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| **IN THE MATTER OF** | * | **BEFORE THE MARYLAND** |
| **NORMAN B. ROSEN, M.D.** | * | **STATE BOARD OF PHYSICIANS** |
| **Respondent.** | * | **Case Number: 2008-0018** |
| **License No. D11985** | * | |

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## FINAL DECISION AND ORDER

Norman B. Rosen, M.D. is a physician licensed by Maryland State Board of Physicians ("Board") since 1971. The issues in this case are whether (1) Dr. Rosen prescribed excessive amounts of opioids in treating a patient for chronic pain, and failed to properly monitor the patient for addiction and diversion, in violation of appropriate standards of quality medical care; and (2) engaged in unprofessional conduct in the practice of medicine by failing to properly supervise the prescribing practices of a physician assistant that he employed.

## Procedural History

The Board began an investigation after receiving information from the Maryland Division of Drug Control about an ongoing Drug Enforcement Agency ("DEA") investigation regarding the diversion of controlled drugs by a male patient who was prescribed large quantities of oxycodone by physicians and physician assistants at Dr. Rosen's practice. In March, 2012, the Board subsequently charged Dr. Rosen with engaging in unprofessional conduct in the practice of medicine and failure to meet appropriate standards for the delivery of quality medical care, in violation of the Maryland Medical Practice Act, Md. Code Ann., Health Occ. § 14-404(a)(3)(ii) and (22), respectively. Dr. Rosen requested and received an evidentiary hearing in December, 2012, at the Office of Administrative Hearings before an Administrative Law Judge ("ALJ"). The evidence included expert witness testimony from Jeffrey A. Gudin, M.D. and Marcia D. Wolf, M.D. on behalf of Dr. Rosen, and from Ira D. Kornbluth, M.D. and Damean W.B. Freas, D.O.,

on behalf of the State. In a Proposed Decision, the ALJ recommended that the charges be dismissed. The State filed exceptions to the ALJ's Proposed Decision and Dr. Rosen filed a response. Both parties appeared before the Board on June 26, 2013 for an oral exceptions hearing. This Final Decision and Order is based on the Board's consideration of the entire administrative record before the Board on that date. The evidence includes the patient's medical records, the exhibits and testimony produced at the hearing before the ALJ, the Proposed Decision, the written exceptions and response to exceptions, and the arguments by both parties to the Board during the written and oral exceptions process.

## I. FINDINGS OF FACT

Dr. Rosen directs a practice specializing in pain management and rehabilitation. He supervised Employee A, a physician assistant ("PA") who treated patients and prescribed narcotic medication under a delegation agreement with Dr. Rosen from August, 2005 to July 13, 2007. The patient in this case - Patient A - was treated at Dr. Rosen's practice for complaints of chronic pain from February 2, 2005 through June 20, 2007. Patient A's course of treatment by Dr. Rosen and Employee A, and the documentation of that treatment, is not disputed.[1] The Board has evaluated the evidence in the medical records about the patient's course of treatment in 2005, 2006 and 2007, Dr. Rosen's testimony about his treatment, and the reports and testimony of expert witnesses, the bases for their opinions, and the ALJ's proposed decision. The Board makes the following findings of fact by a preponderance of the evidence.[2]

[1] The parties stipulated to these facts. *See* page 6 of the Proposed Decision ("PD"), numbered findings (" #") 1-7.
[2] The Board will indicate in footnotes similar findings made by the ALJ, whether made in the Proposed Decision's numbered findings of fact or in relevant paragraphs of pages in the ALJ's discussion.

## The Medical Records and Dr. Rosen's Testimony

1. Patient A was treated by Dr. Rosen, Employee A, and other physicians and physician assistants at Dr. Rosen's practice.[3] Dr. Rosen testified that he takes primary responsibility for training all physicians and physician assistants ("PAs") at his practice, and as a supervising physician, sees and reviews patients seen by PAs and generally confirms findings made. (T. 337-39) [4]

## History and Initial Evaluation

2. Patient A was a 37 year-old male with a history of opioid addiction, depression, alcohol abuse and low back pain which was aggravated in January, 2005, by lifting a heavy object. Following examination by a neurosurgeon, Magnetic Resonance Imaging ("MRI") of his cervical spine and lumbar spine showed bulging disc at C3-4 and C4-5, bulging disc at L5-S1 and minimal bulging disc and facet arthritis at L4-5.[5]

3. When Patient A was referred to Dr. Rosen in February, 2005, he was already on Percocet and Lortab, two Schedule II opioid medications - equivalent to a daily dose of 60 milligrams (mg) of oxycodone.[6]

4. Dr. Rosen performed appropriate initial evaluations on February 2 and 7, 2005, and diagnosed the patient with mechanical low back pain, sacroiliac dysfunction, myofascial pain, and degenerative disc disease at L5-S1 with possible central herniation. He recommended that the patient begin daily physical therapy for the next 4-6 weeks, and psychotherapy visits weekly. He prescribed one to two tablets of Percocet 5 mg every four hours with a maximum of six tablets daily as needed for pain as well as anti-inflammatory, muscle relaxers and antidepressant medications. Dr. Rosen also scheduled the patient for a lumbosacral corset fitting and a follow up visit to consider epidural injections.[7]

5. The patient signed an opioid agreement on February 7, 2005, affirming his understanding of the significant side effects of opioids and the alternative pain relieving strategies recommended by Dr. Rosen.[8]

## Course of treatment from February-December, 2005

Opioid Prescribing

6. Between February and December, 2005, Patient A was seen on a weekly basis by Dr. Rosen and other PAs at the practice.

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[3] PD, p. 9, # 24-29.
[4] (T.-) refers to the page number in the transcript of the administrative hearing.
[5] PD, pp. 9-10, # 30-33.
[6] PD, pp. 10, # 35.
[7] PD, pp. 10-11, # 34-37.
[8] PD, p. 11, # 38.

7. In February and March, 2005, Patient A reported pain levels fluctuating between three and nine on a scale of ten and took Percocet 5 mg eight to twelve times a day. He received myofascial injections on March 24, 2005, and subsequently reported a decrease in pain and a goal of decreasing his medications. On April 20, Patient A stated he was feeling good and did not want to be on medications permanently.[9]

8. In May, 2005, Patient A's pain level decreased. He reported wanting to wean off Percocet, but stated that he needed opiates to function doing construction work. He complained of increased lower back pain in June, 2005, at which point Dr. Rosen recommended that he attend physical therapy and acupuncture, obtain myofascial injections and a referral for epidural injections for his lumbosacral spine.[10]

9. On June 20, based on Patient A's reports of increased pain, Dr. Rosen discontinued the Percocet and prescribed 100 pills of oxycodone 5 mg. On June 27, Dr. Rosen prescribed an additional 200 pills of oxycodone 5 mg - up to 12 times a day.[11]

10. By July, 2005, Patient A was taking oxycodone 5 mg 12-16 pills a day. Dr. Rosen prescribed Morphine Sulphate (an opioid) on July 19, but discontinued the drug after Patient A reported that it made him high.[12]

11. The medical record on August 11 and 25 shows the patient took 5 mg of oxycodone 14-16 times a day. Patient A indicated that he would like to decrease and get off pain medication, increase physical therapy and have epidural injections.[13]

12. Patient A continued to complain of constant low back and neck pain and by September 22, Dr. Rosen was prescribing 5 mg of oxycodone 16-20 (80 -100 mg) times a day. Patient A characterized the opioids as "taking my light and edge away" and complained of being "flat all the time." Dr. Rosen testified that Patient A's negative comment about the opioids was taken out of context. He believed the patient was just a "little bit wired" because of a mental illness (T. 345-46) but later acknowledged to the ALJ that there was no formal diagnosis of such a mental illness in the patient's record. (T. 378)

13. Dr. Rosen discussed with the patient the options of detoxing from opioids or shifting to a longer acting drug such as Kadian (a Morphine Sulphate extended release capsule) or Methadone (a Schedule II synthetic opioid). Patient A told Dr. Rosen that he was not currently willing to taper off opioids because he needed six to eight weeks of strenuous work to pay bills.[14]

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[9] PD, pp. 11-12, # 40-47.
[10] PD, p. 12, # 48-51.
[11] PD, pp. 12-13, # 52-53.
[12] PD, p. 13, # 54-56.
[13] PD, p. 13, # 57-58.
[14] PD, pp. 13-14, # 59-60.

