IN THE OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Steve Fanto, M.D. Holder of License No. 21415 For the Practice of Allopathic Medicine In the State of Arizona	No. 24A-21415-MDX **CERTIFICATION OF DECISION OF ADMINISTRATIVE LAW JUDGE**

Pursuant to the licensee's timely request, the Office of Administrative Hearings hereby certifies the recommended decision in this matter as the final agency decision pursuant to A.R.S. § 41-1092.08(I).

Done this day, September 5, 2024.

/s/ Tammy L. Eigenheer
Assistant Presiding Administrative Law Judge

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IN THE OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Steve Fanto, M.D. Holder of License No. 21415 For the Practice of Allopathic Medicine In the State of Arizona	**No. 24A-21415-MDX** **ADMINISTRATIVE LAW JUDGE DECISION**

HEARING: June 20, 2024 and June 21, 2024

APPEARANCES: The Arizona Medical Board was represented by Assistant Attorney General Roberto Pulver. Respondent Steve Fanto, M.D. appeared and was represented by Sara Stark.

ADMINISTRATIVE LAW JUDGE: Amy M. Haley

EXHIBITS ADMITTED INTO EVIDENCE: Arizona Medical Board's exhibits 1 through 94 were admitted. Steve Fanto, M.D.'s exhibits 95 through 106 were admitted.

BACKGROUND

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. Steve Fanto, M.D., (Respondent) is the holder of License No. 21415 for the practice of allopathic medicine in Arizona.

3. On or about April 30, 2024, the Board issued a Complaint and Notice of Hearing to Respondent alleging Respondent had engaged in unprofessional conduct pursuant to A.R.S. § 32-1401(27)(e) ("[f]ailing or refusing to maintain adequate records on a patient"); 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").

4. The allegations set forth in the Complaint and Notice of Hearing date back more than ten (10) years ago beginning in 2011.

5. Respondent signed an Interim Consent Agreement for Practice Restriction dated July 11, 2017 (ICA) fully restricting his ability to practice medicine pending a formal

hearing for revocation, which is still currently in effect. As a result, Respondent has been unable to practice medicine at all for the last seven (7) years.

STIPULATED FINDINGS OF FACTS

6. Respondent is a graduate of the State University of New York, Downstate Medical College of Medicine, and completed his residency in Physical Medicine and Rehabilitation.

7. Respondent is or was board certified in Physical Medicine and Rehabilitation with a subspecialty certification in Pain Management, and later recertified in these two medical specialties.

8. In 2017, Respondent was in private practice for 24 years with a focus on treating "patients who have failed usual and customary treatments including physical therapy, chiropractic treatment, over-the-counter pain medications, low-dose opiate treatment, and extensive adjuvant medications."

9. From 2016 through 2017, Respondent was a clinical preceptor at Midwestern University providing practicum guidance to its 3rd and 4th year medical students.

10. In his pain management practice one of the opioids Respondent prescribed to his patients with chronic pain was Subsys, which is a "Fentanyl Spray" administered under a patient's tongue and is classified by the federal Food and Drug Administration ("FDA") as a Transmucosal Immediate Release Fentanyl ("TIRF") product.

11. Subsys is the trade name for the fentanyl sublingual spray, which is manufactured and sold exclusively by Insys Therapeutics, Inc. ("Insys"), an Arizona-based corporation, and is available in the following dosage strengths: 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, and 1600 mcg fentanyl solution.

12. Fentanyl is a synthetic opioid that is up to 100 times more potent than morphine.

13. Subsys was first approved for use by the FDA in January 2012.

14. At all relevant times herein, the only FDA-approved use for Subsys, as a TIRF medication, is for the management of breakthrough cancer pain in patients who are already receiving and who are tolerant to regular opioid therapy for their persistent cancer pain.

15. The FDA warning accompanying Subsys states in part: "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

16. In December 2011, the FDA mandated the manufacturers of TIRF medications to develop and implement a REMS program – the TIRF Risk Evaluation and Mitigation Strategy ("REMS") Access Program.

17. The purpose of the TIRF REMS Access Program is to ensure informed risk-benefit decisions are made *before* initiating treatment, and also *while* patients are in treatment, to ensure appropriate use of TIRF medicines.

18. To successfully enroll in the Program, and gain the ability to prescribe TIRF medicines to outpatients, a physician must satisfy several requirements. The physician must (a) review the TIRF REMS Access education materials, including the Program's "Education Program" and the "full[ ] prescribing information" for each TIRF medicine the physician intends to prescribe; (b) successfully complete an online "Knowledge Assessment," a quiz to test the physician's knowledge of TIRF medicines; and (c) complete and sign a "Prescriber Enrollment Form." (See 2014 REMS Pamphlet, pp. 2 of 16).

19. Upon satisfaction of the above requirements, the Program provides the physician written confirmation that he or she is permitted to prescribe TIRF medicines. (See 2014 REMS Pamphlet, pp. 2 of 16).

20. Additionally, a "Patient-Prescriber Agreement Form" must be completed and signed by the physician and each patient to whom the physician will prescribe a TIRF medicine before such prescription can be given. The confirmation letter the physician receives upon enrollment in the Program reminds the physician of the Program's requirement that, before prescribing a TIRF medicine to a particular patient, he must "complete and sign a TIRF REMS Access Patient-Prescriber Agreement Form ("PPAF") for each patient that is new to the TIRF REMS Access Program." (See 2014 REMS Pamphlet, pp. 5 of 16).

21. When Respondent enrolled in the Program, he completed and submitted the "Prescriber Enrollment Form," read the full prescribing information for all TIRF medications, including Subsys, and successfully completed the Knowledge Assessment.

22. By completing and submitting the Prescriber Enrollment Form, Respondent acknowledged and agreed to the following:

a. I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the responsible use conditions for TIRF medicines and the risks and benefits of chronic opioid therapy.

b. I understand that TIRF medicines can be abused and that this risk should be considered when prescribing or dispensing TIRF medicines in situations where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.

c. I understand that TIRF medicines must not be used to treat any contraindicated conditions described in the FPI [Full Prescribing Information], such as acute or postoperative pain, including headaches/migraines.

d. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in a fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations . . .

e. I understand that the initial starting dose for TIRF medicines for <u>all</u> patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.

f. I will provide a Medication Guide for the TIRF medicine that I intend to prescribe to my patient or their caregiver and review it with them. If I convert my patient to a different TIRF medicine, the Medication Guide for the new TIRF medicine will be provided to, and reviewed with, my patient or their caregiver.

g. I will complete and sign a TIRF REMS Access *Patient-Prescriber Agreement Form* with each new patient, before writing the patient's first prescription for TIRF medicine, and **renew the agreement every two (2) years**.

h. I will provide a completed, signed copy of the *Patient-Prescriber Agreement Form* to the patient and retain a copy for my records.

i. At all follow-up visits, I agree to assess the patient for appropriateness of the dose of the TIRF medicine, and for signs of misuse and abuse.

j. I understand that TIRF medicines are only available through the TIRF REMS Access program. I understand and agree to comply with the TIRF REMS Access program requirements for prescribers. (Emphasis in original).

23. The Program gives these definitive instructions as to administering Subsys as to (a) initial dose; (b) maximum dose per episode; (c) frequency; and (d) titration:

a. [The initial dose of] SUBSYS is always 100 mcg [,] (unless the patient is being converted from ≥ 600mcg ACTIQ – please see Full Prescribing Information).

b. If the breakthrough pain episode is not relieved after 30 minutes, patients may take 1 additional dose using the same strength. Patients should not take more than 2 doses of SUBSYS per episode of breakthrough pain.

c. Patients must wait at least 4 hours before treating another episode of breakthrough pain with SUBSYS.

d. Closely follow patients and change the dosage level until adequate analgesia is achieved using a single dose per episode of breakthrough cancer pain.

24. Nevertheless, the Program Respondent participated in did not prohibit using Subsys for off-label usage for non-cancer pain in opioid-tolerant patients provided there were clinical justifications for such use; the patients were adequately informed of the risks, benefits, and side-effects of Subsys; and patients were properly monitored.

/ / /

MD-16-1248A

Patient CC

25. On October 11, 2016, the Board received a complaint, from a health insurance's Special Investigation Unit ("SIU"), against Respondent.

26. The above complaint stated the SIU did an investigation, after "reviewing an appeal from Respondent's office regarding authorization for one of his patients to receive . . . Subsys."

27. After receiving this complaint, the Board contacted the SIU and requested the name of the patient seeking authorization through Respondent's office to receive Subsys to treat the patient's chronic non-cancer pain.

28. The SIU disclosed that CC was one of the referral patients discussed in its October 11, 2016 complaint to the Board.

29. On October 14, 2016, the Board notified Respondent of the SIU complaint and attached the actual SIU complaint and all of the Board's correspondence with the SIU.

30. On October 26, 2016, the Board sent Respondent a letter notifying him to provide the complete medical records under his possession and/or control for patients CC and DK to the Board. And the letter notified Respondent the Board was opening an investigation against him for the "Inappropriate prescribing of Subsys."

31. On October 31, 2016, Respondent responded to the Board's October 26th letter and submitted the medical records for patients CC and DK from 2011 to 2016 that were under his possession and/or control.

32. The Board allowed Respondent to submit these patients' medical records from 2011 to 2016 and not the complete medical records. The Board allowed this because Subsys was approved in January 2012 and the initial complaint was about the inappropriate subscribing of Subsys.

33. On July 7, 2017, the Board's 1st medical consultant provided her Medical Consultant Report and Summary opining on Respondent's care and treatment of patients CC and DK.

34. Before the Board's 1st medical consultant provided her Medical Consultant

Report and Summary, the Board received three other complaints against Respondent as to his opioid prescribing practices, which at times included prescribing Subsys, in controlling chronic non-cancer pain in patients. Those cases were: MD-16-1012A, opened by the Board on August 25, 2016; MD-17-0092A, opened by the Board on January 26, 2017; and MD-17-0388A, opened by the Board on April 10, 2017.

