BEFORE THE ARIZONA MEDICAL BOARD

In the Matter of	Case No.22A-27651-MDX
SHEILA R. MANE, M.D., Holder of License No. 27651 For the Practice of Allopathic Medicine In the State of Arizona.	**FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

On April 5, 2023, this matter came before the Arizona Medical Board ("Board") for consideration of Administrative Law Judge ("ALJ") Sondra J. Vanella's proposed Findings of Fact, Conclusions of Law and Recommended Order. Sheila R. Mane, M.D., ("Respondent") appeared on her own behalf; Assistant Attorney General Carrie Smith represented the State. Assistant Attorney General Diane DeDea was available to provide independent legal advice to the Board.

The Board, having considered the ALJ's Decision and the entire record in this matter, hereby issues the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. The Arizona Medical Board ("Board") is the authority for the regulation and control of the practice of allopathic medicine in the State of Arizona.

2. Respondent Sheila R. Mane, M.D. is the holder of License No. 27651 for the practice of allopathic medicine in Arizona.

3. On October 19, 2022, the Board issued a Complaint and Notice of Hearing For Letter of Reprimand and Probation to Dr. Mane alleging Dr. Mane had engaged in unprofessional conduct pursuant to A.R.S. § 32-1401(27)(e) ("[f]ailing or refusing to maintain adequate records on patients") and A.R.S. § 32-1401(27)(r) ("[c]omitting any conduct or practice that is or might be harmful or dangerous to the health of the patient or the public").

MD-18-0299A

4. Raquel Rivera, Manager of Investigations for the Board, provided foundation for the admission of the Board's exhibits.

5. On or about March 29, 2018, the Board received a complaint about Dr. Mane's care and treatment of patient JB.[1] The complaint alleged that JB was admitted to Kingman Regional Medical Center for altered mental status and that Dr. Mane was overprescribing controlled substances to JB.[2]

6. On or about March 29, 2018, the Board sent a letter to Dr. Mane informing her of the complaint and provided her with a copy of the complaint.[3]

7. On or about April 19, 2018, the Board sent a letter to Dr. Mane directing her to provide a written response as to the complaint of "[i]nappropriate prescribing of controlled substances" to patient JB. Further, the letter directed Dr. Mane to provide a "**copy of the patient[ ] [JB's] complete medical chart AND any images**" to the Board.[4]

8. On or about April 26, 2018, Dr. Mane responded to the Board's letter and provided JB's medical records to the Board.[5] Those medical records disclosed that Dr. Mane provided eight (8) consultations to JB from December 20, 2016, to April 18, 2018.[6]

9. On or about October 19, 2018, the Board's medical consultant, Dr. Mark Zaetta, provided his Medical Consultant Report and Summary opining on Dr. Mane's care and treatment of patient JB.[7]

10. On or about November 1, 2018, the Board sent a letter to Dr. Mane informing her that the Board's investigation was near completion and provided her a web link to review all reports and investigative materials used in the investigation and to respond to any of the materials.[8]

11. On or about December 10, 2018, Dr. Mane, through counsel, responded to the Board's November 1, 2018 letter.[9]

12. On or about January 6, 2019, Dr. Zaetta provided his Supplemental Report and Summary in response to Dr. Mane's December 10, 2018 response.[10]

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[1] *See* Board's Exhibit 1.
[2] *Id.*
[3] *Id.*
[4] *See* Board's Exhibit 2. Emphasis in original.
[5] *See* Board's Exhibit 4.
[6] *Id.*
[7] *See* Board's Exhibit 6.
[8] *See* Board's Exhibit 7.
[9] *See* Board's Exhibit 8.

Dr. Mark Zaetta's Testimony

13. Dr. Zaetta testified regarding his credentials and experience in treating patients over the age of 65. Dr. Zaetta testified that he prescribes controlled substances to less than ten percent of his patients and that he prescribes "as few as possible because of the risks of the medications." Dr. Zaetta explained that there is a higher risk of adverse effects from controlled substances in the elderly population, as well as a higher "drug to drug interaction" due to the decrease in metabolism in an elderly patient. Therefore, lower doses should be used due to the decreased ability for an elderly patient's body to break down the medication.

14. Dr. Zaetta testified that the Beers List is an ongoing list of "highly hazardous medications that should be avoided in the elderly" and that all benzodiazepines and opioids are on the list. Dr. Zaetta opined that physicians should be aware of the risks that outweigh the benefits of certain medications. Dr. Zaetta testified that physicians should document in their respective patients' charts the reasons for prescribing controlled substances and the risks involved.

15. Dr. Zaetta also testified that he utilizes a controlled substances medication agreement with his patients that sets forth the criteria that must be followed by the patient. Dr. Zaetta testified regarding some of the criteria that are contained in the controlled substances medication agreement, including that a patient must only obtain such prescriptions from a single provider, the medications must be refilled at the same pharmacy, there are no early refills, and random urinalysis are conducted to determine compliance and not diversion. Dr. Zaetta testified that he does not prescribe opioids and benzodiazepines simultaneously due to the significant side effects, drug interactions, and abuse potential. If a patient violates the agreement, they are discharged from the practice with a thirty (30) day notice. Dr. Zaetta opined that this is "best practice" to protect the physician and to have an honest partnership with the patient.

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[10] *See* Board's Exhibit 9.

16. Dr. Zaetta further testified that he sometimes treats patients who are already taking both opioids and benzodiazepines, because they have been referred from other physicians. When that occurs, he has a "heart to heart conversation" with them and has them sign a controlled medication agreement that is put into effect immediately. Dr. Zaetta testified that he delegates his medical assistant to check the Controlled Substance Prescription Monitoring Program ("CSPMP"), a statewide database for controlled medications, for each patient to see the prescribing history and if there are any overlapping prescriptions.