14. On September 29, 2005, the patient reported that he planned to file for unemployment. The idea of switching to a longer acting medication was also discussed at that visit.[15]

15. In October, November and December, 2005, Patient A had weekly office visits with Dr. Rosen and other physicians and PAs in the practice, including Employee A.[16] He complained of increased pain in his back and legs from work and said he could not continue in construction. On October 12, Employee A prescribed 170 pills of oxycodone 5 mg for two weeks (13 pills a day). On October 27, another PA prescribed 150 pills for pain for one week (14 pills a day).

16. Dr. Rosen substituted Methadone for oxycodone on November 3, 7 and 10,[17] and wrote concurrent prescriptions for Lyrica (an anticonvulsant), Soma (a muscle relaxer) and Sonata (a hypnotic). (10152, 10154, 10156, 10457) [18] Dr. Rosen discontinued the Methadone when the patient claimed he passed out three times and had a car accident due to drowsiness.

17. On November 17, a Duragesic patch (another opioid) was prescribed for pain, and the dosage was increased on subsequent visits. (10142, 10144, 10146, 10150, 10464, 10466)

18. On December 15, a PA at Dr. Rosen's practice discontinued the Duragesic because Patient A didn't like it, and prescribed 32 pills of Percocet 10 mg/325. The patient also reported taking oxycodone 10 mg based on 20 pills prescribed by his primary care physician.

19. On December 22, Patient A complained of a gum infection and said that Hydrocodone prescribed by his dentist did not help. The PA issued a prescription for 180 pills of oxycodone 10 mg. (10478) The PA also discussed in great detail the long term risks of opiates with Patient A on that visit. (10139). During an office visit on December 29, the PA noted that "according to the patient and NBR [Dr. Rosen]" a prescription for oxycodone 5 mg was filled at the pharmacy and the dose increased to 120 mg/day (24 pills a day) due to a dental abscess. (10479) The PA prescribed 112 pills of oxycodone 5 mg for one week (80 mg/day or 16 pills/day). (10481)

Use of other medications and alternative pain relief modalities in 2005

20. In addition to oxycodone and other opioids, Dr. Rosen also prescribed anti-anxiety, anti-inflammatory, anti-seizure, corticosteroid and muscle relaxant medications in 2005 for Patient A, including Valium, Naprosyn, Lyrica, Flexeril, Prednisone, Soma and Sonata.

21. Patient A attended sixteen physical therapy sessions and four acupuncture sessions from March through November, 2005. He did not attend physical therapy after that due to financial constraints.[19]

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[15] PD, p. 14, # 61-63.
[16] PD, p. 14, # 64.
[17] PD, p. 15, # 70.
[18] The parenthetical 5-digit numbers refer to pages in the medical record. (Respondent's Exh. 1 or State's Exh. 12).
[19] PD, p. 20, # 100, 103.

22. On February 2, 2005, Patient A met briefly with an in-office social worker who established that he was agreeable to social work services, had significant family and financial stressors, and had ended treatment with a psychotherapist because he disagreed with the recommendations. (10361) Patient A did not have mental health treatment in Dr. Rosen's office in 2005. He reported having mental health counseling in a health system (Wellspan Health) outside the office.

Drug Screening

23. Dr. Rosen did not perform any drug screening tests on Patient A between July and November, 2005. He obtained urine toxicology tests twice on November 10 and 17, 2005. The patient tested positive for marijuana. Dr. Rosen did not schedule Patient A for increased urine screens as a result of the positive tests.[20] At the hearing, he testified that there was no reason to do so. In his view, the patient was complicated and multi-layered, marijuana was a cheap and safer Xanax, the positive test was not relevant and was not going to change what he did with this patient. (T. 374-75)

**Course of treatment from January-December, 2006**

24. In 2006, Patient A requested less frequent office visits because he had no health insurance after February. From March through July, and in September, October and November, Patient A had office visits once a month, and two visits in August.[21] He saw Dr. Rosen, Employee A, and other physicians and physician assistants, and had a pain rating of between three and five. His pain treatment consisted mainly of oxycodone 80 mg a day of 5 mg pills (16 pills a day), and he received prescriptions at each visit for 480 pills, except on August 8, when Employee A wrote a script for 385 pills.

25. Dr. Rosen did not obtain any drug screens in 2006. The patient did not attend physical therapy or in-office social work counseling at any time in 2006.[22] He reported performing home exercises and seeing a mental health provider outside of the office.

26. On January 19, another PA discussed Patient A's opioid dependence with him, encouraged him to take less and to use opioid sparing techniques.

27. On January 19, the patient also signed another opiate agreement. (10489) He agreed not to seek pain medications from other medical providers, to take medications as prescribed, and pledged not to increase medications himself without first discussing with Dr. Rosen. Based on the language of the agreement, Patient A understood that those practices were strictly enforced, and that non-compliance could result in serious consequences.

28. In March, Patient A's pharmacy sent a letter to Dr. Rosen's practice expressing concern about the potential health detriment posed by the patient's long-term, continuous use of oxycodone 5 mg. Dr. Rosen replied that he and Patient A were aware of the long-term

[20] PD, p. 14, # 65.
[21] PD, p. 14, # 66.
[22] On April 20, Employee A documented that the patient saw the social worker "for a few minutes. . ."

risks of chronic opioid use, and were making continued efforts to use as many opiate sparing techniques as possible, including physical therapy, mental health counseling and use of alternative medications. (10500, 10507)

29. On April 20, Employee A documented a plan to start decreasing the patient's oxycodone at the next visit. At that next visit on May 18, she maintained Patient A on the same regimen of oxycodone 80 mg a day in 5 mg doses (16 pills a day). A notation in the medical record stated that Patient A was not ready to decrease the oxycodone, and wanted to stay on 16 pills a day. Employee A continued that same regimen during office visits in June, July and August. In June, Dr. Rosen's office notified Patient A (10516) by mail that a check he had written to the practice had bounced.

30. On August 30, Employee A had a lengthy discussion with Patient A about the need to try longer acting medications and the risk that his high dosage of oxycodone would lead to tolerance and dependence.

31. On September 26, Employee A documented a goal for the patient to wean off oxycodone "in [the] near future." On October 24, she further noted another proposal to "to wean down" the patient's oxycodone. At each visit, she also discussed with Patient A the need for him to restart physical therapy when his finances improved.

32. On November 17, another physician at the practice prescribed the routine dose of 480 pills of oxycodone 5 mg for Patient A before the patient went out of town.[23]

November - December, 2006: Car accident and treatment in Pennsylvania

33. On December 1, 2006, Patient A was treated at a hospital emergency department in York, Pennsylvania, after reporting that his car was rear ended in an accident on November 22. The patient described his pain as a ten out of ten and complained of increasing neck pain, bilateral hand numbness, and increased pain in his left buttock, left knee and left foot. He received Dilaudid 2 mg IV (an opioid), and was discharged with a 5 day prescription for Prednisone 20 mg (a corticosteroid) and 120 pills of oxycodone 5 mg.

