.

4. If Respondent ever files an application for licensure or a petition for reinstatement in the State of California, the Board shall treat it as a petition for reinstatement. Respondent must comply with all the laws, regulations, and procedures for reinstatement of a revoked or surrendered license in effect at the time the petition is filed, and all of the charges and allegations contained in First Amended Accusation No. 800-2021-074525 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the petition.

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5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of $60,330.00 (sixty thousand three hundred thirty dollars, and zero cents) prior to issuance of a new or reinstated license.

6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in First Amended Accusation No. 800-2021-074525 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Disciplinary Order and have fully discussed it with my attorney Ian A. Scharg, Esq. I understand the stipulation and the effect it will have on my Physician's and Surgeon's Certificate. I enter into this Stipulated Surrender of License and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Medical Board of California.

DATED: 11/22/2024

BRENDA LAURIE MANFREDI, M.D.
Respondent

I have read and fully discussed with Respondent Brenda Laurie Manfredi, M.D., the terms and conditions and other matters contained in this Stipulated Surrender of License and Disciplinary Order. I approve its form and content.

DATED: 11/22/2024

IAN A. SCHARG, ESQ.
Attorney for Respondent

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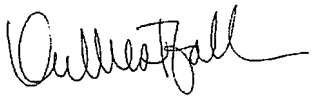
ENDORSEMENT

The foregoing Stipulated Surrender of License and Disciplinary Order is hereby respectfully submitted for consideration by the Medical Board of California of the Department of Consumer Affairs.

DATED: 12/3/24

Respectfully submitted,

ROB BONTA
Attorney General of California
ALEXANDRA M. ALVAREZ
Supervising Deputy Attorney General



KAROLYN M. WESTFALL
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 800-2021-074525

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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
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STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **BRENDA LAURIE MANFREDI, M.D.** **6408 Peppermill Dr.** **Oak Ridge, NC 27310-9803** **Physician's and Surgeon's Certificate No. G 129943,** Respondent.	Case No. 800-2021-074525 **FIRST AMENDED ACCUSATION**

PARTIES

1. Reji Varghese (Complainant) brings this First Amended Accusation solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about April 25, 2014, the Medical Board issued Physician's and Surgeon's Certificate No. G 129943 to Brenda Laurie Manfredi, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein. The Physician's and Surgeon's Certificate expired on July 31, 2021, and has not been renewed.

JURISDICTION

3. This First Amended Accusation, which supersedes the Accusation filed on January 4, 2024, is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 118 of the Code states, in pertinent part:

...

(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

...

5. Section 2227 of the Code states, in pertinent part:

(a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the board, may, in accordance with the provisions of this chapter:

(1) Have his or her license revoked upon order of the board.

(2) Have his or her right to practice suspended for a period not to exceed one year upon order of the board.

(3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the board.

(4) Be publicly reprimanded by the board. The public reprimand may include a requirement that the licensee complete relevant educational courses approved by the board.

(5) Have any other action taken in relation to discipline as part of an order of probation, as the board or an administrative law judge may deem proper.

...

6. Section 2228.1 of the Code states.

(a) On and after July 1, 2019, except as otherwise provided in subdivision (c), the board and the Podiatric Medical Board of California shall require a licensee to provide a separate disclosure that includes the licensee's probation status, the length of the probation, the probation end date, all practice restrictions placed on the licensee

by the board, the board's telephone number, and an explanation of how the patient can find further information on the licensee's probation on the licensee's profile page on the board's online license information internet web site, to a patient or the patient's guardian or health care surrogate before the patient's first visit following the probationary order while the licensee is on probation pursuant to a probationary order made on and after July 1, 2019, in any of the following circumstances:

(1) A final adjudication by the board following an administrative hearing or admitted findings or prima facie showing in a stipulated settlement establishing any of the following:

(A) The commission of any act of sexual abuse, misconduct, or relations with a patient or client as defined in Section 726 or 729.

(B) Drug or alcohol abuse directly resulting in harm to patients or the extent that such use impairs the ability of the licensee to practice safely.

(C) Criminal conviction directly involving harm to patient health.

(D) Inappropriate prescribing resulting in harm to patients and a probationary period of five years or more.

(2) An accusation or statement of issues alleged that the licensee committed any of the acts described in subparagraphs (A) to (D), inclusive, of paragraph (1), and a stipulated settlement based upon a nolo contendre or other similar compromise that does not include any prima facie showing or admission of guilt or fact but does include an express acknowledgment that the disclosure requirements of this section would serve to protect the public interest.