35. The ICA took effect the following day and Respondent to this day has been fully prohibited from practicing medicine.

36. On July 27, 2017, the Board notified Respondent about another complaint against him as to his opioid prescribing practices, which included prescribing Subsys, in controlling chronic non-cancer pain for an elderly, male patient, afflicted with Crohn's disease. But the Crohn's disease was not treated with Subsys.

37. On August 18, 2017, through his then-attorney, Respondent provided an extensive Response to these complaints, Case Numbers MD-16-1012A, MD-16-1248A, MD-17-0092A, and MD-17-0388A, and to the Board's 1st medical consultant's Reports and Summaries for the above-mentioned cases.

38. Respondent's Response quotes the following: "Since the Arizona medical board adopted new pain guidelines in late 2014, physicians became aware of this in 2015. My practice starting [sic] changing in 2015 and through 2017 underwent significant changes to comply with the new guidelines."

39. Respondent further quotes in his Response that "he [Respondent] is well aware of the 'Arizona Medical Board Guidelines for Opioid Addiction in the Medical Office' and he carefully complies with them. [ ] he learned of the guidelines in early 2015 and immediately changed some of his practices to comply with them. Indeed, he helped formulate them."

40. On September 1, 2017, the Board's 1st medical consultant provided a Supplemental Response to Respondent's August 18th Response.

41. In response to Respondent stating he is well aware of the "Arizona Medical Board Guidelines for Opioid Addiction in the Medical Office," the Board's 1st medical consultant states the cited guidelines of Opioid Addiction in the Medical Office are inapplicable to the Board's investigations of Respondent because none of the

investigations involve addiction treatment; they involve the treatment of chronic pain using opioids. Respondent misquoted the applicable guidelines.

42. The Supplemental Response further states that Respondent did not formulate the "Reference for Physicians on the Use of Opioid Analgesics in the Treatment of Chronic Pain, in the Office Setting" but it was the Board's 1st medical consultant who created the Reference for Physicians from a template document provided by The Federation of State Medical Boards.

43. The Supplemental Response additionally explains that in the creation of the above "Reference for Physicians on the Use of Opioid Analgesics . . . ," Respondent's name is not listed as a participant in the creation of the template nor in the modifications to the template as the final work product adopted by the Board.

44. On September 2, 2017, the Board's 1st medical consultant provided the Board an Addendum.

45. The Addendum spotlighted four physicians who provided written testimonials on behalf of Respondent. Those testimonials stated Respondent was a competent pain specialist physician or his treatment for certain patients for chronic pain met the standard of care.

46. On September 14, 2018, Board staff sent to Respondent's then-attorney all the Board's investigative materials for the following cases: MD-16-1012A, MD-16-1248A, MD-17-0092A, MD-17-0388A, and MD-17-0719A.

CC's Consultations During 2011

47. From the medical records provided by Respondent, patient CC had a consultation with Respondent on October 12, 2011 and the last consultation was on October 13, 2016.

48. The October 12, 2011 consultation was a follow-up visit for CC and she was diagnosed with osteoarthritis and fibromyalgia. Her chief complaint was "diffused pain."

49. At the October 12th consultation, CC was a female, 69-year-old, non-smoker, non-drinker, married, weighting 239 pounds, claiming her pain index was 5 on a scale of 0 to 10.

50. During that consultation, CC was taking these pain medications:

(a) Fentanyl 100 microgram patch to apply 3 such patches every 48 hours;

(b) Fentanyl 1600 microgram lozenge on a handle (Actiq – only prescribed under the TIRF REM Access Program) to be used every 3 hours as needed and dispensed a total quantity of 60;

(c) Methadone (a synthetic opioid) 10 milligrams to be taken 2 tablets twice a day;

(d) Opana (a opioid analgesic to relieve moderate to severe pain) to be used every 4 hours as needed;

(e) Xanax (a benzodiazepine) 0.5 milligrams at bedtime;

(f) Dextromethorphan (temporary nonprescription medicine for coughs);

(g) Lunesta (sedative hypnotic prescription for insomnia); and

(h) Rozerem (hypnotic prescription for insomnia).

51. The physical examination for the October 12th consultation stated patient "appears to be in pain," "interactive during examination," "tired appearing," and "jaw pain."

CC's Consultations During 2012

52. CC's chief complaint during her 2012 consultations with Respondent was "diffuse pain," and the various diagnoses to explain the diffuse pain were chronic fatigue, myofascial pain, fibromyalgia and/or osteoarthritis.

53. During 2012, sleep apnea continued to be listed as a health problem for CC.

54. The above-mentioned health problems continued to be treated with opioids, benzodiazepine, and sedative hypnotics.

55. On March 3 and 7, 2012, CC filled **two different prescriptions** written by Respondent for Opana 10 mg tablets, 210 count, at two different pharmacy retail chains.

56. On September 12, 2012, the consultation notes disclosed that CC had "increased breakthrough pain, current breakthrough medication not working."

57. The September 12th notes did not explain the location, timing, quality, intensity, triggers, or ameliorating factors, if any, associated with the increased breakthrough pain. The notes did state Respondent increased the prescribed methadone from 40 to 60 milligrams daily.

58. But the September 12th notes did not have any information about Respondent discussing with CC about proposed treatment goals and objectives to minimize breakthrough pain or other possible alternatives.

59. The September 12th notes stated that CC had an updated EKG, which was the only documented EKG for CC during her five years of receiving methadone treatment.

60. In 2006, the FDA released a safety alert that methadone use for pain control may result in death and life threating changes in breathing and heart rate, especially noting those patients being treated for pain with large, multiple doses of methadone.

61. On December 5, 2012, the consultation notes stated CC continued to have "diffuse pain" and a history of "fibromyalgia, myofascial pain, and osteoarthritis. Pain complaints improve with medication management. No adverse events noted."

62. Yet with the above-mentioned confirmatory statements and with no pain complaint from CC, Respondent began a "trial of Subsys 800 mcg for breakthrough pain."

63. There was no information found in Respondent's consultation notes for CC that he comprehensively assessed CC at each visit when she was prescribed Subsys to determine whether Subsys and other opioid prescriptions were safe and efficacious for her.

CC's Consultations During 2013

64. At this time CC was 71 years of age and continued to consult with Respondent on a monthly basis.

65. At her January 3, 2013 consultation, CC was taking these pain medications:

(a) Fentanyl 100 microgram patch to apply 3 such patches every 48 hours;

(b) Fentanyl 1600 microgram lozenge on a handle (Actiq) to be used every 3 hours as needed and dispensed a total quantity of 45;

(c) Methadone 10 milligrams to be taken 2 tablets three times a day;

(d) Opana ER (extended release) take 1 tablet by mouth twice a day for a total count of sixty;

(e) Xanax 0.5 mg tablet to take 1 tablet by mouth at bedtime, as needed, for a total count of thirty;

(f) Lunesta 2 mg tablet by mouth at bedtime, as needed, total count of sixty;

and (g) Dextromethorphan SR 1 capsule by mouth three times a day.

66. On January 3, 2013, Respondent sent a "To whom it May concern" letter to CC's insurance company that stated CC had the diagnoses of osteoarthritis, myofascial pain, chronic fatigue syndrome, and fibromyalgia. In that letter, Respondent further stated

CC had “severe sudden onset of intractable breakthrough pain” and she is “currently utilizing [A]ctiq but is having side effects secondary to the sugar and dental issues. We would like patient to be authorized for [S]ubsys as it has 5 minutes onset data and limits the sugar is present in the [A]ctiq.”

67. The 2012 consultation notes did not mention dental issues due to sugar related to Actiq and those notes stated “no adverse events noted” with her pain medications.

68. On January 31, 2013, Respondent prescribed to CC Subsys 800 micrograms spray to be used under the tongue 4 times a day as needed for pain for a total count of 120.

69. On February 27, 2013, as confirmed by the CSPMP, Respondent prescribed a second benzodiazepine, Temazepam, to CC. But the February 27th notes did not state Respondent prescribed the second benzodiazepine, Temazepam, to CC.

70. During 2013, CC continued to complain about “diffuse pain” with the diagnoses of osteoarthritis, myofascial pain, and fibromyalgia. Despite intermittent generic verbatim notations in the consultation notes of “function improved with current treatment plan,” there was no indication of what was her functionality. And there was no indication of functional goals achieved and any identification of a treatment plan other than the prescribing of high dose opioid drugs with two different daily benzodiazepines.

71. CC’s 2013 medical history continued to document sleep apnea, which had been ongoing for more than a year.

72. On April 25, 2013, the consultation notes stated that CC was receiving new chiropractic treatment, but there were no changes to the medications; the chief complaint continued to be “diffuse pain” or “arthralgias”; and the medical history continued to be arthritis, myofascial pain, and fibromyalgia.

73. On May 23, 2013, Respondent wrote in the consultation notes that CC had increase breakthrough pain from “increase oral surgery,” but there were no further details to explain how the “oral surgery” was exacerbating the breakthrough pain or any consultation with the oral surgeon to explore CC’s breakthrough pain.

74. The remainder of the consultation notes for 2013, with the exceptions explained above, continued to be essentially verbatim from visit to visit, with the physical examinations at times being different due to vital signs.

CC's Consultations During 2014

75. At this time CC was 72 years of age and continued to consult with Respondent on a monthly basis and had the same vague complaints of arthralgia or diffused pain associated with her history of arthritis and fibromyalgia.

76. Respondent's 2014 consultation notes for CC continued to state "function improved with current treatment plan," but there were no functional goals or achievements noted.

77. Respondent's 2014 consultation notes continued to disclose the treatment plan was ultrahigh doses of opioid combined with a benzodiazepine.

78. The consultation notes for 2014 did not provide any clinical explanation or rationale for prescribing high opioid dosages combined with a benzodiazepine for diffuse, vague pain and poorly described pain complaints or the rationale for not utilizing a multidisciplinary treatment plan outside of prescribing controlled substances.

79. The remainder of the consultation notes for 2014, with the exceptions explained below, continued to be essentially verbatim from visit to visit, with the physical examinations at times being different due to vital signs.