34. An x-ray of Patient A's lumbar spine and a CT scan of his cervical spine on December 1 and an MRI of his cervical spine on December 18, 2006, showed no substantial changes from the MRI tests performed before his first assessment in February, 2005 by Dr. Rosen.[24]

35. On December 19, Patient A returned to Dr. Rosen's office complaining of increased pain due to the car accident. He was prescribed Prednisone 20 mg, and his pain medication was increased by a physician assistant to 350 pills of oxycodone 5 mg (110 mg or 22 pills a day).

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[23]PD, p. 15, # 71-72;
[24]PD, pp. 15-16, # 73-75;

## Course of treatment from January 10 – June 20, 2007

January, 2007

36. Patient A saw the same PA again on January 10, 2007. He complained of neck and shoulder pain and worsening pain symptoms since his car accident. He reported escalating the medication dosage himself. The PA noted no signs of overdose or withdrawal. She prescribed 130 pills of oxycodone 5 mg (90 mg or 18 pills a day). Patient A wanted an increase in his medication. When the PA left the room to call Dr. Rosen to discuss that request, Patient A left the office expressing frustration with his pain regimen and stated that he did not want to see that PA anymore.

37. On January 17, Patient A saw Dr. Rosen and Employee A, had a pain rating of 8 and reported taking 110 mg a day of oxycodone 5 mg or 22 pills a day. He received a prescription for 160 pills of oxycodone 5 mg (20 pills a day). The patient was due to start physical therapy the following week but became sick so the session was cancelled.

38. On January 25, Employee A noted that Patient A was not seeing an in-office social worker or receiving physical therapy. She prescribed 250 pills of oxycodone 5 mg for two weeks, recommended that the patient take 21-22 pills a day and noted a plan to continue to decrease the opioid.[25]

39. On January 30, Patient A was seen on an emergency basis by Employee A due to his reports of worsening pain. He told Employee A that the oxycodone "wears off too quick, and that he had taken more of the medication for increased pain (30 pills a day). Employee A prescribed 65 pills of oxycodone 5 mg and added 14 pills of OxyContin 10 mg, a long-acting opioid every twelve hours to Patient A's regimen.[26] She recommended that he see a social worker for anxiety.

February - March, 2007

40. From February 6 through 27, 2007, Employee A prescribed a total of 1,060 pills of oxycodone 5 mg and an additional 50 pills of OxyContin 10 mg [27] (2.3 pills a day-equivalent to 4.6 a day of 5 mg oxycodone pills) during four office visits.[28]

41. On February 6, Employee A prescribed 280 pills of oxycodone 5 mg (24 pills a day) in addition to 50 pills of OxyContin 10 mg (1 to 2 pills every 12 hours). On February 13, she discontinued the OxyContin because the patient reported severe nausea and vomiting,[29] and prescribed 300 pills of oxycodone 5 mg (28 pills a day). One week later, on February 20, Patient A told her he had taken more medication because of increased pain from shoveling snow,[30] and that oxycodone 5 mg "is the only thing that works." Employee A prescribed an additional 260 pills of oxycodone 5 mg. On February 27,

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[25] PD, p.16, # 76-78.
[26] PD, pp. 16-17, # 79.
[27] The medical record indicates an apparent statement by the patient that OxyContin is "not too expensive."
[28] PD, p. 17, # 81.
[29] PD, p. 17, # 82.
[30] PD, p. 17, # 80.

Patient A reported taking 29 pills a day. Employee A prescribed an additional 220 pills of oxycodone 5 mg.

42. During the patient's visits, Employee A also discussed with the patient the need to decrease his opioid dependence, and recommended a plan for Patient A to see Dr. Rosen in the near future to consider treatment options such as trigger point injections, physical therapy and Suboxone (an opioid medication used to treat opioid addiction).

43. During three office visits in March, 2007, Employee A prescribed a total of 830 pills of oxycodone 5 mg, increasing the opioid to 175 mg a day or 35 pills a day. A dipstick urine screen on March 6 did not test positive for any illicit drugs.[31]

April, 2007

44. On April 5, Patient A came for an office visit with a roommate and a letter he had written to Dr. Rosen stating that his goal was to change the manner in which his pain was treated.

45. He wrote that his pain, pain medication and financial difficulties had increased since his car accident in November, 2006, that he took an average of 150 mg of oxycodone 5 mg or 30 pills a day to function and took over 200 mg or 40 pills a day when his schedule was full. Patient A expressed appreciation for the latitude given him concerning his medication and acknowledged that he had resisted Employee A's attempts to move him to a controlled release of the opioid.

46. He also wrote that he took a "drug holiday" on March 23, 2007 for 15 days, turned his medications over to a friend in order to find out if he was dependent on or addicted to the opioids, and disposed of the medications entirely when "the craving was intense." Dr. Rosen testified that the patient said he flushed them.

47. According to Patient A, withdrawal was uncomfortable but acceptable and he found he was unable to physically function without analgesic relief.[32] He believed that oxycodone was highly effective in managing his pain and suggested a plan to return to a regimen of 120-150 mg of oxycodone a day with half of the dose consisting of the short-acting immediate release (IR) oxycodone and the other half controlled release (CR) OxyContin.

48. Patient A stated that he wanted a solid medication exit strategy, that nausea from OxyContin was just a minor nuisance and the cost of OxyContin was outweighed by the efficacy.

49. Employee A documented the patient's history of alcohol abuse and AA meetings in his medical record and prescribed 570 pills of oxycodone 5 mg (150 mg or 30 pills a day).[33]

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[31] PD, p. 17, # 83-84.
[32] PD, pp. 17-18, # 85-86.
[33] PD, p. 18, # 87.

50. Around this time, Employee A also dictated a letter to Patient A's file summarizing his main pain complaints, his car accident and efforts to detox himself off oxycodone "cold turkey." She noted that he was back on oxycodone, and was supposed to take it only when he was working. According to Employee A, the patient was very cautious about taking the medication and worried about going back to his old ways of abuse and addiction.

51. She also stated that Suboxone would be a good choice for Patient A but that he did not want to try it at this time.

52. Employee A also noted that the patient's friend would monitor his medications.

53. On April 24, Patient A was seen by another physician at Dr. Rosen's practice who evaluated him and documented no sign of overdose or withdrawal. That physician increased Patient A's dosage of oxycodone to 175 mg or 35 pills a day, and prescribed another 520 pills of oxycodone 5 mg.[34]

May, 2007

54. On May 8, Patient A complained of relatively new pain in his right knee and presented with swelling and tenderness. With Dr. Rosen's approval, Employee A maintained Patient A on 200 mg or 39-40 pills a day of oxycodone 5 mg, and wrote a prescription for 550 pills.[35]

55. On May 22, Patient A was seen again by Employee A. He reported a pain rating of 5 and told her that he had been to the hospital the previous week due to worsening pain and had received IV Morphine and Medrol (a corticosteroid). Employee A again prescribed a total of 550 pills of oxycodone 5 mg pills - 200 mg or 40 pills a day for a 13¾ days supply. Employee A noted that Patient A was to inquire if the pharmacy stocked 15 mg tablets of oxycodone.[36] The medical records do not indicate any follow up on the issue by the practice.

June 2007

56. At Patient A's next office visit on June 5, 2007, Employee A's documented plan of treatment included trigger point injections, starting physical therapy, beginning counseling with a social worker and decreasing his opioid dependence. In addition, the patient was to ask his attorney to pay Dr. Rosen's practice so he could begin physical therapy. On that day, Employee A prescribed a total of 820 pills of oxycodone 5 mg or 40 pills a day for 20½ days.[37]

57. The patient returned for an office visit two weeks later on June 20, 2007. He told Employee A that his pain was constant with a rating of 4, that the pharmacy did not have all 820 pills of oxycodone and that he had received a partial fill. Employee A confirmed

[34] PD, p. 18, # 88.
[35] PD, p. 18, # 89-90.
[36] PD, pp. 18-19, # 91-92.
[37] Another supervising physician, Dr. Hoffberg, signed off on Employee A's note. *See* PD, p. 19, # 93-94.

with the pharmacy that Patient A had been provided with the total amount of 820 pills prescribed on June 5. This meant that a six-day supply or 220 of the 820 pills prescribed on June 5 were unaccounted for.