(b) A licensee required to provide a disclosure pursuant to subdivision (a) shall obtain from the patient, or the patient's guardian or health care surrogate, a separate, signed copy of that disclosure.

(c) A licensee shall not be required to provide a disclosure pursuant to subdivision (a) if any of the following applies:

(1) The patient is unconscious or otherwise unable to comprehend the disclosure and sign the copy of the disclosure pursuant to subdivision (b) and a guardian or health care surrogate is unavailable to comprehend the disclosure and sign the copy.

(2) The visit occurs in an emergency room or an urgent care facility or the visit is unscheduled, including consultations in inpatient facilities.

(3) The licensee who will be treating the patient during the visit is not known to the patient until immediately prior to the start of the visit.

(4) The licensee does not have a direct treatment relationship with the patient.

(d) On and after July 1, 2019, the board shall provide the following information, with respect to licensees on probation and licensees practicing under probationary licenses, in plain view on the licensee's profile page on the board's online license information internet web site.

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(1) For probation imposed pursuant to a stipulated settlement, the causes alleged in the operative accusation along with a designation identifying those causes by which the licensee has expressly admitted guilt and a statement that acceptance of the settlement is not an admission of guilt.

(2) For probation imposed by an adjudicated decision of the board, the causes for probation stated in the final probationary order.

(3) For a licensee granted a probationary license, the causes by which the probationary license was imposed.

(4) The length of the probation and end date.

(5) All practice restrictions placed on the license by the board.

(e) Section 2314 shall not apply to this section.

7. Section 2234 of the Code, states, in pertinent part:

The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.

(b) Gross negligence.

(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

(2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

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8. Section 2266 of the Code states: The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.

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9. Section 725 of the Code states:

(a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, optometrist, speech-language pathologist, or audiologist.

(b) Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both that fine and imprisonment.

(c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution under this section.

(d) No physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with Section 2241.5.

COST RECOVERY

10. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licensee to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

11. Respondent has subjected her Physician's and Surgeon's Certificate No. G 129943 to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (b), of the Code, in that Respondent was grossly negligent in her care and treatment of Patients 1, 2, and 3,[1] as more particularly alleged hereinafter:

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[1] To protect the privacy of the patients involved, the patients' names have not been included in this pleading. Respondent is aware of the identity of the patients referred to herein.

PATIENT 1

12. On or about February 16, 2015,[2] Patient 1, a then twenty-three-year-old male, presented to Respondent for an initial visit and medication refill. Patient 1 had a complicated medical history that included multiple serious injuries from a motor vehicle accident in 2009, including, but not limited to, femur fractures, tibial and fibial fractures, splenic rupture, pulmonary contusion, pneumothorax, transection of the distal aorta, tears of the small bowel and sigmoid colon, and colostomy (with subsequent reversal). Patient 1 had previously seen pain management and was told to take ibuprofen or Tylenol as needed for pain. Patient 1 informed Respondent that he had recovered fairly well from his injuries, and reported that most of his pain was in his left ankle and both knees. At the conclusion of the visit, Respondent prescribed Patient 1 Norco [3] for pain.

13. Between on or about February 16, 2015, and on or about August 22, 2019, Respondent provided care and treatment to Patient 1 that included monthly prescriptions of Norco.

14. Between on or about February 16, 2015, and on or about August 22, 2019, Respondent did not utilize any risk assessment tools for the prescribing of long-term use of opioids to Patient 1, did not classify Patient 1's risk of long-term opioid use, did not specify measurable goals and objectives to evaluate Patient 1's treatment progress, and did not prepare an exit strategy for discontinuing controlled substance therapy in the event that tapering or termination of controlled substances became necessary.

15. Between on or about February 16, 2015, and on or about August 22, 2019, Patient 1 exhibited signs or "red flags" of abuse/misuse and addiction. For example, on or about July 17, 2015, Patient 1 had admitted to unsanctioned controlled substance use by stating that he was

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[2] Any facts alleged to have occurred more than seven years prior to the filing of Accusation No. 800-2021-074525 are for informational purposes only and are not alleged as a basis for discipline.