80. On January 21, 2014, CC had a consultation with a pulmonologist, which is found in Respondent's notes. The pulmonologist stated CC has "severe OSA [obstructive sleep apnea] at 117. She is on large doses of narcotic and now may have central sleep apnea. She has poor sleep quality and sleeps in a chair."

81. Further the pulmonologist stated, "[w]e had a long discussion about the impact of her pain therapy has on breathing with sleep." Despite the above statement from the pulmonologist as to CC's sleep apnea and health, there were no notations about this visit in Respondent's consultation notes that the pain therapy he was providing to CC was affecting her health. Respondent's consultation notes showed no consultation with the pulmonologist and there were no opioid adjustments despite the pulmonologist's opinion.

82. On January 30, 2014, Respondent sent a "To whom it May concern" letter to CC's insurance company that stated CC "has chronic intractable noncancer pain diagnosis secondary to fibromyalgia and osteoarthritis. Patient . . . has episodes of sudden onset breakthrough pain. Patient has tried and failed all oral analgesics . . . Patient is in need of authorization for . . . namely [S]ubsys. As this product . . . help[s] her manage her pain more optimally. It would cause patient unnecessary harm to discontinue current treatment plan. Please expedite authorization ASAP."

83. On May 28, 2014, Respondent's consultation notes stated Restoril (temazepam, a benzodiazepine) had been reinstituted due to increase insomnia.

84. The May 28th consultation notes, and subsequent notes, were bereft of any discussions between Respondent and CC: (a) to determine the underlying causes of her sleep apnea; (b) to determine what medications should have been used to treat the apnea; (c) to determine CC sleep hygiene, stimulus control and relaxation techniques; and (d) to determine if Respondent was unable to treat the sleep apnea and insomnia then a referral to a sleep specialist should have been given.

CC's Consultations During 2015

85. At this time CC was 73 years of age and continued to consult with Respondent on a monthly basis and had the same complaints of arthralgia or diffused pain associated with her history of arthritis and fibromyalgia.

86. Respondent's consultation notes for CC continued to state vague non-specific comments of "improved function" and prescribing high doses of opioid was the treatment plan.

87. The remainder of the 2015 consultation notes, with the exceptions explained below, continued to be essentially verbatim from visit to visit, with the physical examinations at times being different due to vital signs.

88. On February 4, 2015, Respondent's consultation notes stated, "[p]atient having refractory insomnia. Patient developing tolerance to Xanax."

89. At the February 4th visit, Respondent prescribed the new medications of Lunesta (sedative hypnotic), Sonata (sedative hypnotic), Xanax (benzodiazepine), and Ativan (benzodiazepine).

90. On April 28, 2015, Respondent prescribed Belsomra (sedative hypnotic) to CC.

91. Respondent's solution to CC's severe apnea and insomnia for an elderly patient exacerbated by central nervous system depressant medications was to exchange and then add other central nervous system depressant medications to take at bedtime.

CC's Consultations During 2016

92. At this time CC was 74 years of age and continued to consult with Respondent on a monthly basis and had the same vague complaints of arthralgia or diffused pain associated with a history of arthritis and fibromyalgia.

93. Respondent's consultation notes for CC continued to state "[p]ain complaints improved with current treatment plan" and "[f]unction improved with current treatment plan."

94. The 2016 consultation notes for CC, with the exceptions explained below, continued to be essentially verbatim from visit to visit, with the physical examinations at times being different due to vital signs.

95. Within Respondent's consultation notes there is a July 5, 2016 report from an Alzheimer's Institute. The report from the Institute's neurologist stated around "2012 the patient frequently misplaced items around the home, followed by decreased memory for what she read sin[ce] 2013, and episodes of geographic disorientation in familiar territory in 2015. These symptoms were gradual in onset and insidiously progressive."

96. The neurologist gave a cognitive evaluation to CC that showed she had "variable deficits in orientation, and persistent problems in attention, abstraction, executive control, and memory registration, consolidation, and recall." The neurologist's impressions of CC were that she had chronic pain, on stable dosages of opioids and possible dementia.

97. On July 21, 2016, Respondent's consultation notes stated tapering of methadone and duragestic and follow-up with neurologist for memory.

98. On September 15 and October 13, 2016, Respondent's consultation notes for both dates stated the continuing tapering of methadone.

99. The October 13th consultation notes stated CC was taking Aricept for her memory.

100. From July 21, 2016 through October 13, 2016, the last available consultation notes from Respondent, there does not appear any discussion or consultation between Respondent and the neurologist as to the coordination of care for CC, an elderly woman suffering from dementia.

101. Respondent's care and treatment of CC deviated from the standard of care as follows:

a. The standard of care required Respondent to collaborate and create with CC a chronic pain management treatment plan for opioid use, but also discuss other noninvasive techniques or strategies such as physical therapy, non-opioid medications and specialist consultations as needed.

b. The standard care required Respondent to do intermittent reassessments of CC's underlying pain problems to determine if ongoing opioid prescribing was warranted, and/or if there was the development of new progressive pathologies. Intermittent reassessments include targeted physical re-examinations, updated diagnostic testing and specialist consultation(s) as needed. Given the strong evidence for serious risk in prescribing ultrahigh doses of opioids intermittent reassessment was required for CC.

c. The standard of care required Respondent to provide a clinical rationale as to the necessity to prescribe opioids and benzodiazepines to an elderly patient with a substantive history of sleep apnea knowing that these combinations of medications to be highly addictive and increase the risk of exacerbating pre-existing sleep apnea with repeated intermittent hypoxic events during sleep, respiration depression, accidental overdose and death.

MD-17-0092A

Patient AS

102. On January 26, 2017, the Board received notification from the National Practitioner Data Bank ("NPDB") of a $500,000 settlement payment on behalf of

Respondent, based on the survivors' allegation of "negligent pain management with polydrug toxicity and death" of a forty-one-year old patient, AS.

103. The following day, the Board notified Respondent it received a notification from the NPDB as to Respondent's medical malpractice settlement. The Board's notification to Respondent also contained the NPDB documents provided to the Board.

104. On February 6, 2017, the Board sent a letter to Respondent that it opened an investigation as to his malpractice settlement for "[i]mproper pain management with polydrug toxicity and death" and directed him to provide AS's complete medical records under his possession and/or control to the Board.

105. On February 15, 2017, Respondent responded to the Board's February 6th letter and submitted AS's complete medical records from January 17, 2012 to January 22, 2013.

106. From the medical records provided by Respondent, patient AS had her first consultation with him on January 17, 2012 and her final consultation on January 22, 2013, two days before her death.

107. AS had a total of 14 consultations with Respondent.

108. From Respondent's medical records, AS previously received care from a pain relief center from June 22, 2009 through August 31, 2009. She had a hiatus from the center, then returned for care from February 1, 2011 through October 25, 2011 and then sought care with Respondent.

109. On February 24, 2011, at the pain relief center, AS requested injectable Demerol to control her migraine headaches. The pain specialist attending to her stated: "it is not the standard of medical care to provide narcotics for migraines, however in her case we did make an exception secondary to her fusion . . . however, that we would be extremely uncomfortable providing her with injectable Demerol for this [migraines]."

110. AS's last prescription of Demerol from the pain center was July 5, 2011.

111. When AS had her first assessment with Respondent, on January 16, 2012, she was given a questionnaire titled "A Tool to Assess Drug Appropriateness: Circle 'Yes' or 'No'". The final question of the questionnaire stated: "If we were to urine test you today, would there be a problem?" AS circled "Yes."

112. When Respondent drug tested AS, on January 17, 2012, she tested positive for a benzodiazepine – a non-prescribed medication as confirmed by the CSPMP. Even after the specimen was sent out for confirmation and the benzodiazepine confirmed, Respondent stated in his medical records that AS had "no evidence of . . . abnormal drug behaviors in the past."

113. Respondent never documented in any treatment notes AS's positive drug test finding, coupled with AS's past drug behaviors, that she had a problem being compliant in taking her medications.

114. There is no indication in any of Respondent's medical records for AS that he provided specific instructions to AS on how to use Demerol.

115. On her first consultation with Respondent, on January 17, 2012, AS was a 40-year-old mother whose primary complaint was "diffused pain" claiming her pain was 5 on a scale of 0 to 10.

116. During the January 17th visit, AS disclosed having a severe car accident in 1991 which caused or contributed to her having degenerative disc disease, fibromyalgia, spinal fusion of C-2 through C-4, arthritis, temporomandibular joint dysfunction, and since her spinal fusion operation she had been on chronic opiate therapy.

117. Further, AS had a history of smoking half a packet of cigarettes per day.

118. During January 17th consultation, Respondent prescribed AS these medications:

(a) Demerol (treats acute pain) 100mg/ml solution;

(c) Lyrica (treats fibromyalgia) take 1 capsule every night;

(d) Oxycodone (treats severe pain) 15 mg tablet, 1 tablet 4 times a day as needed, 60 total;

(e) Promethazine (treats nausea and used to help Demerol work better) 1 suppository every six hours, as needed;

(f) Soma (muscle relaxant) 1 tablet 3 times a day; and

(g) Zanaflex (treats muscle spasms) 4 mg tablet.

119. Respondent's physical examinations of AS over the next 13 consultations were verbatim the same at every consultation with occasional changes for vital signs to make it appear the physical examination was unique for that consultation.

120. Also reiterated verbatim at each subsequent consultation was the "Review of Systems" Section which included items such as "recent weight gain, recent weight loss," and "complaints of anxiety, depression, insomnia, stressed, tenseness and withdrawn behavior."

121. The "Review of Systems" Section, for any of the consultation notes, provided no specificity when AS had recent weight gain or loss or when AS's anxiety, depression, or withdrawn behavior were heightened or lessened or what caused AS's insomnia to be exacerbated or lessened.

122. For each of the 13 follow-up consultations it was noted "Pain complaints improved with current treatment plan. No adverse events noted. No abnormal drug behaviors noted" and AS was instructed at each consultation to continue home exercise, medications, physical therapy, and follow-up with her primary physician.

123. An exception to the verbatim consultation notes, on April 25, 2012, Respondent gave AS another drug test. The drug test disclosed AS positive for hydrocodone, which had not been prescribed over the previous 4 years according to the CSPMP. Yet, Respondent claimed on that day for AS that her "Arizona state pharmacy profile [is] consistent with proper medication use."