58. Employee A wrote another prescription for 525 pills of oxycodone 5 mg.[38] She recommended close monitoring of Patient A's medications, a plan to wean him down from the oxycodone, physical therapy, and to be seen by Dr. Rosen and a social worker.

59. The patient also tested positive for marijuana (and oxycodone) on a urine screening test on June 20. Employee A strongly advised him to stop using marijuana.

60. On that same day, Patient A was arrested for selling his medication.[39]

## II. EVALUATION OF THE EVIDENCE

### The ALJ's Proposed Decision and State's Exceptions

The issues before the Board are whether Dr. Rosen met the standard of quality care and whether he properly supervised the prescribing practices of Employee A. In her proposed decision, the ALJ concluded that Dr. Rosen's treatment of and opioid prescribing for Patient A met the standard of care, that he appropriately monitored the patient for addiction and diversion and properly supervised Employee A's prescribing practices.

The State excepted to the ALJ's proposed findings and conclusions. The State argued that the ALJ's findings were not consistent with the evidence and that she incorrectly rejected the testimony of the State's experts and gave greater weight to the opinions of Dr. Rosen's experts. In his response, Dr. Rosen argued that the Board should affirm the ALJ's proposed decision because her findings were based primarily on demeanor-based credibility determinations. Dr. Rosen further argued that the State presented conflicting and inconsistent evidence regarding the opioid prescribing and screening for abuse and diversion, failed to meet its burden of proof on those issues and did not present sufficient evidence to support a failure to supervise Employee A.

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[38] Employee A's note in the medical record states that she prescribed 252 pills of oxycodone on June 20, 2007.
[39] PD, p. 19, # 95-99.

The Board finds that the ALJ made no demeanor-based credibility findings concerning any fact or expert witness in this case. Dr. Rosen's assertion to the contrary is a misstatement of Maryland law. Unlike fact witnesses, "demeanor has been held to be of little consequence in evaluating the testimony of experts who provide conflicting testimony." *Consumer Protection Div. v. Morgan,* 387 Md. 125, 202 (2005). The Court of Appeals explained that "credibility [of the conflicting experts] is a function of logical analysis, credentials, data base, and other factors readily discernible to one who reads the record." *Morgan,* 387 Md. at 202 (quoting *Nuclear Pollution v. United States Nuclear Regulatory Comm'n,* 582 F.2d 87, 100 (1st Cir. 1978); *see also State Bd. of Physicians v. Bernstein,* 167 Md. App. 714, 761 (2006) ("the Board may make its own decisions about . . . credentials of expert witnesses, the logic and persuasiveness of their testimony and the weight to be given their opinions."). The Board owes no deference to the ALJ's credibility determinations based on the expert evidence or her derivative findings based on the medical record in this case.

Based on its evaluation of the entire record, the Board disagrees with the ALJ's analysis of the medical record and expert opinions and her proposed conclusions on pages 21-37 of the proposed decision. The Board finds that Dr. Rosen violated the prevailing standards of quality care from 2005-2007 by prescribing excessive amounts of opioids and failing to monitor this patient's risks for addiction and diversion. The Board also finds that Dr. Rosen inadequately supervised Employee A's prescribing practices.

The experts for each side held divergent views on the standard of care and supervision charges. In carefully considering the credentials and opinions of Dr. Kornbluth and Dr. Freas on behalf of the State and of Dr. Gudin and Dr. Wolf on behalf of Dr. Rosen, the Board has focused on the factual foundations and medical reasoning for their opinions as well as their education,

knowledge, training and experience. The Board's evaluation of the respective testimony of each expert is based on the logic, credibility and persuasiveness of their opinions as it relates to the totality of the evidence presented at the hearing, particularly the medical records of Patient A. The Board has used its knowledge and medical expertise to evaluate the evidence and make the final determination as to what the standard of care required in 2005-2007 when Dr. Rosen prescribed opioids for this patient. In addition to its findings based on the medical record, the Board will address the State's exceptions and make further findings on the standard of care and supervision issues based on Dr. Rosen's testimony and the evidence presented by the experts for each side.

## The Standard of Quality Care Requirements

### Expert Qualifications

All four physician experts were qualified to testify on the applicable standards of care in this case by their education, training and experience. All are reputable physicians who are board-certified in pain management.[40] All experts practice pain and opioid management and routinely prescribe opioid medications to patients with chronic pain. Dr. Kornbluth and Dr. Freas own and operate multidisciplinary pain management practices that employ physician assistants, and incorporate physical therapy, psychotherapy, acupuncture, opioid agreements, regular drug testing, non-opioid medications, short and long-acting opioids, as well as interventions such as trigger point and epidural injections. They treat pain and degenerative disc disease in the lower back, spine and neck, as well as joint pain, pinched nerves, arthritic, neurologic and muscle conditions. Both physicians engage in clinical practice. Dr. Kornbluth sees 50 patients a week and Dr. Freas sees 25-30 patients daily.

[40] Dr. Rosen is not board-certified in pain management. (Resp. Exh. 14)

The State's experts are also board certified in physical medicine rehabilitation, as is Dr. Wolf, who testified on behalf of Dr. Rosen. Dr. Wolf directs a pain management practice, sees 40-50 patients a week, teaches at Johns Hopkins Medical School and the University of Maryland, and acts as an investigator in clinical trials. She described herself as a physiatrist like Dr. Rosen who sees complicated patients and she refers patients to him. (Resp. Exh. 13; T. 381-82)

Dr. Gudin has board certifications in anesthesiology, addiction medicine and palliative care. He spends 80% of his week seeing patients. He is a national educator and speaker in pain management and addiction medicine, acts as an investigator in clinical trials, and has published in peer review medical literature on safe opioid prescribing. (Resp. Exh. 12; T. 261-69)

The qualifications of each expert meet the standard for providing an expert opinion. The Board declines to give less weight to the reports and testimony of Dr. Kornbluth and Dr. Freas because their practice experience is less lengthy than that of Dr. Gudin and Dr. Wolf, or because they integrate interventional procedures and injections to alleviate chronic pain and lessen the need for narcotics. The medical record shows that Dr. Rosen also utilized 15 trigger point injections to treat the patient's pain between March 2005 and March 2007,[41] and recommended, but did not follow up with, epidural injections. The Board rejects the disparagement of these procedures by Dr. Rosen's experts and their denigration of pain management physicians who incorporate these procedures into their practices. In contrast to the ALJ, the Board does not find that an expert's use of interventional procedures undermines the value of his or her opinion. As the State's experts testified, they prescribe pain medication in addition to using such procedures, but do so rationally and conservatively. It was also clear from their testimony that they strongly believe in utilizing a multidisciplinary approach to pain management in their practices to decrease the need for and reliance on opioid prescribing.

[41] PD, p. 20, # 100, 101, 102, 103, and footnotes 19, 20, 21.

The ALJ also gave more weight to the opinions of Dr. Rosen's experts because she found that they referred to medical journals to support their opinions on the standard of care. Dr. Wolf, however, did not identify any specific medical literature in her report and testimony. (Resp. Exh. 13; T. 380-96) Dr. Gudin's references to pain literature were neither enlightening nor relevant to the specific issues in this case. He cited 1997 published guidelines by the American Academy of Pain Medicine and the American Pain Society that recommend judicious use of opioids for certain patients with chronic non-cancer pain. (Resp. Exh. 12) Because a fact has some basis in scientific literature does not preclude the Board's evaluation of the relevance of that basis. The Board finds that Dr. Gudin's mere reference to this literature sheds little light on the essential question in this case - whether Dr. Rosen's use of opioids for Patient A was judicious.