JB's Hospitalization

17. Dr. Zaetta testified that he reviewed the hospital records for JB including the list of JB's medications which included three controlled substances, Diazepam, Zolpidem, and Lorazepam, as well as Risperidone, an anti-psychotic.[11] The medication list further included Glipizide, a diabetes medication that is also on the Beers List. Dr. Zaetta testified that benzodiazepines are not preferred medications for insomnia, a diagnosis that Dr. Mane was attempting to address for JB. Therefore, four of JB's medications appear on the Beers List and can interact with one another.

18. Dr. Zaetta testified that the emergency room physician diagnosed JB with moderate chronic obstructive pulmonary disease ("COPD"), dehydration, and altered mental status.[12]

19. Dr. Mane's hospital notes for JB dated March 26, 2018, show that Dr. Mane examined JB at the emergency room.[13] In the progress notes, Dr. Mane listed JB's chief complaint as "[a]ltered mental status."[14] Dr. Mane listed JB's home medications as follows: Atorvastatin, Diazepam, Glipizide, Ibuprofen, Lorazepam, Losartan, Metformin, Risperidone, and Zolpidem.[15]

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[11] *See* Exhibit 5 at 67.
[12] *Id.* at 81.
[13] See Board's Exhibit 5 at 111.
[14] *Id.*
[15] *Id.* at 111-112.

20. Dr. Mane's progress notes dated March 28, 2018, stated that JB's altered mental status was improving and the plan was to discontinue Valium. As for the insomnia, Dr. Mane stated that the clinical status was stable and the plan was to prescribe Xanax.[16]

21. Dr. Zaetta testified that in his opinion, JB was prescribed too many benzodiazepines by Dr. Mane, that one drug should have been sufficient, and three to four overlapping drugs of this type is potentially dangerous. Dr. Zaetta testified that various benzodiazepines have different half-lives and that given JB's age, the amount prescribed by Dr. Mane could create confusion, be sedative and create a fall risk. Dr. Zaetta testified that Xanax is prescribed for anxiety and is not a sleep aid. Dr. Zaetta testified that it is not the standard of care to prescribe more than one benzodiazepine and that Xanax, Lorazepam and Diazepam are all benzodiazepines.

22. Dr. Zaetta testified that Dr. Mane's hospital notes do not document as to why changes in medication were made.[17] Dr. Zaetta explained that the reasons for medication changes need to be documented, and that if JB's altered mental status was to be relieved by the discontinuation of Valium, that should be noted. Further, there was no reason documented as to why Dr. Mane chose to prescribe Xanax to treat JB's insomnia.

23. On March 29, 2018, Dr. Mane's hospital note indicated that JB has altered mental state, to discontinue Valium, and administer Ativan as needed.[18] Ativan and Xanax are both benzodiazepines. Dr. Zaetta opined that again, too many benzodiazepines were prescribed for JB and there was no explanation for the change in medication in Dr. Mane's notes.

24. Dr. Zaetta also testified that Dr. Mane failed to note that JB had a history of smoking 80 packs of cigarettes per year and that such should be part of JB's history as it is "probably significant." Dr. Zaetta explained that because smoking is an addictive behavior, JB had a higher risk for addictive behavior that involves controlled substances.

25. Dr. Zaetta testified in reference to Dr. Mane's March 29, 2018 hospital notes, that JB's benzodiazepine use could have been a contributing factor to JB's noted unstable clinical status and that JB's noted hypercapnic respiratory failure could have been

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[16] Id. at 134-135.
[17] *Id.* at 134-135.

worsened by the medications because they slow a patient's breathing.[19] Dr. Zaetta testified that Dr. Mane's note regarding insomnia inferred that the multiple psychoactive drugs taken by JB could be the cause of his altered mental status.[20]

26. Dr. Zaetta also testified regarding JB's mental status examination conducted in the hospital by Dr. Narcedallia Zegarra on April 2, 2018, the notes for which state: "1. Delirium, multifactorial most likely [due] to medications, metabolic resolving[;] 2. Benzodiazepine use, prescribed for anxiety control[;] 3. Anxiety disorder [;] 4. Rule out cognitive disorder."[21]

27. Dr. Zegarra recommended that: i) JB's need for medications be revaluated; ii) JB's use of benzodiazepines be reassessed as they may be contributing to his cognitive changes, falling, and muscle weakness; iii) Diazepam be discontinued; iv) the gradual tapering of Lorazepam; and v) lowering JB's dosage of Zolpidem.[22]

28. On that same date, JB underwent the Montreal Cognitive Assessment ("MCA"). JB scored 18 out of 30 on the MCA, which indicated cognitive impairment.[23] Dr. Zaetta testified that he believes the benzodiazepines that JB was taking contributed to his low score.

29. On April 3, 2018, JB had his second psychiatric consultation with Dr. Zegarra. Dr. Zegarra wrote in the consultation notes that JB's attention and concentration had improved since their last consultation, however, JB's "thought process remains with some intermittent confusion. . ." and that JB's delirium was multifactorial and may be resolving "possibly due to metabolic and medications."[24] Dr. Zegarra recommended "tapering the benzodiazepine until discontinuation, due to adverse effects of cognitive changes and anxiety and falling."[25]

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[18] *Id.* at 140.
[19] *Id.* at 147.
[20] *Id.*
[21] *Id.* at 175.
[22] *Id.* at 175-176.
[23] *Id.* at 177.
[24] *Id.* at 178.
[25] *Id.* at 178-179.