124. On June 12, 2012, AS's chief complaint was "cervical spine pain" and in the notes it stated, "pain complaints improved with current treatment plan. No adverse events noted. No abnormal drugs behaviors noted."

125. On December 6, 2012, AS reported during her consultation with Respondent that she was in a recent "motor vehicle accident November 25, [causing] exacerbation of previous pain complaints." The above statement was the only information about the recent accident.

126. On January 22, 2013, AS had her final consultation with Respondent.

127. The January 22nd consultation was similar to all the other previous consultations AS has had with Respondent. And Respondent continued to prescribe the same medications to AS as previously prescribed during her first consultation with the exception oxycodone from 15 mg, 60 total tablets, to 30 mg, 120 total tablets.

128. Respondent stated, while he was treating AS, that her family practitioner was prescribing to her Soma and doxepin. But Respondent's medical notes for AS

showed no evidence that he ever consulted or coordinated treatment with AS's family practitioner or her other physicians.

129. On January 24, 2013, AS was found dead at her home.

130. The medical examiner's autopsy report stated: "it is my opinion that the decedent [AS], a 41-year-old female, died of an acute polydrug toxicity involving the combined effects of multiple prescription drugs, including oxycodone, doxepin, diphenhydramine, and meperidine [Demerol]. It is further my opinion the manner of death is [due to an] accident."

131. Respondent's care and treatment of AS deviated from the standard of care as follows:

a. The standard of care required Respondent, as a last resort, to prescribe injectable Demerol to a patient to treat her intractable severe episodic acute pain, which is unresponsive to other treatments, under these circumstances: (a) only when there is a thorough initial risk assessment of the patient; (b) only when a patient establishes a history of safe and compliant drug use; (c) only where there is meticulous attention to a comprehensive pain evaluation; (d) only when there is intensive, ongoing monitoring of the patient for misuse, abuse, and addiction; (e) only when there is detailed and repeated patient education in the safe use of Demerol; and (f) only when there is careful frequent reassessment for the efficacy and adverse effects of Demerol upon the patient.

b. The standard of care required Respondent to closely monitor AS for non-compliance and/or aberrant drug seeking behavior through drug tests and any positive drug results should be promptly recognized and addressed with AS for the patient's safety.

c. Respondent deviated from the standard of care when he failed to do a comprehensive analysis of AS's baseline and breakthrough pains to determine their underlying causes. Respondent failed to do the required diagnostics for the breakthrough pain episodes to determine whether AS needed a change in the treatment plan or refer her to specialists to treat these pains.

MD-17-0719A

Patient VR

132. On July 27, 2017, the Board received notification from VR's health insurance company complaining that Respondent was inappropriately prescribing Subsys to VR, a non-cancer patient.

133. On that same day, the Board sent two letters to Respondent. One letter notified Respondent of the insurance company's complaint against him with the accompanying documentation. The second letter notified Respondent that the Board opened an investigation as to his "[i]nappropriate prescribing of Subsys."

134. The second letter from the Board to Respondent also directed him to provide VR's complete medical records under his possession and/or control to the Board.

135. On August 18, 2017, through his then-attorney, Respondent provided a response to complaint, MD-17-0719A, and later provided his complete medical records on patient VR.

136. From Respondent's medical records, VR's first consultation with Respondent was August 17, 2011 and the last consultation was June 28, 2017, with approximately 75 total consultations occurring.

VR's Consultations During 2011

137. At the August 17, 2011 consultation, VR's chief complaint was "[c]ervical spine pain" and this consultation was a follow-up visit "for patient with work comp related chronic spinal degenerative disc and degenerative joint disease."

138. At the August 17, 2011 consultation, VR was a 67-year-old, male, married, non-smoker with a medical history of Crohn's disease, right side of his colon resected and removed, and partial removal of small intestine.

139. During the August 17th consultation, VR claimed his pain was 6 on a scale of 0 to 10.

140. Respondent wrote in the August 17th notes VR's "[p]ain complaints improved with medication management. No adverse events noted. No abnormal drug behavior noted. Patient still with severe episodes of breakthrough pain." Further, Respondent wrote VR was having cervical pain, headache, and thoracic back pains.

141. Respondent wrote in the notes that VR was taking these medications:

(a) alprazolam (a benzodiazepine) 1 mg tablet by mouth 4 times a day for 30 days;

(b) Ambien (generic name: zolpidem, treats insomnia) 10 mg tablet, take 11/2 tablet by mouth at bedtime for 30 days;

(c) B12 injection, administer once every two weeks;

(d) Cymbalta (generic name: duloxetine, treats depression and anxiety) 60 mg capsule, take 1 capsule by mouth every night for 30 days;

(e) fentanyl (brand name: Duragesic, for chronic pain) 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days;

(f) Humira Crohn's Start Pack, inject 1 pen subcutaneously every two weeks for 30 days;

(g) Loperamide (treats sudden diarrhea);

(h) Nuvigil (generic name: armodafinil, treats extreme sleepiness) 150 mg tablet, take 1 tablet by mouth every morning for 30 days;

(i) Pentasa (generic name: mesalamine, treats ulcerative colitis) 500 mg capsule extended release, take 2 capsules by mouth twice a day for 30 days;

(j) Phazyme (brand name: GasX);

(k) Roxicodone (generic name: oxycodone, treats severe pain) 30 mg tablets, take 1 tablet by mouth every 8 hours, as needed for pain, total 60 tablets;

(l) triamterene-hydrochlorothiazid (a diuretic) 37.5-25 mg tablet, take 1 capsule by mouth every morning;

(m) Wellbutrin SR (treats major depression) 150 mg tablet extended release, take 1 tablet by mouth every morning for 30 days; and

(n) Zocor (generic name: simvastatin, treats bad cholesterol) 20 mg tablet, take 1 by mouth at bedtime for 30 days.

142. As of August 17th 2011, the daily morphine equivalent from the opioid medications VR was taking was 495.

143. Daily morphine equivalent ("DME" or "MME/D") is defined as establishing an equivalency in terms of dose when comparing any opioid to morphine.

144. The August 17, 2011 notes stated, "[i]ncrease Roxycodine 30 mg [from 60 tablets to] 90 tablets, continue home exercise program, follow [up] with primary care physician, [the] patient's questions answered, and the risks, benefits, side effects of current treatment plan discussed with patient, [and] reevaluation in four weeks." The progress notes failed to provide Respondent's clinical rationale for the increase in Roxycodine and how it fits in the current treatment plan.

145. Moreover, the August 17th notes did not provide any specificity as to what were VR's questions and whether they were answered.

146. For September 14, 2011, the CSPMP only listed the fentanyl prescription of 100 mcg/hr, total 15, every 48 hours.

147. The September 14th notes further stated another medication change in Roxycodone 30 mg, every 8 hours by mouth, as needed for pain, from 60 tablets to a total of 90.

148. Further, the September 14th notes stated patient's pain complaints had improved with medication management, but the pain level was 6 on a 0 to 10 pain scale. There was no improvement in VR's self-perceived pain of 6 from the previous consultation of August 17, 2011.

149. On November 9, 2011, VR stated during this consultation of having severe break-through pain. His pain scale was 6 on a 0 to 10 pain scale.

150. During the November 9th consultation, Respondent prescribed to VR Abstral – using trial samples for the first time. Abstral is a fentanyl tablet that is placed under the tongue for severe breakthrough cancer pain. Respondent initially started VR on Abstral 100 mcg and later titrated up to 800 mcg.

151. The November 9, 2011 consultation notes failed to have Respondent's rationale for prescribing Abstral to VR for off-label use and there was no discussion with VR that his prescription of Abstral was off-label.

152. In the November 9th notes, there was no discussion between Respondent and VR as to the benefits, risks, side-effects, misuses, abuses, addictions, overdose problems, and other complications due to taking Abstral.

153. At the December 7, 2011 visit, VR's chief complaint was cervical spine pain and the oxycodone was unhelpful in relieving his pain.

154. At the December 7th visit, the pain level for VR was 6 out of 10.

155. During the December 7th visit, Respondent prescribed Abstral 400 mcg, a total of 64 tablets, and then directed that VR's use of oxycodone be discontinued.

VR's Consultations During 2012

156. During 2012, VR was 68 years of age and continued to consult with Respondent on a monthly basis and had the same complaint of cervical spine pain.

157. At the February 1, 2012 consultation, VR complained that his perceived pain was 8 out of 10.

158. During the February 1st consultation, Respondent increased VR's Duragesic (fentanyl) from 100 mcg/hr patch every 72 hours to 150 mcg/hr patch every 2 days and increased the Abstral from 400 mcg to 800 mcg, total tablets 64.

159. At the February 29, 2012 consultation, VR stated his pain was improving with the medication management and his pain was at 6 out of 10.

160. At the February 29th consultation, VR stated he would like to utilize a low dose of fentanyl for breakthrough pain, but more frequently.

161. Current pain medications listed for February 29, 2012 were (a) fentanyl 100 mcg every 72 hours and 50 mcg every 72 hours; (b) Abstral 400 mcg tablet every three hours, as needed; and (c) Roxicodone (oxycodone) 30 mg tablet 1 every 8 hours, as needed for pain.

162. The CSPMP listing for February 29, 2012 prescriptions were for fentanyl 100 mcg #15, fentanyl 50 mcg #15, and Abstral 400 mcg, #96, for a total MME/D (daily morphine equivalent) of 956.

163. Further, the February 29th notes listed Oxycodone (Roxicodone), under current medications, but it was last prescribed November 9, 2011, three months before.

164. During February 2012, per the CSPMP, VR was prescribed alprazolam 1 mg, total 120, and Nuvigil 150 mg, total 30, by the family physician.

165. Respondent stated in his notes for the February 29th consultation that VR's "[u]rine drug screen results [are] consistent with proper medication use, pending laboratory results."