Similarly, Dr. Gudin did not link his statement on 2009 clinical practice guidelines to the applicable standard of care requirements in this case. His opinion about a lack of evidence on the accuracy of formal screening instruments for predicting benefits or other harms associated with the initiation of opioids is also irrelevant. The issue in this case is not the initiation of opioids, but whether Dr. Rosen violated the standard of care by escalating and failing to taper the opioids.

In contrast to Dr. Gudin, Dr. Freas's general references to pain literature were highly relevant to the issues before the Board. He referred to studies and data on major risk factors in opioid prescribing as well as data on patients likely to abuse or divert. (T. 188-89, 213) Dr. Kornbluth referred to pain literature on the efficacy of Methadone for pain control. This reference was relevant to Dr. Rosen's brief use of Methadone for Patient A. (T. 75)

The Board rejects the ALJ's criticism of Dr. Kornbluth's testimony as inherently biased because of his strong preferences for reducing inappropriately high levels of opioids when treating patients. In the Board's view, having strong opinions on what constitutes the standard of

quality care does not disqualify an expert or detract from the weight to be given his testimony. Dr. Kornbluth testified evenhandedly that opioids have an acceptable use if prescribed in reasonable amounts for an appropriate period of time, if they are properly monitored, and if there is consideration for the potential harmful ramifications to the individual and the community. (T. 29, 32-33, 93) Both Dr. Kornbluth and Dr. Freas were consistently fair in commending Dr. Rosen for his initial examination of Patient A, as well as his credentials and experience. (T. 53, 87, 90,100, 207-08, 236-37) In contrast, the views of Dr. Gudin and Dr. Wolf regarding physicians who use interventional procedures revealed a marked lack of objectivity.

**Expert Reports and Testimony**

Dr. Gudin and Dr. Wolf opined that Dr. Rosen met the standard of care based on factors discussed in their expert reports and in their testimony. (Resp. Exhs. 12, 13; T. 260-309; 380-96) They agreed that Dr. Rosen used a multidisciplinary approach, prescribed non-opioid and other long acting opioid medications, and obtained urine toxicology screens. They opined that the opioid doses and increases were always justified by clinical findings in the medical record.

Dr. Gudin further opined that Dr. Rosen met appropriate standards because he saw the patient frequently, had two opioid agreements, communicated with the pharmacy and had social workers see the patient for a period of time. According to Dr. Gudin, Dr. Rosen acted in good faith in prescribing opioids to Patient A, and operated a legitimate multidisciplinary pain practice, not a pill mill. Dr. Gudin testified that Dr. Rosen properly evaluated the patient for dependence, addiction and diversion. He based this opinion on Dr. Rosen's description of appropriate management as "tightening the leash" if there are signs of misuse, his letter telling the pharmacy that they were aware of the risks and the fact that Dr. Rosen kept a closer eye on the patient every two weeks after the car accident. In his opinion, Dr. Rosen complied with the

standard of care because a 200 mg dose falls within accepted ranges of 40-240 mg in pain practices, and a lot of Americans are maintained on 80 mg three times a day and higher.

Dr. Gudin conceded that Dr. Rosen's use of oxycodone in this case did escalate over time, and that one of the evils is the longer you stay on it, the more you need. He opined that the patient's history of abuse made the case more challenging, because such patients can be difficult, persuasive and manipulative. With respect to diversion, Dr. Gudin stated that doctors are not policemen or responsible for patient misbehavior. He defended Dr. Rosen as a caring physician who "in general" promotes proper medical treatment. (Resp. Exh. 12)

According to Dr. Wolf, Dr. Rosen met the standard of care because he fully examined the patient, performed diagnostic studies, set up and adapted a treatment plan, and changed medications based on roadblocks. She opined that the patient was properly evaluated for withdrawal or overdose, and was opioid dependent but not addicted. In her view, diversion is the most difficult behavior to predict but Dr. Rosen was aware of risks and problems and tightened controls. Dr. Wolf could not say that a certain mg amount was too much for a given patient and testified that that she has some patients on 300-400 mg or 30-40 pills a day. She posited that for a patient with a genetic abnormality, maybe the dose was very low. Dr. Wolf conceded that decreasing medication is always a goal, but stated it is not always practical. She was aware that the patient demanded an increase in the medication and became frustrated when refused, that he had expressed an interest in being detoxed and said he had difficulty in controlling his usage.

Apart from these specifics about Patient A, much of Dr. Gudin and Dr. Wolf's reports and testimony consisted of observations about opioid prescribing generally. The facts of this case do not involve many of the generalizations on which Dr. Gudin and Dr. Wolf based their opinions. Topics like the use of 300-400 mg doses for hypothetical patients, the undertreatment

of chronic pain, and the purported medical efficacy of marijuana in pain management are not relevant to whether Dr. Rosen adhered to his individualized treatment plan for this patient. Nor does the specific prescribing for and monitoring of Patient A involve the range of acceptable doses for opioids in the pain practice community, common standards regarding doses and volume of opioid medication, or the propriety of treating chronic pain patients with psychiatric disorders. There is no indication in the medical record that the patient had a genetic abnormality. Dr. Gudin and Dr. Wolf did not present any evidence to support their opinions that genetic variables explained Patient A's need for the higher doses prescribed.

To the extent that the ALJ's proposed decision was predicated on these general observations by Dr. Rosen's experts, that reliance was misguided. Despite Patient A's history and complexity, the ALJ oversimplified the evidence by concluding that Dr. Rosen met the standard of care based on these generalizations. Dr. Rosen's experts provided only a cursory assessment of the specific medical considerations and risk factors that applied to Patient A. The ALJ's proposed conclusions based on these assessments are thus off the mark.

For example, the medical record reveals that Dr. Rosen's use of a multidisciplinary approach was limited to 2005, and that he relied almost exclusively on opioids to manage the patient's pain in 2006 and 2007. Neither of his expert witnesses addressed this shortcoming. They did not explain how having the patient's friend monitor his use of opioids after the April, 2007 meeting with Dr. Rosen met the standard of care. In the Board's opinion, it is the responsibility of the treating physician to monitor a patient's opioid use, especially a complex patient with recognized risk factors. Nor did they specifically address how Dr. Rosen "tightened controls" in response to Patient A's risk factors. Dr. Gudin's opinion that Dr. Rosen met the standard of care is also unpersuasive because he mistakenly assumed that Patient A was seen by

social workers for counseling at Dr. Rosen's practice. Based on the evidence, that is not the case. The medical records established that the patient never received mental health counseling from social workers at Dr. Rosen's practice.