[3] Norco (brand name for Hydrocodone-Acetaminophen combination) is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e), and a dangerous drug pursuant to section 4022 of the Code. It is an opioid medication used to treat pain.

taking oxazepam,[4] although it was unclear where he had obtained that medication. From approximately January 2017 through May 2018, CURES[5] reports reveal at least five early refills of Patient 1's controlled medications. Also, from approximately November 2015 through August 2019, records showed multiple instances when Patient 1 reported that he had either taken more medication than recommended by Respondent, or needed more of his pain medication for various reasons. In addition, on or about August 22, 2019, Patient 1 informed Respondent that he was recently taken to the emergency room after taking drugs with friends.

16. Between on or about February 16, 2015, and on or about August 22, 2019, Respondent did not evaluate Patient 1's progress toward any treatment objectives. Patient 1's pain levels described were vague, frequently failed to specifically describe the anatomical location of pain, quality of pain, timing of pain, palliation, and provocation of pain. Respondent also failed to consistently evaluate other treatment goals such as Patient 1's activity level (functional goals), adverse effects (side effects), aberrant behaviors (signs of drug or alcohol use, unsanctioned dose escalation, and early refill requests), and affect (changes to mood, depression or anxiety).

17. Between on or about February 16, 2015, and on or about August 22, 2019, Respondent failed to discuss and/or document a discussion with Patient 1 regarding the potential risks of long-term opioid use. When Respondent was made aware that Patient 1 drank alcohol, Respondent did not discuss and/or document a discussion with Patient 1 regarding the added risk of the combination of opioids and alcohol. Additionally, Respondent did not discuss and/or document a discussion with Patient 1 regarding the risk of dependence, misuse, addiction, or overdose. Although Respondent documented that she reviewed CURES, there was no

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[4] Oxazepam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to section 4022 of the Code. It is a benzodiazepine medication used to treat anxiety, depression, and symptoms of alcohol withdrawal.

[5] CURES is the Controlled Substances Utilization Review and Evaluation System (CURES), a database maintained by the Department of Justice of Schedule II, III, IV, and V controlled substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement.

documentation that Respondent utilized drug screens or pill counting, despite learning of the "red flags" described above, which should have prompted a higher level of scrutiny from Respondent.

18. On or about October 22, 2019, Patient 1 died as a result of acute mixed polysubstance intoxication/drug overdose (cocaine, fentanyl, diazepam, and alcohol).

19. Respondent committed gross negligence in her care and treatment of Patient 1, which included, but was not limited to, the following:

A. Prescribing long-term opioids without establishing measurable treatment goals and objectives;

B. Prescribing long-term opioids without utilizing appropriate objectives to evaluate the patient's controlled substance needs;

C. Prescribing long-term opioids without discussing and/or documenting a discussion regarding the risks and benefits of the medications; and

D. Prescribing long-term opioids without appropriately monitoring compliance.

PATIENT 2

20. On or about June 30, 2015, Patient 2, a then fifty-year-old female, presented to Respondent for an initial visit. Patient 2 had a complicated medical history that included gastric bypass surgery in 2000 that resulted in malnutrition and malabsorption, heart, liver, and kidney failure in 2009, and terminal stage 4 non-alcoholic liver cirrhosis[6] diagnosed in 2010. Patient 2 complained of right upper quadrant pain and swelling. At the conclusion of the visit, Respondent maintained Patient 2 on prescriptions of temazepam[7], methadone[8], and hydromorphone.[9]

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[6] In the pain management of patients with liver cirrhosis, opiates should be avoided or used sparingly at low and infrequent doses because of the risk of precipitating hepatic encephalopathy.

[7] Temazepam (brand name Restoril) is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d), and a dangerous drug pursuant to section 4022 of the Code. It is a benzodiazepine medication used to treat insomnia.

[8] Methadone is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c), and a dangerous drug pursuant to section 4022 of the Code. It is an opioid medication used to treat pain.

[9] Hydromorphone (brand name Dilaudid) is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b), and a dangerous drug pursuant to section

21. Between on or about June 30, 2015, and on or about July 17, 2020, Respondent provided care and treatment to Patient 2 that included monthly prescriptions of opioids that ranged from approximately 1446 to 2083 MME daily.[10] Between on or about June 30, 2015, and on or about February 13, 2017, Respondent maintained Patient 2 on monthly prescriptions of temazepam for insomnia.[11]

22. Between on or about June 30, 2015, and on or about July 17, 2020, Respondent did not utilize any risk assessment tools for the prescribing of long-term use of opioids to Patient 2, did not classify Patient 2's risk of long-term opioid use, did not specify measurable goals and objectives to evaluate Patient 2's treatment progress, and did not prepare an exit strategy for discontinuing controlled substance therapy in the event that tapering or termination of controlled substances became necessary.