166. At the March 28, 2012 consultation, Respondent's notes stated, "replace [A]bstral with [S]ubsys 200 mcg #90." There was no discussion in the consultation notes

why there was a necessity to replace the Abstral with Subsys and why the dosage for Subsys was not 100 mcg, the lowest dosage.

167. During the March 28th consultation, VR's stated his pain was 6 out of 10.

168. The March 28th notes for this visit continued to list oxycodone (Roxicodone) as a current pain medication; however, VR's oxycodone prescription was last prescribed for 90 tablets in November 2011, five months prior.

169. On April 25, 2012, Respondent's consultation notes stated VR was not tolerating Subsys and his pain was 6 out of 10.

170. Yet the April 25th notes stated VR's "[p]ain complaints improved with current treatment plan."

171. The April 25th notes stated the plan was to resume Abstral 400 mcg, 128 tablets, follow up with cardiologist, follow up with primary care physician, and reevaluate in four weeks. There was no clinical rationale provided in the notes why to resume Abstral and why consideration was not given to try other non-narcotic methods to control VR's pain.

172. On May 23, 2012, this was VR's 11th visit with Respondent. Respondent's consultation notes stated the plan was to re-try Subsys at 800 mcg, 120 spray applications.

173. The May 23rd notes, or any subsequent notes, did not have a customized pain management plan on how to control VR's breakthrough pain and what objective markers would be used to determine whether progress was being made to control or reduce VR's pain.

174. Additionally, there did not appear in the May 23rd notes, or any subsequent notes, any meaningful reassessment, diagnostic testing, specialist consultation(s) or even an updated physical examination to understand what was causing VR's pain.

175. In the May 23rd notes there was no discussion about VR's follow-up appointments with his cardiologist and primary care physician, which previously were mentioned in prior consultation notes.

176. On June 20, 2012, Respondent's consultation notes stated Abstral and Tamsulosin prescriptions were being discontinued because the therapy was completed.

177. During the June 20th visit, VR stated his pain was still 6 out of 10.

178. The June 20th notes again stated VR was to follow up with his cardiologist, family physician, and that a reevaluation was scheduled in four weeks.

179. From July 2012 to December 2012, VR had several more consultations with Respondent and the notes for each of these consultations stated patient appeared to be in pain and distress. VR stated that during this time, as recorded in the notes, his pain fluctuated between 6 or 7 on a scale of 10.

180. From July 2012 to December 2012, the consultations notes for this time stated that VR was to continue the current medication management.

VR's Consultations During 2013

181. On January 2, 2013, Respondent's consultation notes stated that Amlodipine (treats high blood pressure) and Atenolol (treats high blood pressure) were now current medications for VR.

182. During the January 2, 2013 visit, VR stated his pain index was 6 out of 10.

183. Additionally, the January 2, 2013 notes stated Subsys to be increased to 1200 mcg, 120 spray applications. The CSPMP listed this prescription to cover 30 days, representing four sprays per day.

184. During the January 2, 2013 visit, Respondent increased VR's Subsys dosage, which translated, over a 30 day period, to an MME/D of 864.0.

185. On January 30, 2013, Respondent's consultation notes stated VR was functionally improving with the current treatment plan and the pain complaints had improved with medication management. Yet VR's pain index was still 6 out of 10.

186. The January 30, 2013 notes stated the discontinuation of Cymbalta, Roxicodone, and Triamterene/HCTZ.

187. The January 30, 2013 notes also indicated a prescription change to Subsys 1200 mcg (600 mcg spray x 2), one sublingual spray four times a day, as needed, 120 spray applications.

188. On March 27, 2013, Respondent's consultation notes stated VR was having massage therapy five times per week when he went through detox. Now, VR was back on medication management and needed massage therapy three times a week.

189. The March 27th notes reiterated the phrase, "[p]ain complaints improved with current treatment plan, adverse events controlled, no abnormal drug behaviors." This

phrase was consistently repeated at every consultation and there was no explanation in any of the notes how the current treatment plan quantitatively and qualitatively was alleviating VR's pain.

190. During 2013, VR continued to have consultations with Respondent and his pain was recorded during those consultations as fluctuating from 6 to 8 on a 0 to 10 scale.

191. At the September 11, 2013 consultation, there was no recording of VR's pain.

192. On November 11, 2013, Respondent's notes recorded VR was recently hospitalized for kidney stones and pancreatitis.

193. There was in the November 11th notes the statement that VR had decreased left C6 C8 sensation, slight antalgic gait, decreased range of motion and tenderness, but there was no further investigation to determine the underlying factors causing these observations and possible treatments to alleviate these symptoms.

194. At the December 10, 2013 consultation, VR stated he was hospitalized for hypertension, which was now under control.

195. VR stated, during the December 10th visit, that his pain was 6 out of 10.

VR's Consultations During 2014

196. During 2014, VR was 70 years of age and continued to consult with Respondent on a monthly basis and had the same complaint of cervical spine pain.

197. Respondent's 2014 consultation notes continued to have the rote phrase, under History of Present Illness: "Pain complaints improved with current treatment plan. Adverse events controlled. No abnormal drug behaviors noted."

198. On January 9, 2014, Respondent's consultation notes stated that VR had been recently diagnosed with bladder cancer.

199. The January 9th notes stated VR's pain index was 7 out of 10. And the notes stated VR still continuing with his current medication management.

200. On February 6, 2014, Respondent's consultation notes stated that VR's cancer tumor had been removed from his bladder.

201. The February 6th notes stated VR's pain index was 7 out of 10. And the notes stated VR was to continue with the current medication management.

202. On July 16, 2014, Respondent's consultation notes stated VR's pain index was 8 out of 10.

203. The July 16th notes stated Respondent prescribed to VR these new medications: (a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, starting 7/16/2014, stop date 8/15/2014; and (b) fentanyl 50 mcg/hr patch, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start 7/16/2014, stop date 8/15/2014.

204. On October 9, 2014, Respondent's consultation notes stated VR's pain index was 6 out of 10.

205. The October 9th notes stated Respondent prescribed these new medications to VR: (a) fentanyl 100 mcg/hr patch every 48 hours for 30 days, disp. 15; (b) fentanyl 50 mcg/hr patch every 48 hours for 30 days, disp. 15; and (c) Subsys 1200 mcg (600 mcg x 2), spray 2 times under tongue four times a day, disp. 240. All these medications had the stop date of November 8, 2014.

206. The October 9th notes further stated that these medications were discontinued (a) fentanyl 100 mcg, (b) fentanyl 50 mcg, and (c) Subsys 1200 mcg. These medications were discontinued due to dosage changes.

207. On November 6, 2014, Respondent's consultation notes stated VR's pain index was 8 out of 10.

208. The November 6th notes stated Respondent renewed the prior medications prescribed on October 9th because they would expire on November 8th.

209. Further, the November 6th notes stated VR's chief complaint was not cervical spine pain but lower back pain.

210. In the November 6th notes there was no record of Respondent having a discussion with VR whether the prior prescription changes of fentanyl and Subsys had exacerbated, ameliorated, or maintained VR's pain index that he was experiencing daily from cervical or lower back pain.

211. On December 11, 2014, VR had his last consultation of the year with Respondent. VR's pain index was 7 on a 0 to 10 scale.

212. The December 11th visit notes stated VR's chief complaint was cervical spine pain.

VR's Consultations During 2015

213. During 2015, VR was 71 years of age and continued to consult with Respondent on a monthly basis and had the same complaint of cervical spine pain.

214. On January 8, 2015, Respondent's consultations notes stated VR's pain index was 7 out of 10.

215. During the January 8th consultation, VR's opioid medications were as follows:

(a) 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/2014, stop date 1/10/15;

(b) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/14;

(c) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/14, stop date 1/10/15;

(d) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/14;

(e) Subsys 1,200 mcg (600 mcg/spray x 2) spray, spray 2x under tongue four times a day, as needed for 30 days, disp. 240, start date 12/11/14, stop date 1/10/15; and

(f) Subsys 1,200 mcg (600 mcg/spray x 2) spray, spray 2x under tongue four times a day, as needed for 30 days, disp. 240, start date 12/11/14.

216. The January 8th notes stated that Respondent prescribed these new medications to VR:

(a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 1/8/15, end date 2/7/15;

(b) 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 1/8/15, stop date 2/7/15; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2 times under the tongue four times a day, as needed for 30 days, start date 1/8/15, stop date 2/7/15.

217. On February 5, 2015, Respondent's consultation notes stated VR's pain was 7 out of 10.

218. During the February 5th visit, Respondent prescribed the following medications to VR:

(a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 2/5/2015, stop date 3/7/15;

(b) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 2/5/15, stop date 3/7/15; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2x under the tongue four times a day, as needed for 30 days, disp. 240, start date 2/5/15, stop date 3/7/15.

219. During the February 5th consultation, Respondent administered to VR the Alere Drug test and the test was positive for alprazolam, fentanyl, but zolpidem (Ambien) and amitriptyline were not detected.

220. The Alere drug test showed that VR was not taking his prescribed medications and there was no notation in any of the consultation notes that Respondent discussed with VR his failure to take his medications.

221. For the next several consultations until June 2015 there was no change in the opioid medications that Respondent prescribed to VR.

222. On June 25, 2015, Respondent's consultation notes stated VR's pain index was 5 out of 10.

223. The June 25th notes stated Respondent changed VR's opioid medications to the following:

(a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 6/25/15, stop date 7/25/15;

(b) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 6/25/15, stop date 7/25/15; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2 x under tongue four times a day, as needed, disp. 240, start date 6/25/15.

224. For the subsequent 2015 consultations, the opioid medications that Respondent prescribed to VR remained the same.

225. On September 17, 2015, Respondent prescribed a Medrol Dosepak to alleviate VR's increased back pain and left-sided sciatica.

226. During the September 17th consultation VR's pain index was 8 out of 10.

227. On December 10, 2015, this was VR's last consultation for 2015.

228. The December 10th notes stated VR's pain index was 6 out of 10.

VR's Consultations During 2015

229. During 2015, VR was 71 years of age and continued to consult with Respondent on a monthly basis and had the same complaint of cervical spine pain.