Whether Dr. Rosen violated the standard of care in treating Patient A does not turn on the generalizations discussed by Dr. Gudin and Dr. Wolf. Nor does it turn on the identification of precise dates or isolated incidents of treatment and prescribing, as the ALJ found, but on Dr. Rosen's entire pattern of opioid prescribing, escalation and monitoring throughout the patient's care from 2005-2007. The Board declines to adopt the ALJ's reasoning. Dr. Kornbluth and Dr. Freas correctly focused on Patient A's specific risk factors as detailed in the medical record, as well as Dr. Rosen's overall prescribing patterns and use of screening tests. They agreed that Dr. Rosen violated the standard of care by overprescribing short-acting opioids for the pain condition being treated, and by failing to obtain sufficient screening tests and adequately monitor the patient's risks for addiction and diversion. (St. Exhs. 4, 5; T. 19-121;178 -254)

Dr. Kornbluth opined that Dr. Rosen's treatment of Patient A did not meet the standard of care for multiple reasons: Dr. Rosen prescribed a level and volume of oxycodone pills in excess to that commonly provided for such a pain problem and did not follow up to wean the drug despite repeated discussions with the patient on the risks associated with it; he escalated the dose without a clear rationale and did not alter his prescribing habits, despite the patient's concerns about the effects of the drug and urine tests that were positive for an illicit substance; the patient did not appear to have a significant reduction in pain to warrant continued use of the high levels prescribed; and although the treatment plan called for weaning the amount of opioids prescribed, the opposite was done. (St. Exh. 5)

Dr. Freas opined that Dr. Rosen failed to meet appropriate standards because he prescribed an excessive amount of short-acting oxycodone given the patient's diagnosis, and especially because the patient did not take the opioids as prescribed. As support for his opinion, Dr. Freas pointed out that the number of pills prescribed by Dr. Rosen and Employee A increased to 40 a day in 2007 and totaled over 1,200 tablets in one four-week period. (St. Exh. 4) He testified that the 2007 levels prescribed by Dr. Rosen in a four-week period were very, very high and outside the standard of care in 2007 for this young, otherwise healthy patient in his late thirties with a small disc bulge condition and minimal findings on an MRI. (T. 210-12, 222-23) Based on its evaluation of the medical record, the Board agrees with Dr. Kornbluth and Dr. Freas.

**Risk Evaluation and Response**

All four experts agreed that the ultimate goal in prescribing opioids is to balance prevention of abuse and diversion with legitimate medical use. Dr. Wolf opined that the main issue in this case was risk evaluation and reaction and that Dr. Rosen and the Employee A were aware of the inherent risks. (Resp. Exh. 13) The Board concurs. The question is not whether simultaneous addiction to and diversion of oxycodone are mutually exclusive concepts, as the ALJ believed, but whether Dr. Rosen failed to monitor the patient for these inherent risks. The charges did not allege, and the Board does not find, that Patient A was addicted to oxycodone during his treatment. The ALJ misconstrued the evidence on this issue. The Board rejects her analysis.

Patient A's history, behavior and conversations revealed the existence of multiple risk factors. He told Dr. Rosen of his discomfort with oxycodone's effects, periodically expressed his desire to get off opioids and requested a solid medication exit strategy in April, 2007. By that

date, Dr. Rosen and Employee A knew of the patient's alcohol abuse and opioid addiction history.[42] Dr. Kornbluth testified that the patient's history of alcohol abuse was significant because it increased the likelihood of him becoming addicted to potentially addictive substances. In Dr. Kornbluth's view, the patient's self-escalation of oxycodone and his pressure for an increase in January, 2007, suggested that greater concern be given to the potential for addiction. (T. 71-73) The Board finds that by taking marijuana, obtaining opioids from other providers and self-escalating the drug, Patient A violated his opioid agreements and engaged in opioid misuse. He consistently resisted efforts to switch him to long-acting medications. He requested short-acting IR oxycodone by name. It was the patient's drug of choice as "the only thing that works."

Dr. Kornbluth and Dr. Freas opined that Dr. Rosen's virtually exclusive use of the drug in short-acting form was problematic given inherent addiction and diversion risks. Dr. Kornbluth testified that short-acting opioids have a higher propensity toward addiction because more pills are popped on a more frequent basis. (T. 31) Dr. Freas also testified that short-acting narcotics are highly addictive, with significant abuse and diversion risks in the younger population. (T. 188, 212) According to Dr. Freas, data shows that the likelihood of abuse or diversion increases when a young person is taking illicit substances along with short-acting, high dose opioids, is not taking the drugs as prescribed and is not following the treatment plan. (T. 188-89, 213)

Patient A's other risks and co-morbidities were recurring themes in his medical record. The patient did not hide his depression, anxiety, psychosocial and financial stressors but freely disclosed them on most office visits. He owed money to the practice, struggled to pay bills, and sought an insurance payout in 2007 from his car accident, all of which Dr. Rosen was aware. His personal life and employment situation were unstable. Dr. Rosen's use of mental health

[42] It is unclear from the medical record if Dr. Rosen knew of the patient's addiction history before April, 2007. The Board has given Dr. Rosen the benefit of the doubt that he did not.

counseling as an alternative strategy to address these dynamics, was merely aspirational. No social worker at the practice ever provided mental health counseling to Patient A. Dr. Rosen and Employee A relied on the patient's self-reporting and did not confirm at any time during his treatment that he actually received outside counseling to help him cope with pain, depression and anxiety. Nor did they conduct any type of inquiry into his alcohol use or confirm that he attended AA meetings when he reported a history of alcohol abuse in April, 2007. In her interview with the Board, Employee A acknowledged that it was unknown if patients did home exercises in the absence of physical therapy. (Resp. Exh. 8, T. 25)

The Board finds that Dr. Rosen relied almost exclusively on opioids to treat the patient's pain complaints without attempting to reduce the dose in 2006 and 2007. The medical record does not support Dr. Rosen's assertion that he did everything "by the book." The existence of a multidisciplinary practice had little impact on Patient A's treatment regimen for those eighteen months. On every visit, the patient came for and left with a prescription for oxycodone.

It is abundantly clear from the medical record that Dr. Rosen, Employee A and other practitioners recognized the patient's risk factors for potential addiction. From July, 2005 through June 2007, they documented a consistent theme of frequent plans and discussions to wean the opioids. There was no meaningful follow up action to do so except for a brief period from November 3 to December 15, 2005 when Methadone and Duragesic were substituted for oxycodone. Their interactions with Patient A were a series of missed opportunities to taper the opioid. The prescribers repeatedly talked to Patient A about his opioid dependence, the long-term risks of opioids and the need to decrease oxycodone and substitute long-acting medication. The ALJ correctly found that this goal was the opposite of what occurred. (Proposed Dec., p. 31)

The Board, however, disagrees with the ALJ's conclusion that the patient's complexities somehow vindicate Dr. Rosen's inaction. Rather, the reverse proposition is true in this case. The patient's overall psychosocial and medical history, including his substance abuse and opioid addiction history, depression, anxiety and financial stressors, were reasons for increased vigilance by Dr. Rosen. Instead, Dr. Rosen acquiesced in the patient's resistance to taper the medication or switch to a long-acting form. Dr. Rosen continued to prescribe high levels and volumes of this short-acting opioid for a patient with unremarkable pathology based on the patient's requests. There is no evidence to support the ALJ's finding that Dr. Rosen escalated the drug because the patient always worked in physically demanding jobs. The medical record shows that Patient A gave up heavy construction in 2005.

In his testimony, Dr. Rosen indicated that he failed to screen for diversion or even consider the potential for diversion despite his awareness of the patient's psychosocial and financial problems. (T. 345-47) When asked at the hearing if he trained physicians and PAs to recognize signs and symptoms of diversion and addiction, Dr. Rosen testified that from a risk standpoint, they were not so much concerned with diversion in 2005-2007 as with the use of heroin, cocaine, tobacco and substance abuse. (T. 340-41) It also appears that Dr. Rosen was more troubled that Employee A decreased the oxycodone on June 20, 2007, than about the patient's diversion of the drug. When asked on direct examination if Employee A cut back the oxycodone on that date, Dr. Rosen answered "unfortunately." (T. 362)

Dr. Gudin and Dr. Wolf testified that the medical record showed no signs of possible diversion. Based on its evaluation of the medical record, however, the Board finds that Dr. Rosen never screened the patient to verify that he was taking all the oxycodone prescribed. At each office visit, Patient A filled out a routine questionnaire in his record listing all his medications

because Dr. Rosen was "interested in what medications you are actually taking." Apart from two urine screens obtained in November, 2005, Dr. Rosen did not perform quantitative tests to confirm medication levels in the patient's system. The dipstick urine screens performed in March and June, 2007, were limited to showing the presence of oxycodone but not the amount the patient was actually taking. In December, 2005, and from January through June, 2007, when Employee A and other practitioners escalated the oxycodone with Dr. Rosen's approval, Dr. Rosen did not obtain oxycodone levels to confirm whether the patient was in fact ingesting the number of pills prescribed or possibly diverting some of the drug. Nor did he do so in 2006 when the patient resisted efforts to wean the medication on most visits.