30. Dr. Zaetta's October 19, 2018 Report and Summary set forth that on March 25, 2018, JB, a 67 year-old male, was taken by ambulance to the emergency room for altered mental status.[26] JB lived alone and had a recent history of weakness and falling. While in the hospital for a period of ten days, JB underwent a psychiatric consultation with Dr. Zegarra who found that JB was "experiencing delirium 'most likely from medications,'" and that JB's condition "appeared to improve with tapering and withdrawal of offending medications during his inpatient stay . . . The prescription medications that deserved the most focus were the pre-hospital usage of the benzodiazepines, Diazepam and Lorazepam, as well as the sleep aid Zolpidem. All of these prescriptions are potentially habit forming, with drug interactions and know[n] risks to the elderly for falls and confusion."[27]

31. Dr. Zaetta stated in his October 19, 2018 Report and Summary that Dr. Mane deviated from the standard of care in treating JB as follows:

> [JB] had been prescribed large and overlapping quantities of the benzodiazepines diazepam and lorazepam along with the sleep aid zolpidem. A dispensed quantity of #360 diazepam, #180 lorazepam, and #90 zolpidem were filled within 3 months of the hospitalization under review. Justification for these prescriptions is not available for my review as office notes from Dr. Mane were not provided. However, in her licensee response letter she states that these medications were prescribed for insomnia. The dosing sig on these prescriptions did not match the indicating diagnosis . . . All of these medications exceed the recommended dose and duration for usage . . .[28]

32. In his Report and Summary, Dr. Zaetta identified actual harm to JB as his mental status changes were "greatly influenced by the use of the controlled pharmaceuticals. . . Limiting or avoiding use of these medications would have likely prevented the admission . . ."[29]

33. Dr. Zaetta identified the potential harm to JB as: "inappropriate prescribing practices for the controlled medications in question could have led to a disabling or life

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[26] *See* Board's Exhibit 6.
[27] *Id.*
[28] *Id.*
[29] *Id.*

threatening fall at home that may have gone unwitnessed or unattended."[30] JB was also receiving a hypoglycemic to treat his diabetes.[31] "Over sedation or confusion resulting from the use of theses sedatives may have interfered with his perception of hypoglycemia or other warning signs and symptoms that [JB] could have experienced in his delirium."[32]

34. Dr. Zaetta noted in his Report and Summary as an aggravating factor that Dr. Mane "did not heed usual quantity limits and dosing regimens for controlled medication in the elderly nor regard [JB's] risk factors for misuse and abuse of these drugs."[33]

35. Dr. Zaetta found no mitigating factors after a review of Dr. Mane's progress notes.[34]

36. Dr. Zaetta concluded that "Dr. Mane may have been irresponsible in the drug management of [JB's] sleep/anxiety disorder. It is highly likely that these medications led to the delirium and physical impairment that resulted in his hospitalization."[35]

Progress Notes for JB's Office Visits

37. Dr. Zaetta testified that he reviewed Dr. Mane's progress notes for JB for his eight office visits between December 2016 and August 2018. Dr. Zaetta testified that although JB was noted to suffer from insomnia, Dr. Mane did not prescribe any medication to JB on his first visit.[36]

38. Dr. Zaetta testified that the standard of care for a primary care physician to treat insomnia is to first review a patient's sleep hygiene, and without using medication, implement exercise, stress reduction techniques, and over-the-counter supplements such as melatonin. Dr. Zaetta referred to this approach as a "step-wise approach." Dr. Zaetta testified that "if all else fails," short courses of a prescription sleep aid should be discussed. Dr. Zaetta testified that benzodiazepines are not typically used as sleep aids due to their potential risk. Patients can also be referred for a sleep study to determine if they suffer from sleep apnea that may be the cause of sleep disturbances, or to a psychiatrist to

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[30] *Id.*
[31] *Id.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *See* Board's Exhibit 4 at 19-20

determine if there is a psychiatric component leading to insomnia. Dr. Zaetta testified that all steps taken to treat a patient should be well documented in the patient's progress notes.

39. Regarding the April 11, 2017 progress note, Dr. Zaetta testified that JB's diabetes was addressed, however, his insomnia was not, and therefore a provider would have no idea whether that condition was improving or not.[37]

40. Dr. Mane's progress note for JB dated April 25, 2017, includes insomnia on the Master Problem List, however, none of JB's medications are "linked" to that diagnosis and Dr. Zaetta could not determine whether any of JB's prescribed medications were for the treatment of insomnia.[38]

41. Regarding Dr. Mane's June 27, 2017 progress note for JB, Dr. Zaetta testified that JB's diagnoses included restless leg syndrome and primary insomnia, however JB was prescribed Valium four times per day and there was no explanation in the notes as to the reason for this prescription as restless leg syndrome primarily occurs in the late afternoon and evening.[39]

42. Dr. Mane's November 21, 2017 progress note for JB contains insomnia as a diagnosis, yet does not include a plan for treatment and does not specify any medication specific to insomnia.[40]

43. On December 4, 2017, JB had his sixth consultation with Dr. Mane and his chief complaint was insomnia. Dr. Mane's notes indicate that JB claimed he "feels well" though he "went back to Ambien at hs and Diazepam. He stopped the Lorazepam. Wakes up at 12 midnight and takes another Valium, then sleeps the rest of the night."[41] The progress notes do not contain any information regarding why JB stopped Lorazepam and started Ambien and Diazepam again.[42] Dr. Mane did not provide her reasoning for the change in medications and Dr. Zaetta opined that JB was "driving the decisions, not Dr. Mane." Dr. Zaetta also testified that there was no discussion in the notes regarding what

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[37] *Id.* at 22-23.
[38] *Id.* at 24.
[39] *Id.* at 26-27.
[40] *Id.* at 28.
[41] *Id.* at 31-32.
[42] *Id.*

medications JB should be using, JB's unilateral decision to discontinue or resume certain medications for his insomnia, and no clear direction as to how to handle his condition. Dr. Zaetta testified that it is not recommended to use Ambien and Diazepam together because they are both sedatives.

44. Dr. Zaetta testified that from a review of Dr. Mane's progress notes, she did not meet the standard of care in treating JB's insomnia, as the frequency and dosing of JB's medications "does not align with insomnia treatment," and JB was prescribed "overlapping medications," specifically Zolpidem and Lorazepam. Further, JB's restless leg syndrome was never elaborated upon and Dr. Mane's management of this condition was not clearly documented.

45. Regarding Dr. Mane's record keeping, Dr. Zaetta testified that her management plan is "sparse," and there was not a great deal of detail regarding changes being made, and that another physician "could not follow" her notes.