230. On January 8, 2015, Respondent's consultations notes stated VR's pain index was 7 out of 10.

231. During the January 8th consultation, VR's opioid medications were as follows:

(a) 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/2014, stop date 1/10/15;

(b) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/14;

(c) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/14, stop date 1/10/15;

(d) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 12/11/14;

(e) Subsys 1,200 mcg (600 mcg/spray x 2) spray, spray 2x under tongue four times a day, as needed for 30 days, disp. 240, start date 12/11/14, stop date 1/10/15; and

(f) Subsys 1,200 mcg (600 mcg/spray x 2) spray, spray 2x under tongue four times a day, as needed for 30 days, disp. 240, start date 12/11/14.

232. The January 8th notes stated that Respondent prescribed these new medications to VR:

(a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 1/8/15, end date 2/7/15;

(b) 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 1/8/15, stop date 2/7/15; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2 times under the tongue four times a day, as needed for 30 days, start date 1/8/15, stop date 2/7/15.

233. On February 5, 2015, Respondent's consultation notes stated VR's pain was 7 out of 10.

234. During the February 5th visit, Respondent's prescribed the following medications to VR:

(a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 2/5/2015, stop date 3/7/15;

(b) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 2/5/15, stop date 3/7/15; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2x under the tongue four times a day, as needed for 30 days, disp. 240, start date 2/5/15, stop date 3/7/15.

235. During the February 5th consultation, Respondent administered to VR the Alere Drug test and the test was positive for alprazolam, fentanyl, but zolpidem (Ambien) and amitriptyline were not detected.

236. The Alere drug test showed that VR was not taking his prescribed medications and there was no notation in any of the consultation notes that Respondent discussed with VR his failure to take his medications.

237. For the next several consultations until June 2015 there was no change in the opioid medications that Respondent prescribed to VR.

238. On June 25, 2015, Respondent's consultation notes stated VR's pain index was 5 out of 10.

239. The June 25th notes stated Respondent changed VR's opioid medications to the following:

(a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 6/25/15, stop date 7/25/15;

(b) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours for 30 days, disp. 15, start date 6/25/15, stop date 7/25/15; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2 x under tongue four times a day, as needed, disp. 240, start date 6/25/15.

240. For the subsequent 2015 consultations, the opioid medications that Respondent prescribed to VR remained the same.

241. On September 17, 2015, Respondent prescribed a Medrol Dosepak to alleviate VR's increased back pain and left-sided sciatica.

242. During the September 17th consultation VR's pain index was 8 out of 10.

243. On December 10, 2015, this was VR's last consultation for 2015.

244. The December 10th notes stated VR's pain index was 6 out of 10.

VR's Consultations During 2016

245. During 2016, VR was 72 years of age and continued to consult with Respondent on a monthly basis and continued to have the complaint of cervical spine pain.

246. During 2016, VR's pain index fluctuated from 5 to 7 on a scale of 0 to 10.

247. On January 7, 2016, Respondent's consultation notes stated VR's chief complaint was cervical spine pain, but he was experiencing increased left-sided sciatica pain and left leg pain.

248. The January 7th notes stated VR was awaiting an evaluation by his primary care physician. And VR was recently hospitalized for recurrent pneumonia from December 12 – 23, 2015.

249. VR first reported sciatica pain on September 17, 2015 and Respondent prescribed a Medrol Dose pack to treat the sciatica. Further, Respondent instructed VR to follow up with his primary care physician and later Respondent would do a reevaluation of VR's pain in four weeks.

250. From September 17, 2015 to January 7, 2016, Respondent's consultation notes stated VR had been experiencing left-sided sciatica pain or left leg pain.

251. On March 31, 2016, VR's 60th consultation, Respondent's consultation notes continued to state VR's chief complaint was cervical spine pain and his pain index was 6 out of 10.

252. The March 31st consultation notes continued to state VR had "Pain complaints improved with current treatment plan. Adverse events controlled. No abnormal drug behavior noted."

253. During the March 31st consultation, Respondent prescribed two months' worth of prescriptions with the first batch of prescriptions to start dispensing on 2/4/16

and the second batch of prescriptions to start dispensing on 3/31/16. The first batch of prescriptions were:

(a) Fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours, disp. 15 NR, Start Date: 02/04/2016;

(b) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours, disp. 15 NR, Start Date 02/04/2016; and

(c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2 x under the tongue four times a day, as needed, disp. 240 NR, Start Date 02/04/2016.

254. The above batch of prescriptions were again prescribed, but with the start date of 3/31/16.

255. On August 23, 2016, Respondent's consultation notes stated VR was again hospitalized for pneumonia.

256.]The August 23rd notes stated Respondent continued prescribing VR the same opioid prescriptions previously prescribed.

257. On September 21, 2016, Respondent's consultation notes stated that VR's chief complaint was cervical spine pain and his pain index was 5 out of 10.

258. As of September 21, 2016, the opioid prescriptions Respondent was prescribing to VR, as confirmed by the CSPMP, indicated the MME/D total was 2268.

259. The December 21st note discussed discontinued, current, and new medications for VR. In the "notes" section it stated "balance of script sent."

VR's Consultations During 2017

260. During 2017, VR was 73 years of age and continued to consult with Respondent until June 28, 2017.

261. During 2017, VR's chief complaints were lower back pain radiating down his right leg, during one consultation, and cervical spine pain.

262. On January 11, 2017, Respondent's consultation notes stated VR was experiencing, "[p]ain complaints increase in right lower back region radiating to right lower extremity recently. Adverse events controlled. No abnormal drug behavior. Function improved with current treatment plan."

263. On April 5, 2017, VR's 75th visit with Respondent, the consultation notes stated that VR continued to have cervical spine pain and his pain index was 4 out of 10.

264. Nevertheless, the April 5th notes stated that VR had increased hip pain, but no hip examination was conducted to further understand the underlying factors or causes of the hip pain.

265.]During the April 5th consultation, Respondent prescribed these opioid medications to VR (a) fentanyl 100 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours, disp. 15, start date 4/5/17; (b) fentanyl 50 mcg/hr patch 72 hours, apply 1 patch to skin every 48 hours, disp. 15, start date 4/5/17; and (c) Subsys 1,200 mcg (600 mcg/spray x 2) spray 2 times under the tongue four times a day, as needed, disp. 240, start date 4/5/17.

266. On April 27, 2017, Respondent's consultation notes contained a letter sent to VR's insurance company claiming, VR "has been utilizing transmucosal fentanyl medications for several years for breakthrough pain with great success. Secondary to patient's diagnosis of Crohn's disease he is unable to absorb oral pain medications properly. Therefore patient requires bypassing the GI tract for his breakthrough medications. The only options available are Transmucosal fentanyl products. These agents are FDA approved for only cancer pain, however are much more readily utilized for noncancer patients. . . Please expedite continuing authorization as you have over the past several years for this medication. Lack of authorization will lead to undue harm and suffering for this patient."

267. On May 31, 2017, Respondent's consultation notes stated VR's chief complaint was cervical spine pain and his pain index was 5 out of 10.

268. The May 31st notes also stated VR's insurance declined the authorization for the Subsys prescription.

269. These May 31st notes further stated that VR was still experiencing "increased right hip pain."

270. On June 28, 2017, this was VR's last consultation with Respondent.

271. On the June 28th visit, the notes stated VR's pain index was 5 out of 10 on a scale of 0 to 10.

272. The June 28th notes stated that VR's chief complaint was cervical spine pain and "[p]ain complaints improved with current treatment plan. Adverse events controlled. No abnormal drug behavior."

273. The June 28th notes also stated that VR continued to experience, "increase right hip pain."

274. The current medication prescribed to VR found in the June 28th notes were alprazolam, Ambien, Diltiazem, fentanyl 100 mcg, fentanyl 50 mcg, Flomax, mitomycin, Nuvigil, Pentasa, Phazyme, Spirivia Respimat, Subsys (600 mcg spray x 2) disp. 240, Wellbutrin SR and Zocor.

275. As of June 28, 2017, the opioid prescriptions Respondent prescribed to VR, as confirmed by the CSPMP, indicated the MME/D total was 2268, which MME/D number was the same for the opioid medications prescribed on September 21, 2016.

276. Respondent's care and treatment of VR deviated from the standard of care as follows:

a. The standard of care required Respondent to carefully state the rationale for the off-label use of Subsys, to "start low and go slow" to find the effective dose, provide careful safe use instructions, and to follow standard principles related to opioid prescribing for chronic pain. Specifically, Subsys under the TIRF REMS Program instructs physicians as to dosage, initiation, titration, maintenance and patient education that must be followed meticulously due to concerns about misuse, abuse, addiction, overdose, and serious complications due to medication errors. The instruction for the initial dose of Subsys is always 100 mcg and then patients are individually titrated to find the lowest effective dose with the patient's treatment plan and provide constant assessment and monitoring of the patient at all follow-up visits.

b. Respondent deviated from the standard of care by violating his agreement under the TIRF REMS Access Program by prescribing an initial dose of 200 mcg of Subsys to VR instead of 100 mcg and later failing to titrate the lowest effective dose consistent with VR's treatment goals. Respondent failed to provide any clinical rationale as to why VR was prescribed the initial Subsys dose of 200 mcg. Later, Respondent discontinued prescribing Subsys to VR, but then restarted prescribing

Subsys to VR at the initial dose of 800 mcg though previously VR could not tolerate Subsys.

c. The standard of care required Respondent to carefully state the rationale for the off-label use of Abstral, to "start low and go slow" to find the effective dose, provide careful safe use instructions, and to follow standard principles related to opioid prescribing for chronic pain. Specifically, Abstral under the TIRF REMS Program instructs physicians as to dosage, initiation, titration, maintenance and patient education that must be followed meticulously due to concerns about misuse, abuse, addiction, overdose, and serious complications due to medication errors. The instruction for the initial dose of Abstral is always 100 mcg and then patients are individually titrated to find the lowest effective dose with the patient's treatment plan and provide constant assessment and monitoring of the patient at all follow-up visits.