The Board agrees with Dr. Kornbluth that the standard of care required more adequate scrutiny of the patient's behavior, and weaning of the opioids, not continued escalation, after the positive test results for marijuana in November, 2005. (T. 83-84) The ALJ inaccurately characterized the State's position and Dr. Kornbluth's testimony by conflating two entirely different questions of continued opioid treatment vis-à-vis continued escalation. (Proposed Dec. pp. 29-30) The State's main concern was not Dr. Rosen's continued opioid treatment, but his continued escalation of and failure to wean the medication. The Board disagrees with the ALJ's finding that Dr. Rosen used appropriate professional judgment after those positive screens. The medical record conflicts with her finding that the patient was monitored thereafter on weekly office visits and had counseling. For most of 2006, the patient had monthly office visits for insurance reasons, and had no mental health counseling and no further urine screens.

Dr. Kornbluth opined that maintaining the patient on 200 mg a day after May 8, 2007, was not only an excessive dose for this type of pain problem, but that the possibility of diversion was more worrisome because a patient taking 40 pills a day raises a concern that some of it could

go elsewhere. (T. 61-62, 64) Dr. Freas testified that the standard of care requires closer monitoring, getting urine or drug screens every month and not giving a high dose of a short-acting drug if there are behaviors consistent with addiction or diversion. In Dr. Freas's view, pain doctors who give out a lot of narcotics to patients have a responsibility to patients and to society to take monitoring and responsible prescribing seriously. (T. 216) The Board agrees with the opinions of Dr. Freas and Dr. Kornbluth.

Dr. Rosen presented no evidence to support his contention that his two-and-a-half-year doctor-patient relationship with Patient A helped him evaluate the patient's risk for addiction or diversion. In violating his opiate agreements without consequence, misusing oxycodone by self-escalation and obtaining additional opioids from other providers, the patient abused Dr. Rosen's trust. Dr. Rosen was not concerned about the patient's aberrant behavior or about the letter from the patient's pharmacy regarding the potential health detriment posed by the dosage and long-term, continuous use of oxycodone 5 mg in March, 2006. Dr. Rosen did not view the letter as an opportunity to reassess his prescribing strategy. In his testimony, he dismissed it as a routine form letter, and stated that most of his patients get doses of 400 or 500 mg. (T. 372-73)

In opining that Dr. Rosen met the standard of care, Dr. Rosen's experts essentially discounted the patient's risks for potential addiction and diversion. There is no evidence that Dr. Rosen tightened controls as stated by Dr. Gudin and Dr. Wolf. The Board gives little weight to their opinions. Dr. Rosen failed to balance the risks by failing to obtain appropriate drug screens, failing to wean the opioids in 2005, 2006 and 2007, and by approving opioid increases by Employee A in 2007. Dr. Rosen's inaction ignored the inherent risks for addiction and diversion, facilitated the diversion that ultimately occurred and violated the standard of quality care.

**Opioid Prescribing and Escalation**

Dr. Kornbluth testified that between February and September 22, 2005, Dr. Rosen increased the patient's opioids (Percocet to oxycodone) by 67% to 100 mg a day (16-20 pills a day) – a significant increase in a short time. (T.58) Dr. Freas had the same concerns about this rapid increase of short-acting oxycodone of up to 20 pills a day, and Dr. Rosen's overall failure to wean the drug despite the patient's comments about the negative effects. (T. 208-11, 232, 241) He opined that Dr. Rosen's escalation of the drug in 2005 and through 2007 deviated from the standard of care given the patient's minimal disc problem. (T. 233)

Dr. Kornbluth further testified that the prescriptions for 480 pills of oxycodone a month on multiple office visits in 2006 were also excessive and not within the standard of care. (T. 91) He commented that there was no follow up by Dr. Rosen to place the patient on long acting pain medication in 2006, despite Employee A's comments in August, 2006 that she would like to see him on a long-acting opioid because of the risks of tolerance and dependence with high doses of IR oxycodone. (T. 74-75) The Board agrees with Dr. Kornbluth. The medical record shows, and the Board finds, that oxycodone 80 mg a day in 5 mg doses (16 pills a day) became routine in 2006. The medical record is replete with discussions to wean the opioid, a plan that never materialized because Dr. Rosen never followed up to implement it.

Dr. Kornbluth believed that the most notable deviation from appropriate standards by Dr. Rosen was between January-June, 2007, when the dose was increased from 100-110 mg a day (20-22 pills a day) to 200 mg a day (40 pills a day). (T 90-91) Employee A prescribed a total of 1,060 pills of oxycodone 5 mg and 50 pills of oxycodone 10 mg in February, 2007, 830 pills in March, 1,920 pills from May 8 through June 5, 2007, and 1,895 pills from May 22 through June

20, 2007.[43] Dr. Gudin's opinion that it is not uncommon to increase medications for a new injury before tapering off has no basis in the medical record. (Resp. Exh. 12) There was no evidence of a new injury after the patient's car accident in November, 2006, because the MRIs performed showed no substantive changes from 2005. More significantly, Dr. Rosen not only failed to taper the oxycodone, he escalated it for the next six months.

The ALJ's conclusion that the State's case was ambiguous conflicts with the State's experts' opinions that both the dose and volume of oxycodone prescribed violated the standard of care. The evidence they presented is inconsistent with the ALJ's finding that one expert testified that excessive dosage violated the standard of care and the other expert testified that the violation was based on the number of pills prescribed. In his report and testimony, Dr. Kornbluth opined unequivocally that both the dosage and volume of oxycodone were outside the standard of care and increased the risks of addiction and diversion for Patient A. (St. Exh. 5; T. 33, 58, 62, 105-07) In discussing Dr. Rosen's standard of care violations, Dr. Kornbluth repeatedly referred to the high amounts, doses and levels of oxycodone as well as the number of pills prescribed for Patient A. (T. 68, 81-83, 90, 93, 99-101) He testified definitively that it was inappropriate to continue to escalate the dose for someone with an addiction history and illicit drug tests without an overwhelming reason to do so. (T. 101)

Dr. Freas testified that the total dose prescribed violated the standard of care. (T. 233, 252) While agreeing in principle that the number of pills is generally not decisive in determining whether prescribing is excessive, Dr. Freas's overall testimony made it clear that limiting the number of pills is necessary to decrease the risk of abuse and diversion. (T. 233, 249, 252) He stressed the heightened potential for diversion created by prescribing this volume of pills in

[43] If the number of pills prescribed by Employee A on June 20 had corresponded to the 252 pills she entered into the medical record, the intended volume of oxycodone prescribed from May 22 through June 20 would still have totaled 1,622 pills.

short-acting form, especially the nearly 2,000 short-acting pills a month prescribed later on in May and June, 2007. (T. 233, 252) In his view, even 20 pills a day would deviate from the standard of care, given the condition being treated, but the prescribing became "very egregious" when it was increased to 40 pills a day. (T. 233) The ALJ inaccurately characterized the State's experts' testimony on this issue.

Nor is there evidence to support the ALJ's finding that a determination of the standard of care depends solely on the daily dose of opioids prescribed, not the number of pills. It was undisputed that no Maryland or federal statute limits the dose or volume that can be prescribed daily. That fact, however, is beside the point. Contrary to what the ALJ inferred from this evidence, physicians do not have free rein to prescribe inappropriately high doses or volumes of opioids, in violation of the standard of care. The Board agrees with Dr. Rosen's argument that the physician's clinical judgment based on a patient's medical record is what controls the issue. Based on the medical record, the Board finds that Dr. Rosen exercised flawed clinical judgment in this case by prescribing a high dose and volume of pills for a patient with obvious risks for the potential harms of addiction and diversion.