23. Between on or about June 30, 2015, and on or about July 17, 2020, Patient 2 exhibited signs or "red flags" of abuse and misuse. For example, Patient 2 requested early refills of her controlled substances on numerous occasions (e.g., CURES shows that there were seven early refills from approximately May 2016 through February 2021), utilized more than one pharmacy on multiple occasions, and would sometimes take more pain medication than prescribed. Patient 2 also had an inconsistent drug screen, reported multiple falls/injuries, memory loss/confusion, slurred words, dizziness, burns, constipation, and insomnia. On or about July 17, 2020, Patient 2 even reported that she could no longer see.[12]

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4022 of the Code. It is an opioid medication used to treat pain.

[10] Morphine Milligram Equivalents (MME) is an opioid dosage equivalency to morphine. The MME/day metric is often used as a gauge of the overdose potential of the amount of opioid that is being given at a particular time. Patients taking 50 or greater MME daily are more at risk for problems related to opioid use.

[11] Long term use of benzodiazepines (i.e. greater than one month) increases the patient's risk for cognitive impairment, motor impairment, and memory loss.

[12] Chronic use of high-dose opioids can affect cognitive functions. It should also be noted that a different doctor treated Patient 2 after July 2020. Specifically, this doctor (Dr. D) noted that Patient 2's care had long been complicated by chronic high-dose opioid usage, and that a reduction in opioid dose had substantially improved the patient's cognition and mental clarity.

24. Between on or about June 30, 2015, and on or about July 17, 2020, Respondent did not adequately utilize objectives to fully evaluate Patient 2's controlled substance needs such as describing the patient's pain level, activity level, adverse effects, aberrant behaviors, and affect. Respondent did not discuss and/or document a discussion with Patient 2 regarding the risks and benefits of opioids or benzodiazepines. Although Respondent documented that she had reviewed CURES, there was no evidence that Respondent acknowledged the concerns for Patient 2's use of multiple pharmacies and early refills. Moreover, although the records show that one drug screen was completed on or about November 13, 2019, Respondent failed to adequately address the possible inconsistent result when Patient 2 tested negative for opioids while taking hydromorphone.

25. On or about October 17, 2020, Patient 2 died as a result of complications of severe liver cirrhosis.

26. Respondent committed gross negligence in her care and treatment of Patient 2, which included, but was not limited to, the following:

A. Prescribing excessive amounts of opioids despite the patient reporting memory loss/ impairment, slurring words, dizziness, falls, burns, head injuries, constipation, and insomnia;

B. Prescribing long-term benzodiazepines for insomnia;

C. Prescribing long-term opioids without establishing measurable treatment goals and objectives;

D. Prescribing long-term opioids and benzodiazepines simultaneously;

E. Prescribing long-term opioids without utilizing appropriate objectives to evaluate the patient's controlled substance needs;

F. Prescribing long-term opioids and benzodiazepines without discussing and/or documenting a discussion regarding the risks and benefits of the medications; and

G. Prescribing long-term opioids without appropriately monitoring compliance.

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PATIENT 3

27. On or about November 23, 2016, Patient 3, a then sixty-four-year-old female, presented to Respondent for a follow-up visit.[13] Patient 3 had a medical history that included chronic pain, chronic headaches, insomnia, fibromyalgia, depression, cervical spine stenosis, panic anxiety syndrome, and kidney dysfunction. Patient 3 also had a history of CSF (cerebral spinal fluid) leak, as well as an unknown neurological issue which caused muscle spasms, falls, tremors, leg and muscle jerking, and an abnormal gait. At this visit, Patient 3 complained of pain, insomnia, and depression. Patient 3 also reported recently hitting her head from a fall backwards. At the conclusion of the visit, Respondent prescribed Patient 3 Norco.

28. Between on or about November 26, 2016, and on or about September 27, 2019, Respondent provided care and treatment to Patient 3 that included monthly prescriptions of Norco.

29. Between on or about November 26, 2016, and on or about September 27, 2019, Patient 3 was assessed with narcotic dependence, and was also seen by multiple specialists including neurologists, neurosurgeons, and a rheumatologist.

30. Between on or about November 26, 2016, and on or about September 27, 2019, Respondent did not utilize any risk assessment tools for the prescribing of long-term use of opioids to Patient 3, did not classify Patient 3's risk of long-term opioid use, did not specify measurable goals and objectives to evaluate Patient 3's treatment progress, and did not prepare an exit strategy for discontinuing controlled substance therapy in the event that tapering or termination of controlled substances became necessary.