d. The standard of care required Respondent to do intermittent reassessments of VR's underlying pain problems, especially breakthrough pain, to determine if ongoing opioid prescribing was warranted, and/or if there was the development of new progressive pathologies. Intermittent reassessments include targeted physical re-examinations, updated diagnostic testing and specialist consultation(s) as needed. Given the strong evidence for serious risk in prescribing ultrahigh doses of opioids intermittent reassessment was required.

e. The CSPMP database indicated the following escalation of opioid dosing:

6/22/11, fentanyl 100 mcg #15, oxycodone 30 mg #60, MME/D 360+90=450

8/17/11, fentanyl 100 mcg #15, oxycodone 30 mg #90, MME/D 360+135=495 VAS (Visual Analogue Scale, a pain scale) 6/10

11/9/11, fentanyl 100 mcg #15, oxycodone 30 mg #90, Abstral 100 mcg #32 for 8 days (4/a day) MME/D 360+135+52=547 VAS 6/10

12/7/11, fentanyl 100 mcg, Abstral 400 mcg #64 for 8 days (8/ a day), MME/D 360+416=776, VAS 6/10

2/1/12, fentanyl 100+50 mcg, MME/D 360+180=540, VAS 8/10

2/29/12, fentanyl 100+50 mcg, Abstral 400 mcg #96 for 12 days (8/a day), MME/D 540+416=956, VAS 6/10

3/28/12, fentanyl 100+50 mcg, Subsys 200 mcg #90 for 11 days (8+/a day), MME/D 540+294.545=834.545, VAS 6/10

4/25-26/12, fentanyl 100+50 mcg, Abstral 400 mcg #32 for 8 days +200 mcg #192 for 24 days, MME/D 540+416=956, VAS 6/10

Note: Subsys discontinued because VR could not tolerate it.

5/23/12, fentanyl 100+50 mcg, Subsys 800 mcg #120 for 30 days (4/a day), MME/D 540+576=1116, VAS 6/10

6/19/13, fentanyl 100+50 mcg, Subsys 1200 mcg #240 for 15 days (8/a day), MME/D 540+1728=2268, VAS 6/10

Note: Subsys, per the CSPMP, was written for 240 total for 15 days, but Rx renewed after 30 days.

8/13/14, fentanyl 100+50 mcg, Subsys 1200 mcg #240, MME/D 540+1728=2268, VAS 8/10

4/30/15, fentanyl 100+50 mcg, Subsys 1200 mcg #240, MME/D 540+1728=2268, VAS 6/10

4/28/16, fentanyl 100+50 mcg, Subsys 1200 mcg #240, MME/D 540+1728=2268, VAS 5/10

6/28/17, fentanyl 100+50 mcg, #15, Subsys 1200 mcg #240, MME/D 540+1728=2268, VAS 5/10

f. Respondent's long term prescribing of opioids to VR potentially exposed him to abuse, addiction, diversion, accidental overdose, aspiration, brain damage, death, as well as hypogonadism, osteoporosis, narcotic bowel syndrome, sleep apnea, opioid induced mood disorder, and opioid induced hyperalgesia (increased sensitivity to pain).

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Patient KV

277. On or about April 10, 2017, the Board received a referral from the Arizona State Board of Pharmacy. The referral notified the Board that Respondent's prescribing practices to his patients raised concerns.

278. On April 26, 2017, the Board notified Respondent of the Pharmacy Board referral and directed him to provide complete medical records under his possession and/or control to the Board for patients LB, CC, LM, and KV.

279. The April 26th letter informed Respondent that the allegation being investigated by the Board against him was the "[i]nappropriate prescribing of controlled substances."

280. Respondent complied and provided his medical records for patients LB, CC, LM, and KV for only the last three years, with the Board's permission, to keep the case size manageable.

281. From the CSPMP, patient KV was regularly prescribed benzodiazepine and testosterone replacement before receiving treatment from Respondent in June 2012.

282. From the CSPMP, patient KV was prescribed opioids on an extremely limited basis over the four years before receiving treatment from Respondent, and what opioids were prescribed were of infrequent, low quantity, low dose short acting opioids.

283. From the CSPMP, the highest morphine equivalent ever prescribed to KV, eight weeks before receiving care from Respondent, was 60 mg morphine equivalent daily (MED) which was prescribed on only two occasions over the previous four years.

284. From the CSPMP, it was not until March 2012 that KV was prescribed a sustained release opioid for the first time consisting of a total of 10 Oxycontin tablets 10 mg.

285. From the CSPMP, KV was prescribed escalating opioid doses by a different prescriber over the eight weeks before the first prescription was written by Respondent.

286. The above five paragraphs contradict Respondent's May 8, 2017 letter to the Board wherein he claims that KV has been "on opiate medications for over a decade."

287. From Respondent's medical records, KV's first consultation with Respondent was May 15, 2014 and his last consultation was April 10, 2017 for a total of 38 visits.

KV's Consultations During 2014

288. At the May 15, 2014 consultation, KV was a 50-year-old male with a history of chronic intractable neuropathic pelvic pain, cervical disc disease, and knee arthritis,

whose pain and function were improving with current treatment, and who had no adverse events or abnormal drug behaviors.

289. The May 15th notes stated that KV's chief complaint was pelvic pain and this visit was a follow-up visit.

290. KV described his pain on the May 15th visit as 7 on a scale of 0 to 10.

291. From the May 15th notes, KV's medical history included, "[a]nxiety, [d]epression, dislocation to left knee, shoulder x 3, head injuries, TMJ, meningitis, chronic pelvic pain, low back pain, neck pain, multiple mva's [motor vehicle accidents]."

292. The May 15th notes further disclosed that KV's surgical history consisted of a joint repair of the right shoulder, knee; Bristol surgery; motor vehicle accident, cosmetic ear surgery; severe groin injury; and penial organ amputation.

293. The May 15th notes also stated KV's social history was that he smoked 1-2 cigarette packs per day, non-drinker, single, and had a past history of street drug use.

294. The May 15th notes stated, in the physical exam section, that KV appeared to be in pain, distressed, frail, having jaw pain and tenderness, TMJ tender, decreased strength to upper extremities, decreased strength to lower extremities, allodynia (pain due to stimulus that does not normally provoke pain) widespread, antalgic gait (a walking gait to avoid pain), using a walker, and 18 out of 18 tender points on the body.

295. The May 15th notes stated that KV was taking these controlled medications:

(a) Dilaudid (hydromorphone) 8 mg, #270, nine tablets daily;

(b) Opana ER (oxymorphone) 40 mg, #180, six tablets daily;

(c) Tramadol (an opioid) 50 mg, two tablets as needed;

(d) Subsys (fentanyl) 1,600 mcg (800 mcg/spray x 2), spray 1 vial under the tongue four times a day, #120;

(e) Lorazepam (a benzodiazepine) 2 mg/ml solution to take as needed;

(f) Restoril (a benzodiazepine) 15 mg two tablets at bedtime; and

(g) Nuvigil (armodafinil, a central nervous system stimulant) 250 mg daily.

296. There was no indication from the May 15th notes whether the above mentioned controlled substances were only prescribed by Respondent or another physician

297. A review of the CSPMP disclosed that two of the benzodiazepines (controlled substances), which KV was taking on May 15th, were written by another physician.

298. The CSPMP also disclosed that Respondent began prescribing opioids to KV in June 2012, all other opioids from that time forward, and all Nuvigil prescriptions.

299. From the May 15th consultation notes, Respondent stated in the "Plan Note" Section the following:

(a) continue medication management;

(b) follow up with pulmonologist;

(c) follow up with interventional pain management cervical spine;

(d) MRI of right knee, pending;

(e) follow up with primary care physician;

(f) follow up with pain counselor;

(g) reevaluation [in] four weeks;

(h) patient questions answered, risks, benefits and side effects of current treatment plan discussed with patient; and

(i) smoking cessation discussed for greater than three minutes.

KV's Consultations During 2015

300. On August 6, 2015, KV's physical examination stated he was now using a wheelchair, not a walker.

301. On the October 1st visit, KV stated his pain was 7 on a scale of 0 to 10.

302. Respondent's consultation notes for 2015 stated in several places that KV's "Arizona state pharmacy profile [is] consistent with proper medication use," but urine and oral drug tests found in the medical records do not support this statement.

303. The urine screen done on July 9, 2015 showed that KV had positive results for lorazepam (last dispensed November 10, 2014) and temazepam (last dispensed March 1, 2015) and negative results for tramadol, though KV was currently prescribed this controlled substance.

304. On October 1, 2015, KV was given an oral fluid drug test (sputum drug screen). That test disclosed KV had a positive result for lorazepam (last dispensed November , 2014).

KV's Consultations During 2016

305. From Respondent's consultation notes, KV's first consultation in 2016 was January 20, 2016 and the last consultation was December 19, 2016.

306. During 2016, KV had a total of 14 visits with Respondent.

307. The January 20, 2016 consultation notes stated KV's chief complaint was "pelvic pain" and his pain was 7 on a 0 to 10 scale.

308. During the January 20th visit, Respondent prescribed Duragesic (fentanyl) patches to KV: One Duragesic patch, 100 mcg/hr patch 72 hour, apply 1 patch to skin every 72 hours, disp. 10 NR.

309. The consultations notes for the next three months (January through March 2016) showed an attempt to transition KV from Opana ER to Duragesic, but KV returned to using Opana ER and discontinued using the Duragesic patches.

310. On April 21, 2016, Respondent reinitiated the prescribing of Subsys, which was absent from KV's medication regimen for the last 16 months.

311. On April 21st, Respondent prescribed to KV the following: Subsys (fentanyl) 1,600 mcg (800 mcg/spray x 2) non-aerosol spray, spray 2 spray under tongue every four hours, as needed for pain, disp. 360 NR, start date 4/21/2016.

312. On that same date above, Respondent prescribed the previous Subsys prescription again with no deviations or changes.

313. The "Notes" Section for the April 21st notes stated: "pending [S]ubsys auth[orization]."

314. On December 19, 2016, the consultation notes stated, under "Plan Note" Section, "unable to stay on [S]ubsys will resume dilaudid."