46. On January 6, 2019, Dr. Zaetta submitted a Medical Consultant Supplemental Report and Summary ("Supplemental Report") to the Board due to having been asked by the Board to re-consider his review of Dr. Mane's care of JB after considering Dr. Mane's response to the Board dated December 10, 2018.[43] Dr. Zaetta concluded that JB's functional decline was "multifactorial," including a respiratory infection as well as emphysema.[44] Dr. Zaetta opined that "both treatment of the infection and withdrawal of psychoactive medication simultaneously led to clinical improvement. Therefore, without the ability to determine the extent each factor played a role, I support the original complaint initiated to the Board that these medications were 'perhaps contributory' to the hospitalization."[45]

47. On February 7, 2019, the Board sent a letter to Dr. Mane informing her that the Board would be reviewing four additional patients.[46] The allegation set forth in the letter was Dr. Mane's "[i]nappropriate prescribing of controlled substances" to these four

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[43] *See* Board's Exhibit 9.
[44] *Id.*
[45] *Id.*
[46] *See* Board's Exhibit 10.

patients.[47] The letter identified patients MH, DM, LW, and LC and directed Dr. Mane to provide these patients' records to the Board by February 25, 2019.[48]

48. On March 19, 2019, Dr. Mane, through counsel, responded to the Board's February 7, 2019 letter and provided the requested medical records for the aforementioned patients.[49]

49. On July 1, 2019, Sydney Jean Lazarus, MD, the Board's second medical consultant, provided to the Board her Medical Consultant Report and Summary opining on Dr. Mane's care and treatment of the four patients.[50]

50. On July 12, 2019, the Board sent a letter to Dr. Mane informing her that the Board's investigation was near completion and provided her a web link to review all reports and investigative materials used in the investigation and to respond to any of the materials.[51]

51. On August 19, 2019, Dr. Mane provided an additional response to the Board due to its July 12, 2019 letter.[52]

52. On September 4, 2019, Dr. Lazarus provided a Supplemental Report and Summary in response to Dr. Mane's August 19, 2019 letter.[53]

53. The Board presented evidence concerning three of the four patients who were the subject of the Board's investigation of Dr. Mane.

54. Although Dr. Mane provided medical treatment to patients MH, DM and LW for many years prior to March 2014, pursuant to A.R.S. § 32-1451.03(A), the Board does not have the authority on "its own motion or on any complaint received by the Board" to investigate allegations of unprofessional conduct against a licensee that occurred more than four years before the complaint was received, with certain exceptions. In this case, on March 29, 2018, the Board received the complaint regarding JB and was authorized to

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[47] *Id.*
[48] *Id.*
[49] *See* Board's Exhibit 11.
[50] *See* Board's Exhibit 12.
[51] *See* Board's Exhibit 13.
[52] *See* Board's Exhibit 14.
[53] *See* Board's Exhibit 15.

investigate Dr. Mane's care and treatment of patients from March 29, 2014, to the present. Therefore, the evidence considered in this case is from March 29, 2014 onward.

Dr. Sydney Jean Lazarus' Testimony

55. Dr. Lazarus testified regarding her training and experience in the medical field, including her Board certification in Internal Medicine and her practice as a hospitalist. Dr. Lazarus testified that between sixty-five percent and seventy percent of her patients are above age 65. Dr. Lazarus explained that older patients' metabolisms slow as they age and therefore, they do not always tolerate controlled substances that affect breathing, and controlled substances can interact with other medications.

56. Dr. Lazarus testified that when prescribing controlled substances, she documents the reason for prescribing, the potential interaction with other medications, and she starts patients on a low dose and increases the dose gradually until the desired effect is achieved.

57. Dr. Lazarus testified that in a primary care practice, when prescribing controlled substances, a medication agreement should be utilized in order to implement certain rules as safety measures for a patient's protection, such as no early renewals, not receiving prescriptions from other providers, and submitting to drug testing.

Patient MH

58. Dr. Mane provided medical treatment to MH from April 23, 2007, to January 23, 2019.[54]

59. Dr. Lazarus testified that after her review of Dr. Mane's records for MH, she determined that Dr. Mane did not follow the standard of care in prescribing controlled substances for pain control.

60. Dr. Lazarus testified regarding numerous examples within Dr. Mane's progress notes for MH that illustrate that the notes were deficient and failed to set forth reasons for prescribing certain medications, as well as increases in medication. Dr. Lazarus explained that although Dr. Mane may have known her reasons for prescribing,

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[54] Only those records from March 29, 2014 onward will be considered.

other providers would not understand her reasoning because her notes are devoid of pertinent information.

61. Dr. Lazarus cited to the records to give some examples as follows:

a. The January 23, 2018 progress note states: MH "falls all the time," "[s]he cannot walk without a walker." However, those notes also state that her gait is normal.[55]

b. The April 5, 2018 progress note states: "Neuropathy, will take Lyrica twice a day."[56] Dr. Lazarus opined that this is insufficient information to ascertain why Lyrica was prescribed. MH was taking five controlled substances simultaneously: Oxycodone 15mg (1 pill, orally, every six hours), Restoril 30 mg (1 pill, orally, every night as needed), Soma 350 mg (1 pill, orally, four times a day, as needed), Lyrica 75 mg (1 pill, orally, twice a day), and Morphine ER 30 mg (1 pill, orally, every 12 hours).[57] Dr. Lazarus testified that these medications can interact with each other to the point that a patient "could stop breathing and die." Dr. Lazarus elaborated that if a patient were dehydrated, they would be unable to metabolize the medications well, resulting in confusion, delirium, decreased functioning, depression of the neurologic system, falls, and could result in withdrawal symptoms and/or hypertension if abruptly stopped. Further, there was no indication in Dr. Mane's notes as to why certain medications had been stopped, and therefore, another provider would have no way of knowing Dr. Mane's thought process in the treatment of MH.

c. Dr. Lazarus testified that there was no discussion in any of MH's progress notes in 2018 of the side effects, risks, and interactions of the medications taken by MH.