31. Between on or about November 26, 2016, and on or about September 27, 2019, Patient 3 exhibited signs or "red flags" of abuse, misuse and/or diversion. For example, Patient 3 reported having multiple falls, confusion and memory loss (e.g., worsening cognitive function,

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[13] Respondent began providing treatment to Patient 3 sometime before this date.

losing time, sleepwalking, loss/lapse of consciousness,[14] etc.), and requested early medication refills.

32. Between on or about November 26, 2016, and on or about September 27, 2019, Respondent failed to discuss and/or document a discussion with Patient 3 regarding the potential risks of long-term opioid use and/or risk of dependence, misuse, addiction, and overdose. Additionally, there was no documentation that Respondent utilized compliance monitoring tools such as drug screens and pill counts, despite Patient 3 having a documented opioid dependence, stating that she often did not use her medication as directed, and demonstrating multiple concerning symptoms such as tremors, frequent falls, and mental confusion despite no definitive neurological diagnosis.

33. Between on or about November 26, 2016, and on or about September 27, 2019, Respondent did not evaluate Patient 3's progress toward any treatment objectives. Patient 3's pain levels remained virtually constant throughout the treatment period. The pain levels described were vague, frequently failed to specifically describe the anatomical location of pain, quality of pain, timing of pain, palliation, and provocation of pain. Respondent failed to consistently evaluate other treatment goals such as Patient 3's activity level (functional goals), adverse effects/side effects, aberrant behaviors (unsanctioned dose escalation, and early refill requests), and Patient 3's affect (changes to mood, depression or anxiety).

34. Respondent committed gross negligence in her care and treatment of Patient 3, which included, but was not limited to, the following:

A. Prescribing long-term opioids without establishing measurable treatment goals and objectives;

B. Prescribing long-term opioids without utilizing appropriate objectives to evaluate the patient's controlled substance needs;

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[14] It is the standard of care for a medical provider in the state of California, when made aware of a patient's disorder characterized by lapses of consciousness, to report immediately to the local health officer, providing the patient information for the purpose of notifying the Department of Motor Vehicles (DMV). There was no documentation that Respondent complied with this mandatory reporting requirement for Patient 3.

C. Prescribing long-term opioids without discussing and/or documenting a discussion regarding the risks and benefits of the medications;

D. Prescribing long-term opioids without appropriately monitoring compliance; and

E. Failing to report the patient's loss of consciousness to authorities.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

35. Respondent has further subjected her Physician's and Surgeon's Certificate No. G 129943 to disciplinary action under sections 2227 and 2234, as defined by section 2234, subdivision (b), of the Code, in that Respondent committed repeated negligent acts in her care and treatment of Patients 1, 2, and 3, as more particularly alleged in paragraphs 11 through 34(E), above, which are hereby incorporated by reference and realleged as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Excessive Prescribing)

36. Respondent has further subjected her Physician's and Surgeon's Certificate No. G 129943 to disciplinary action under sections 2227 and 725, of the Code, in that Respondent excessively prescribed dangerous drugs to Patient 2, as more particularly alleged in paragraphs 20 through 26(G), above, which are hereby incorporated by reference and realleged as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Medical Records)

37. Respondent has further subjected her Physician's and Surgeon's Certificate No. G 129943 to disciplinary action under sections 2227 and 2234, as defined by section 2266, of the Code, in that Respondent failed to maintain adequate and accurate records regarding her care and treatment of Patients 1, 2, and 3, as more particularly alleged in paragraphs 11 through 34(E), above, which are hereby incorporated by reference and realleged as if fully set forth herein.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician's and Surgeon's Certificate No. G 129943, issued to Respondent Brenda Laurie Manfredi, M.D.;

2. Revoking, suspending or denying approval of Respondent Brenda Laurie Manfredi, M.D.'s authority to supervise physician assistants and advanced practice nurses;

3. Ordering Respondent Brenda Laurie Manfredi, M.D., to pay the Board the costs of the investigation and enforcement of this case, and if placed on probation, the costs of probation monitoring;

4. Ordering Respondent Brenda Laurie Manfredi, M.D., if placed on probation, to provide patient notification in accordance with Business and Professions Code section 2228.1; and

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

DATED: MAY 13 2024

REJI VARGHESE
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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