315. On December 19, 2016, KV rated his pain a 7 on a scale of 0 to 10.

316. Respondent's consultation notes for 2016, at times, stated that KV's "Arizona state pharmacy profile [is] consistent with proper medication use," but urine and oral drug tests found in the medical records do not support this statement.

317. On February 18, 2016, a drug test was given to KV with the results positive for temazepam (last prescription given March 1, 2015), negative for fentanyl (currently then prescribed through patches per CSPMP), negative for oxycodone (currently then

prescribed per CSPMP), and negative for tramadol (currently then prescribed per CSPMP).

318. On June 9, 2016, KV was given a sputum drug test having a positive result for temazepam (last prescription dispensed March 1, 2015).

319. There were no notations in Respondent's 2016 consultation notes that he discussed the abnormal drug results with KV to understand what was causing these results or whether KV's former street drug use was impacting his ability to properly use the controlled substances prescribed to him.

KV's Consultations During 2017

320. During 2017, KV had four follow-up visits with Respondent from January through April 10, 2017.

321. The consultation notes for January 16, 2017 stated, under "Plan Note" Section, that Respondent would be "replac[ing] opana with duragesic and dilaudid with oxycodone" for KV.

322. The consultation notes for February 13, 2017 stated, under "Plan Note" Section, that Respondent would replace KV's Opana with Duragesic because he does not tolerate that controlled substance.

323. Two drug tests were administered to KV. The first test, an oral test, was administered on January 16, 2017 and the results were positive for oxycodone (last dispensed November 21, 2016), positive for noroxycodone (last dispensed November 21, 2016) and positive for hydrocodone, which had not been prescribed.

324. The second drug test, a urine test, was administered, on March 10, 2017, and the results were positive of temazepam (last dispensed March 1, 2015, per CSPMP) and positive for morphine, which had not been prescribed.

325. There were no notations in Respondent's 2017 consultation notes that he discussed the abnormal drug results with KV to understand what was causing these results or whether KV's former street drug use was impacting his ability to properly use the controlled substances prescribed to him.

326. Respondent's care and treatment of KV deviated from the standard of care as follows:

a. The standard of care required Respondent to carefully state the rationale for the off-label use of Subsys, to "start low and go slow" to find the effective dose, to provide careful safe use instructions, and to follow standard principles related to opioid prescribing for chronic pain. Specifically, Subsys under the TIRF REMS Program instructs physicians as to dosage, initiation, titration, maintenance and patient education that must be followed meticulously due to concerns about misuse, abuse, addiction, overdose, and serious complications due to medication errors. The instruction for the initial dose of Subsys is 100 mcg and then patients are individually titrated to find the lowest effective dose with the patient's treatment plan and provide constant assessment and monitoring of the patient at all follow-up visits.

b. Respondent deviated from the standard of care by violating his agreement under the TIRF REMS Access Program by prescribing, on January 23, 2013, an initial dose of 800 mcg of Subsys, as disclosed in the CSPMP, to KV instead of 100 mcg.

c. Respondent deviated from the standard of care by violating his agreement under the TIRF REMS Access Program when he discontinued prescribing Subsys to KV for 16 months, but later restarted prescribing Subsys to VR, on March 21, 2016, at the initial dose of 1600 mcg to KV instead of 100 mcg.

d. The standard of care required Respondent to collaborate and create with KV a chronic pain management treatment plan for opioid use, but also discuss other noninvasive techniques strategies such as physical therapy, non-opioid medications, and specialist consultations as needed.

e. Respondent deviated from the standard of care by relying heavily on high dose opioids to treat the presumed diagnoses of arthritis and chronic intractable pelvic pain, in the absence of a coordinated multidisciplinary treatment plan, and with adequate attention to alternative treatments.

f. The standard of care required Respondent to do intermittent reassessments of KV's underlying pain problems, especially breakthrough pain, to determine if ongoing opioid prescribing was warranted, and/or if there was the development of new progressive pathologies. Intermittent reassessments include targeted physical re-examinations, updated diagnostic testing and specialist consultation(s) as needed. Given the strong evidence for serious risk in prescribing ultrahigh doses of opioids intermittent reassessment was required.

g. The standard of care required Respondent to provide a clinical rationale as to the necessity to prescribe opioids and benzodiazepines to a disabled patient with a substantive history of obstructive sleep apnea knowing that these combinations of medications to be highly addictive and increase the risk of respiration depression, accidental overdose and death.

h. The standard of care required Respondent to provide a clinical rationale as to the necessity of prescribing Nuvigil to KV, which Nuvigil (a stimulant) has a significant potential for abuse, addiction, and diversion. Nuvigil may be used to treat adults with established diagnosis of ADHD, narcolepsy or excessive daytime sleepiness ("EDS"). A detailed psychiatric history and evaluation is required for an ADHD diagnosis. Likewise, a detailed neurologic and/or pulmonary evaluation is required to make a diagnosis of narcolepsy or excessive daytime sleepiness.

i. Once the diagnosis of ADHD, narcolepsy or EDS has been properly established, the symptoms persist despite appropriate treatment to address the underlying cause, the use of Nuvigil or another stimulate may be considered to address the ongoing symptoms. Prescribing Nuvigil or another stimulate requires careful follow-up assessment and documentation as to the patient's response to the medication.

j. Respondent deviated from the standard of care by failing to provide a clinical rationale for prescribing Nuvigil to KV, failing to provide any documentation of an appropriate established diagnosis warranting the

use of this stimulate, failing to provide treatment documentation of any underlying causative factors, and failing to systematically assess Nuvigil's efficacy on target symptoms and/or related side effects.

k. Respondent's long term prescribing of opioids to KV potentially exposed him to abuse, addiction, diversion, accidental overdose, aspiration, brain damage, death, as well as hypogonadism, osteoporosis, narcotic bowel syndrome, sleep apnea, opioid induced mood disorder, and opioid induced hyperalgesia (increased sensitivity to pain).

327. Respondent was required to maintain adequate medical records for patients CC, AS, VR, and KV. "'Adequate [medical] records' means legible 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 the treatment.'" A.R.S. § 32-1401(2).

328. Respondent failed to maintain adequate medical records, in accordance with A.R.S. § 32-1401(2), which is a violation of A.R.S. § 32-1401(27)(e). Respondent's medical records for CC, AS, VR, and KV show a pattern and practice wherein there is no discussion and/or clinical rationale written in those patients' records as to why a particular patient was prescribed certain medications (i.e., Subsys, opioids, and other controlled substances), a change in the strength or dosage of the medications, or why certain medications were discontinued or reintroduced. In several instances, Respondent's medical records, particularly the "physical examination" and "Review of Systems" sections, for patients CC, AS, VR, and KV are almost verbatim repeated every consultation with these patients. And at times, Respondent's medical records for patients CC, AS, VR, and KV contain health information from these patients that contradicts or questions Respondent's observations or findings.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over Respondent and the subject matter in this case.

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. 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. Respondent has admitted that Respondent's patient records were incomplete and inadequate as noted above.

6. Therefore, the Board established that Respondent's conduct constituted unprofessional conduct pursuant to A.R.S. § 32-1401(27)(e) in that he failed or refused to maintain adequate records for his patients as defined by A.R.S. § 32-1402(2).

7. The allegations contained in the Complaint and Notice of Hearing involve incidents that occurred from 2011 through 2015. It is undisputed that the standard of care in the medical community is ever evolving and is formed based on both what other physicians in the same field are doing on a regular basis, and published "guidelines" from various sources. It is also undisputed that a physician can deviate from a published guideline if the situation calls for such deviation. Best practices, however, dictate that an explanation for the deviation should be documented. It is also undisputed that a standard of care is not statutorily codified.

8. Both Drs. Rob Ashby (the Board's expert) and Dr. Michael Loes (Respondent's expert) testified the Federation of State Medical Boards' "Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Standard" ("FSMB Model Policy"), issued July 2013, codified the then prevailing standard of care for physicians to safely and effectively treat patients with chronic pain, including, if indicated, the use of opioid analgesics. Therefore, at least from 2013 forward, the standard of care has been established.

9. It may be that Respondent was able to articulate the reasons for his deviation from the standard as to each patient; however, the lack of documentation of the same poses a problem.

10. The weight of the evidence presented established by clear and convincing evidence that Respondent's treatment of the patients outlined *supra* failed to meet the standard of care. Respondent repeatedly prescribed medications without *documented* clinical justification or rationale and failed to document any attempt at monitoring for compliance with medication use. Without proper documentation, it is assumed that it did not occur.

11. Thus, the Board further established that Respondent's conduct constituted unprofessional conduct pursuant to A.R.S. § 32-1401(27)(r) in that he committed any conduct or practice that was or might be harmful or dangerous to the health of the patient or the public.

12. Respondent is in a unique procedural situation in that he has not had an active license for the last seven years due to voluntarily entering into the ICA in 2017. Respondent would still be unable to practice medicine unless he reapplied for a license and met all licensure requirements. If Respondent's license were revoked, he would be statutorily prohibited from reapplying for an additional five years, after having been on a full practice restriction for the past seven years.

RECOMMENDED ORDER

Because of the age of the case, Respondent voluntarily entering into the ICA, the uncertainty surrounding the standard of care *prior* to 2013, and based on the foregoing stipulated facts, it is recommended that on the effective date of the Board's final order in this matter, the Board issue a decree of censure against Respondent's license No. 21415.

It is further recommended that Respondent be assessed the cost of the formal hearing incurred by the Board in this matter.

Pursuant to A.R.S. § 41-1092.08(I), the licensee may accept the Administrative Law Judge Decision by advising the Office of Administrative Hearings in writing not more than ten (10) days after receiving the decision. If the licensee accepts the Administrative Law Judge Decision, the decision shall be certified as the final decision by the Office of Administrative Hearings.

In the event of certification of the Administrative Law Judge Decision by the Director of the Office of Administrative Hearings, the effective date of the Order will be forty (40) days from the date of that certification.

Done this day, August 29, 2024.

/s/ Amy M. Haley
Administrative Law Judge

Transmitted by either mail, e-mail, or facsimile to:

Patricia E. McSorley, Executive Director
Arizona Medical Board

By: OAH Staff