d. The June 1, 2017 progress note indicates that MH had a history of insomnia; however, the records are devoid of any information regarding

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[55] See Board's Exhibit 16 at 688-689.
[56] *Id.* at 690.
[57] *Id.* at 692.

non-controlled substances that may have been used to treat MH's insomnia, or that the standard of care for such treatment had been followed, such as starting with MH's sleep hygiene or a referral to a sleep specialist.[58] Dr. Lazarus testified that such lack of documentation falls below the standard of care.

e. Dr. Lazarus also referenced Dr. Mane's progress notes for MH from September 19, 2014, illustrating that MH had suffered from insomnia for years, and yet there was no documentation of a referral to a sleep specialist or if any alternatives to controlled substances were tried and failed.[59]

f. Dr. Lazarus testified that Dr. Mane's medical records for MH are inadequate, and therefore, one cannot understand Dr. Mane's clinical reasons for prescribing controlled substances.

Patient DM

62. Dr. Mane provided medical treatment to DM from March 16, 2005, to August 29, 2018.[60]

63. Dr. Lazarus testified that Dr. Mane's medical records for DM indicate that she had been taking Temazepam since the age of 14, and Dr. Lazarus was not sure whether that drug existed at that time.[61] Further, there were no details regarding the underlying diagnoses in the notes, and Dr. Mane did not explain the causes of DM's medical issues which included anxiety disorder and insomnia.

64. Dr. Lazarus further testified regarding Dr. Mane's January 28, 2016 progress note for DM that did not list any complaints, however, contained two diagnoses of insomnia and diagnoses of pain.[62] Dr. Lazarus explained that the two insomnia diagnoses should have been clarified and that there is no way to determine from the notes the reason for the joint pain diagnosis. According to Dr. Lazarus, there was no way to ascertain how Dr.

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[58] *Id.* at 683.
[59] *Id.* at 655-667.
[60] Only those records from March 29, 2014 onward will be considered.
[61] *See* Board's Exhibit 17 at 858.
[62] *Id.* at 836.

Mane reached this assessment because there were no exam details or imaging. Dr. Lazarus testified that there should have been a notation regarding a full physical exam or at least a physical exam limited to the area(s) in pain.

65. Dr. Lazarus further testified that at the January 28, 2016 visit, DM was taking Lorazepam, a benzodiazepine, Soma, a controlled substance, Temazepam, another benzodiazepine, and Fentanyl patch, an opioid.[63] Dr. Lazarus explained that there is a possibility of complications resulting from interactions among those drugs, including respiratory failure, and there were no notes indicating that Dr. Mane advised DM of those possible drug interactions.

66. On July 14, 2016, DM had a consultation with Dr. Mane and had no complaints.[64] The progress notes for that visit stated that DM "has cut her fentanyl in ½, it was too strong."[65] The progress notes also stated "[s]igns – Symptoms: doing well."[66] The progress notes were silent as to any discussion by Dr. Mane with DM about the benefits and risks of cutting DM's Fentanyl prescription in half.[67] Further, the progress notes did not explain what caused DM to believe that her Fentanyl prescription was too strong.[68] Therefore, Dr. Mane's progress notes lacked pertinent information.

67. Dr. Lazarus referenced an October 6, 2016 Progress Note that indicates that DM is taking multiple controlled substances, yet there is no discussion in the notes regarding those prescriptions.[69]

68. Dr. Lazarus referenced a January 4, 2017 progress note that contains responses under the History of Present Illness section that do not correspond to DM's medical condition, *e.g.*, as to "Location," Dr. Mane noted, "is stressed," as to "Quality," Dr. Mane noted, "is in Ft. Mohave because they are remodeling her place," and as to "Severity," Dr. Mane explained DM's financial circumstances. [70]

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[63] *Id.*
[64] *Id.* at 840.
[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Id.* at 842.
[70] *Id.* at 845.

69. On April 28, 2017, DM had her next consultation with Dr. Mane and her chief complaint was her medications.[71] In the progress notes it is recorded that DM took Psyllium fiber pills and the "large capsules, they got caught in her throat, drank water, could not get the pill down coughed, choked, it exploded in her esophagus, is still clearing her throat."[72] There is no recorded discussion between Dr. Mane and DM about this event.

70. On June 21, 2017, DM had a consultation with Dr. Mane with the purpose of getting prescription refills, problems with insomnia, left thigh hurting, limping, and the possibility of getting a referral for an orthopedic consult.[73] Additionally, DM informed Dr. Mane that she "is no longer on Fentanyl."[74] The progress notes stated DM's left thigh was hurting and she was starting to limp, but there is no indication in the progress notes whether Dr. Mane determined what was causing the pain in the left thigh and the resulting limping.[75] The progress notes stated that Dr. Mane referred DM for laboratory testing, but there was no indication that a referral was given to DM for an orthopedic consult, x-rays, or other consultations, to determine the cause of her limping.[76]

71. On March 1, 2018, DM had a consultation with Dr. Mane.[77] DM's previous consultation with Dr. Mane was seven months prior. The March 1, 2018 progress notes stated that DM was taking more medication, thyroid medication and vitamin D3.[78] She complained of disc pain that was "killing her," due to cold weather.[79] The March 1, 2018 progress notes did not have a Master Problem Section, but the assessment from this consultation was primary insomnia, polyneuropathy unspecified, and radiculopathy.[80] The March 1, 2018 progress notes stated DM was actively taking the following controlled substances: Soma, Lorazepam, and Temazepam and the progress notes indicated that DM's prescription directions for Soma and Lorazepam were changed from the August 23,

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[71] *Id.* at 848.
[72] *Id.*
[73] *Id.* at 850.
[74] *Id.*
[75] *Id.*
[76] *Id.*
[77] *Id.* at 856.
[78] *Id.*
[79] *Id.*
[80] *Id.* at 857.

2017 consultation.[81] However, the progress notes do not contain any recorded discussion between Dr. Mane and DM as to DM's usage of her controlled substances for the previous seven months, documentation that led to the insomnia diagnosis, and whether other modalities of treatment had been tried and failed.

72. Dr. Lazarus testified that Dr. Mane did not follow the standard of care in treating DM's insomnia because it was not documented in DM's progress notes that Dr. Mane ever attempted to determine the cause of DM's insomnia. Further, Dr. Lazarus testified that Dr. Mane should have tried to minimize the use of medications. Dr. Lazarus testified that Dr. Mane's medical notes for DM are inadequate and that Dr. Mane's care for DM fell below the standard of care for the prescribing of controlled substances for insomnia.

Patient LW

73. Dr. Mane provided medical treatment to LW from August 20, 2008, to January 23, 2019.[82]

74. Dr. Lazarus referenced several inconsistencies in Dr. Mane's progress notes for patient LW.

75. In the January 26, 2018 progress note, Dr. Mane noted in pertinent part, "[s]he has bone on bone," "[w]ithout the pain medication she can barely walk," and does not want surgery.[83] However, Dr. Mane also wrote in the progress notes that LW's "gait normal," which observation contradicted LW's claim that she can barely walk.[84] Dr. Lazarus testified that these notes are contradictory, "not detailed, and not meticulous."

76. On December 3, 2018, LW had a consultation with Dr. Mane.[85] The Medical History Section of the progress notes listed "[i]nsomnia" as a problem affecting LW.[86] Dr. Lazarus testified that there was not enough information in Dr. Mane's progress notes for LW to determine if insomnia was a current problem or whether it was in the past, there was

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[81] *Id.*
[82] Only those records from March 29, 2014 onward will be considered.
[83] *See* Board's Exhibit 18 at 917.
[84] *Id.*
[85] *Id.* at 919.
[86] *Id.*

no physical examination noted, and therefore, Dr. Lazarus could not determine how Dr. Mane arrived at a primary diagnosis of unilateral primary osteoarthritis.[87]

77. Dr. Lazarus further testified that LW's prescribed dose of oxycodone was higher in 2018 than in 2019, however, there was no reason provided in the progress notes for the lesser strength.

78. In her September 4, 2019 Supplemental Report and Summary, Dr. Lazarus summarized her opinion of the allegations of inappropriate prescribing of controlled substances and inadequate medical records as follows:

> Again in returning to this initial allegation of inappropriate prescribing of controlled substances, it may be possible that Dr. Mane had certain reasons to prescribe medications as she has. Several possibilities are presented in her response but, unfortunately, there is a paucity of evidence in her own medical documentation to support her prescribing habits. Dr. Mane's records have minimal documentation explaining her thought process, findings, reasons supporting or declining certain options, what she has considered regarding the patient or details of the patient's previous course. I am unable to substantiate her details provided in her own supplemental response, as these details cannot be substantiated in the records that have been provided. While there is information provided that would indicate alternate explanations for the harm that was seen, there also remains explanations that controlled substances may have had a role, in whole or in part, in the harm that was seen.
>
> An argument that medications were prescribed as a continuance of a previous prescriber's regimen is not valid as Dr. Mane is a licensed independent practitioner who must use her own medical judgment. An argument that Dr. Mane was "forced" to treat patient LW for relief of symptoms is also not valid as this suggests that the chosen medical regimen was the only effective option and that Dr. Mane is not an independent practitioner. As the current information stands, I cannot find appropriate prescribing of controlled substances for these four patients based on the provided medical records. [88]

79. Dr. Lazarus testified that Dr. Mane's records are not adequate in that another provider would be unable to understand her clinical thinking the majority of the time, that Dr. Mane's clinical judgment cannot be ascertained from her progress notes, and that

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[87] *Id.*
[88] *See* Board's Exhibit 15.

overall, another provider would be unable to follow Dr. Mane's pattern of prescriptions and the dosages thereof. Dr. Lazarus further explained that another provider needs to be able to understand a patient's care at any given time in order to ensure continuity and coordination of care, and that details need to be documented for these purposes.

Dr. Sheila Mane's Testimony

80. Dr. Mane testified that patient JB was "serious about taking care of himself," "seemed intelligent," and was "a good person," not a "pill-seeker." Dr. Mane testified that JB "promised her that he would not take too much" and "would only take as much as he needed." Dr. Mane testified that she believed him.

81. Dr. Mane explained that Humana, JB's insurance, had an online mail prescription program for a 90 day supply of free medication, however, if a patient ordered a lesser amount, the patient would have to pay. Therefore, Dr. Mane prescribed a larger quantity of prescriptions for JB in order that JB's medications be more affordable for him.

82. Dr. Mane testified that notwithstanding the receipt of a 90 day supply of medication, a patient who requires medications will only take medications as needed to help them. Dr. Mane testified that JB's prescriptions were "PRN" and therefore, only taken as needed, not on a scheduled basis. Dr. Mane explained that "addicts are different" and that JB's profile is not that of a drug seeker or addict.

83. Dr. Mane testified that the Board did not prove that her patients were doctor or pharmacy shopping, or went to emergency rooms or urgent care centers seeking pills. Dr. Mane testified that there is a mutual trust between doctors and patients, and these patients had been her patients for many years and "never cheated her" or exhibited drug seeking behavior. Dr. Mane testified that when JB was taken to the hospital, he still had most of his prescription pills on hand, illustrating that he only took pills when needed.

84. Regarding JB, Dr. Mane testified that she gave him "leeway to choose his medications" and that he "rotated medications." Dr. Mane testified that she allowed JB to choose his medications because he was a "responsible person," was never confused or drowsy, and "whatever he was choosing he tolerated."

85. Dr. Mane testified that while hospitalized, JB asked for Lorazepam and she told him to only take one pill. Dr. Mane explained that a patient should not stop taking medications abruptly because of the potential for withdrawal effects.

86. Dr. Mane testified that the responding EMTs diagnosed JB with weakness, not a drug overdose. Dr. Mane testified that when JB arrived at the hospital he was fully oriented. Dr. Mane testified that JB tolerated his medications, was never confused in her office, his speech was normal, he drove and lived alone, and "wanted his health in order." Dr. Mane testified that JB did not disclose his smoking history to her and she learned of this through JB's ex-wife while JB was hospitalized.

87. Dr. Mane stressed that JB was not hospitalized for a drug overdose, he was hypoxic and in need of oxygen, was admitted for observation and later, developed pneumonia. Dr. Mane testified that the psychiatrist did not evaluate JB until his fifth day in the hospital and that the psychiatrist did not understand that JB had not been confused upon his admission, and had been treated for pneumonia. Dr. Mane further testified that JB did not need to be weaned off of the medications, thereby establishing that he did not use those medications.

88. Dr. Mane was adamant that JB's hospital admission was caused by low oxygen, not medications, and that JB's confusion while in the hospital was caused by a disconnection of his oxygen that had gone unnoticed by hospital staff.

89. Regarding MH, Dr. Mane testified regarding MH's numerous and painful medical issues, and that MH was the only patient in her practice that was prescribed morphine. Dr. Mane further testified that MH's medications had previously been approved by a specialist, she had tolerated them for years, and would have had to travel out of town in order to see another specialist because her pain specialist was leaving town. Dr. Mane testified that she had known MH for years and knew that she was not abusing the medications.

90. Regarding the treatment of MH's insomnia, Dr. Mane asserted that MH's insomnia was not due to poor sleep hygiene, but rather was due to her severe pain.

91. Regarding the inconsistency in MH's progress note from January 23, 2018, Dr. Mane explained that she was writing the note in the context of having MH excused from

jury duty, and as such, she was indicating that MH could not walk throughout the court as a juror.[89] However, this is an example of Dr. Mane explaining what she *intended* to convey in her progress note, yet this is not clear from what it was that Dr. Mane *actually* wrote in the note.

92. Regarding DM, Dr. Mane testified that DM's neurologist had prescribed her medications previously. However, it became difficult for DM to visit a specialist as frequently and Dr. Mane agreed to treat DM and continue her medications which helped her function. Dr. Mane testified that DM could not sleep on her back due to degeneration of her spine, which led to DM's insomnia and the prescribing of the medications.

93. Regarding LW, Dr. Mane testified about her diagnoses, such as arthritis of the spine and the degeneration of the spine. Dr. Mane explained that LW's medications increased due to her further deterioration and age.

94. Dr. Mane asserted that if another practitioner took over her practice, they would have access to her patients' full medical records and would understand the patients' treatment plans.

95. Dr. Mane explained that her purpose in proceeding with this administrative hearing was to prove that her prescribing of medications to JB did not cause him harm or his hospitalization.

96. Dr. Mane acknowledged that her progress notes are "not that great."

CONCLUSIONS OF LAW

1. The Board has jurisdiction over Dr. Mane and the subject matter in this case.[90]

2. Pursuant to A.R.S. § 41-1092.07(G)(2) and A.A.C. R2-19-119(B), the Board has the burden of proof in this matter. The standard of proof is by clear and convincing evidence.[91]

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[89] *See* Board's Exhibit 16 at 688.
[90] A.R.S. § 32-1403
[91] A.R.S. § 32-1451.04

3. The legislature created the Board to protect the public. *See* Laws 1992, Ch. 316, § 10.

4. A.R.S. § 32-1401(2) provides that:

> "Adequate records" means legible medical records, produced by hand or electronically, containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, accurately document the results, indicate advice and cautionary warnings provided to the patient and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the course of treatment.

5. Pursuant to A.R.S. § 32-1401(27)(r) "unprofessional conduct" includes "[c]omitting any conduct or practice that is or might be harmful or dangerous to the health of the patient or the public."

6. The credible evidence presented established by clear and convincing evidence that for patients JB, MH, DM, and LW, Dr. Mane failed to create and maintain medical records to support their respective diagnoses, and justify their respective treatments, including the prescribing of multiple and overlapping controlled substances in large quantities. Further, Dr. Mane's records do not document advice and cautionary warnings regarding the risks associated with taking controlled substances and the potential interactions between the prescribed controlled substances, as required by statute. The lack of this documentation fails to ensure a continuity of care in the event another practitioner were to assume a patient's care during the course of treatment. The lack of adequate documentation consequently, is a practice that is or might be harmful or dangerous to Dr. Mane's patients. Therefore, Dr. Mane's medical records do not meet the statutory requirements for adequate records and her failure to create and maintain these records is unprofessional conduct.

7. The weight of the evidence presented established by clear and convincing evidence that Dr. Mane deviated from the standard of care by failing to discuss with JB the benefits, risks, and side effects of using an opioid, in conjunction with benzodiazepines, as well as by prescribing large and overlapping quantities of benzodiazepines along with a sleeping medication. Further, Dr. Mane's prescribing of benzodiazepines and Ambien to JB could have led to disabling or life threating falls at home. Additionally, JB was being

treated by Dr. Mane for diabetes and her over-prescribing of sedative medications to JB may have interfered with his perception of hypoglycemia or other health warning signs.

8. The weight of the evidence presented established by clear and convincing evidence that Dr. Mane deviated from the standard of care in treating MH by failing to provide a detailed description of MH's medication usage, especially controlled substance medications, MH's understanding of the consequences of using her medications, and MH's treatment progress as to her pains and illnesses. Dr. Mane's prescribing of controlled substances (opiates, benzodiazepines, and Soma) to MH could have led to disabling or life threating falls, fractures, renal failure, respiratory failure, and death.

9. The weight of the evidence presented established by clear and convincing evidence that Dr. Mane deviated from the standard of care in treating DM by failing to determine DM's underlying causes of her symptoms and diagnoses and to document objective findings to show the treatments/prescriptions were addressing DM's complaints. Dr. Mane failed to explore alternative explanations for DM's complaints, including a psychiatric basis for her symptoms. Dr. Mane fell below the standard of care in treating DM in not performing an annual physical examination of DM to determine the underlying causes of her health complaints. From the medical records provided for DM, Dr. Mane's prescribing multiple controlled substances to DM could have led her to medication dependence.

10. The weight of the evidence presented established by clear and convincing evidence that Dr. Mane deviated from the standard of care in treating LW by failing to perform the needed musculoskeletal examination(s) to determine the underlying causes of LW's hip pain, arthritis pain, her difficulty walking, her falling at times, and outlining a treatment plan to ameliorate these symptoms. Dr. Mane deviated from the standard of care in treating LW by failing to refer her to specialists when LW's symptoms did not improve under Dr. Mane's treatment. Further, LW was diagnosed with insomnia, and the standard of care required Dr. Mane to determine the underlying cause of LW's insomnia and discuss with LW her sleep hygiene and attempt other treatments other than medications, or provide a referral to a sleep specialist. From the medical records provided for LW, Dr. Mane's prescribing of controlled substances could have led to medication dependence for LW.

11. Dr. Mane's conduct as described above constitutes unprofessional conduct under A.R.S. § 32-1401(27)(r), as Dr. Mane's deviation from the standard of care in treating patients JB, MH, DM, and LW resulted in harm or potential harm.

ORDER

Based on the foregoing, it is **ORDERED** that:

1. Dr. Sheila R. Mane's license is issued a Letter of Reprimand;
2. Dr. Sheila R. Mane is placed on probation for a period of two (2) years with the following terms and conditions:

a. Continuing Medical Education

Respondent shall within 6 months of the effective date of this Order obtain no less than 15 hours of Board Staff pre-approved Category I Continuing Medical Education ("CME") in an intensive, in-person course regarding controlled substance prescribing and no less than 10 hours of Board Staff pre-approved Category I CME in an intensive, in-person CME regarding medical recordkeeping. Respondent shall within **thirty days** of the effective date of this Order submit her request for CME to the Board for pre-approval. Upon completion of the CME, Respondent shall provide Board staff with satisfactory proof of attendance. The CME hours shall be in addition to the hours required for the biennial renewal of medical licensure.

b. Chart Reviews

Within 30 days of completion of the CME, Respondent shall enter into a contract with a Board staff pre-approved monitoring company to perform periodic chart reviews at Respondent's expense. The chart reviews shall involve current patients' charts for care rendered after the date Respondent returned to practice as stated herein. Based upon the chart review, the Board retains jurisdiction to take additional disciplinary or remedial action.

c. Obey All Laws

Respondent shall obey all state, federal and local laws, all rules governing the practice of medicine in Arizona, and remain in full compliance with any court ordered criminal probation, payments and other orders.

d. **Tolling**

In the event Respondent should leave Arizona to reside or practice outside the State or for any reason should Respondent stop practicing medicine in Arizona, Respondent shall notify the Executive Director in writing within ten days of departure and return or the dates of non-practice within Arizona. Non-practice is defined as any period of time exceeding thirty days during which Respondent is not engaging in the practice of medicine. Periods of temporary or permanent residence or practice outside Arizona or of non-practice within Arizona, will not apply to the reduction of the probationary period.

e. **Probation Termination**

After three consecutive favorable chart reviews, Respondent may petition the Board to terminate the Probation. Respondent may not request early termination without satisfaction of the chart review requirements as stated in this Order.

Prior to any Board consideration for termination of Probation, Respondent must submit a written request to the Board for release from the terms of this Order. Respondent's request for release will be placed on the next pending Board agenda, provided a complete submission is received by Board staff no less than 30 days prior to the Board meeting. Respondent's request for release must provide the Board with evidence establishing that she has successfully satisfied all of the terms and conditions of this Order.

The Probation shall not terminate except upon affirmative request of Respondent and approval by the Board. The Board may require any combination of examinations and/or evaluations in order to determine whether or not Respondent is safe to prescribe controlled substances and the Board may continue the Probation or take any other action consistent with its authority.

The Board has the sole discretion to determine whether all of the terms and conditions of this Order have been met or whether to take any other action that is consistent with its statutory and regulatory authority.

3. Pursuant to A.R.S. § 32-2501(16), Respondent cannot act as a supervising physician for a physician assistant while her license is on probation.
4. The Board retains jurisdiction and may initiate new action against Respondent based upon any violation of this Order. A.R.S. § 32-1401(27)(s).

RIGHT TO PETITION FOR REHEARING OR REVIEW

Respondent is hereby notified that she has the right to petition for a rehearing or review. The petition for rehearing or review must be filed with the Board's Executive Director within thirty (30) days after service of this Order. A.R.S. § 41-1092.09(B). The petition for rehearing or review must set forth legally sufficient reasons for granting a rehearing or review. A.A.C. R4-16-103. Service of this order is effective five (5) days after date of mailing. A.R.S. § 41-1092.09(C). If a petition for rehearing or review is not filed, the Board's Order becomes effective thirty-five (35) days after it is mailed to Respondent.

Respondent is further notified that the filing of a motion for rehearing or review is required to preserve any rights of appeal to the Superior Court.

DATED this 7th day of April 2023.

THE ARIZONA MEDICAL BOARD

By Patricia E McSorley
Patricia E. McSorley
Executive Director

ORIGINAL of the foregoing filed this 7th day of April, 2023 with:

Arizona Medical Board
1740 W. Adams, Suite 4000
Phoenix, Arizona 85007

COPY of the foregoing filed this 7th day of April 2023 with:

Greg Hanchett, Director
Office of Administrative Hearings
1740 W. Adams
Phoenix, AZ 85007

Executed copy of the foregoing mailed by U.S. Mail and emailed this 7th day of April, 2023 to:

Sheila R. Mane, M.D.
Address of Record

Carrie H. Smith
Assistant Attorney General
Office of the Attorney General
SGD/LES
2005 N. Central Avenue
Phoenix, AZ 85004

By: _____
Arizona Medical Board

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