Dr. Rosen's regimen of short-acting opioid pills was ineffective. The medical record does not indicate any significant improvement in Patient A's overall pain control or functionality, especially in 2007. Dr. Kornbluth correctly pointed out that the patient's pain control from his daily volume was suboptimal, because the duration of effect from a short-acting opioid (only 2-3 hours) is so short that he was on a roller coaster of ups and downs during the course of a day. (T. 60-64) Even Dr. Gudin agreed that the pain was "basically out of control" in 2007. (T. 282) Dr. Kornbluth also disputed Dr. Rosen's claim that a daily dose of 200 mg in May-June, 2007 was either needed or effective. (T. 96) The medical record contradicts Dr. Rosen's testimony (T. 361-

63) that this increase was clinically indicated or improved the patient's pain score. The patient told Employee A that his pain worsened in May, and he later had IV morphine (an opioid) and Medrol (a steroid used to treat inflammation) at the hospital. On June 20, he described his pain as constant. By enabling an ineffective opioid regimen based on the desires of a noncompliant, complex patient, Dr. Rosen violated the standard of care.

The medical record also contradicts the opinions of Dr. Rosen's experts that the increase in opioids was always clinically justified. No rationale is documented for the oxycodone increase from 150 to 175 mg on April 24, 2007. The Board agrees with Dr. Kornbluth that the patient's complaints of pain from a dental abscess in December, 2005, did not justify escalating the opioids. (T. 104-05) When Patient A self-reported obtaining more opioids from his primary care physician and his dentist at that time, Dr. Rosen failed to communicate with these providers to discuss objective findings. In the Board's view, a reasonable physician would have obtained this information before escalating the oxycodone dose for acute dental pain completely unrelated to the patient's complaint of back pain. In her proposed findings, the ALJ ignored this escalation altogether. Dr. Kornbluth also correctly opined that pain from shoveling snow in February, 2007, and a new knee injury in May, 2007, were not legitimate reasons to further escalate already high levels of oxycodone. (T. 104-06, 115) In his opinion, other pain alleviation alternatives were available, including injections, ice or heat, and topical pain medications. (T. 116) The Board declines to adopt the ALJ's proposed conclusions on this issue. The Board further finds that Dr. Rosen's escalation of an existing high level of opioids for these acute pain episodes was not clinically indicated and violated the standard of care.

There is no support in the record for the opinions of Dr. Gudin and Dr. Wolf that the lower cost of oxycodone 5 mg was the only reason for its use by Dr. Rosen. (Resp. Exhs. 12, 13;

T. 391-92). Dr. Rosen testified that he prescribed the short-acting version because it enabled the patient to have flexibility, power and control over his medication taking. (T. 356) Based on the patient's self-escalation, resistance to weaning and aberrant behavior, it is clear that he exercised very little power and control over the medication. As Dr. Wolf testified, the patient became dependent on the opioid. With respect to cost, Patient A described OxyContin as "not too expensive" in February, 2007, and in his April 2007 letter to Dr. Rosen, he stated that the cost of long-acting medication was outweighed by the efficacy. In any event, the Board agrees with Dr. Kornbluth that cost considerations should not supersede appropriate medical judgment. (T. 114)

The Board further finds that Dr. Rosen exercised inappropriate clinical judgment when he discontinued the Methadone prescribed in November, 2005, based on the patient's reports of drowsiness. The Board is not persuaded by Dr. Gudin's opinion that Methadone caused "excessive somnolence." (T. 274-76) Neither Dr. Rosen nor Dr. Gudin apparently considered the sedating effects of Lyrica, Soma and Sonata - the three co-prescribed medications.

The opinions of Dr. Kornbluth and Dr. Freas focused on the relevant prescribing issues in Patient A's case, were supported by the evidence in the medical record, and were consistent with the Board's knowledge and expertise in the field of pain management and risk stratification. The opinions of Dr. Gudin and Dr. Wolf that Dr. Rosen's treatment was reasonable or within the standard of care do not hold up in the face of his deficient opioid prescribing and failure to monitor this patient's significant risks for potential addiction and diversion. The Board's concern with Dr. Rosen's clinical judgment and prescribing patterns was the basis of the Board's charges given its function to protect the public by enforcing the standard of quality care. By failing to use his own expertise and experience to properly manage the patient's pain, Dr. Rosen ignored the

inherent risks to the patient and society in this case, and deviated from the standard of quality care.

**Supervision of Employee A**

Dr. Wolf testified that Dr. Rosen not only supervised Employee A, but was aware of what was happening with the patient. (T. 389) The question before the Board, however, is whether Dr. Rosen properly supervised Employee A and adequately monitored her prescribing practices. It was undisputed that she never prescribed or escalated oxycodone without Dr. Rosen's approval even if he was not physically present in the office when she saw the patient. In Dr. Rosen's testimony, he agreed with the amounts and volume approved by his partners if they signed off on Employee A's prescribing. Regarding employee training for signs of diversion, Dr. Rosen confirmed that diversion was not a concern in his practice in 2005-2007.

Employee A thoroughly documented in the medical record her multiple ongoing discussions with the patient about opioid risks, and her intent to wean the oxycodone and switch to long-acting medication. Dr. Rosen did not heed her concerns and admonitions. He had the last word on the ultimate prescribing decisions and Employee A deferred to her supervising physician's knowledge and experience. Dr. Rosen did not follow up or take action based on the patient's risk factors and the serious concerns documented by Employee A, and thus failed to properly supervise her prescribing practices, thereby engaging in unprofessional conduct in the practice of medicine. The Board agrees with Dr. Freas that Dr. Rosen failed to provide adequate training and guidance to her on how to deal with patients who may be abusing or diverting opioids. (T. 222) As her supervising physician, he was responsible for doing so. The Board declines to give any weight to the opinions of any of the other expert witnesses on the issue of supervision.

Accordingly, the Board rejects the ALJ's recommendation to dismiss the charges against Dr. Rosen. The Board grants the State's exceptions.

## CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, and for the reasons described above, the Board concludes that Dr. Rosen failed to meet appropriate standards for the delivery of quality medical care, in violation of the Medical Practice Act, Md. Code Ann., Health Occ. § 14-404(a)(22). The Board also concludes that Dr. Rosen is guilty of unprofessional conduct in the practice of medicine, in violation of Md. Code Ann., Health Occ. § 14-404(a)(3)(ii).

## SANCTION

Dr. Gudin believed that this was an isolated case of a complex pain patient with multiple medical issues from which Dr. Rosen has learned about the vigilance needed to treat this difficult patient population. Dr. Gudin suggested that remedial training in pain management is not necessary because Dr. Rosen has engaged in serious reflection of his actions and has taken courses in risk evaluation and mitigation to develop appropriate practice strategies. The Board has considered Dr. Gudin's comments and sincerely hopes that is the case. In recognizing that Dr. Rosen is an educator in the field, the Board also hopes that he has since improved his understanding of the fundamentals of appropriate opioid prescribing, and the need to utilize essential screening tools and exercise increased clinical vigilance for patients with recognized risks. The Board will impose a reprimand.

## ORDER

It is hereby:

**ORDERED** that Norman B. Rosen, M.D., License No. D11985, is **REPRIMANDED;** and it is further

**ORDERED** that this Final Decision and Order of the Board is a public document.

06/30/2017
Date

Christine A. Farrelly
Christine A. Farrelly, Executive Director
Maryland State Board of Physicians

**NOTICE OF RIGHT TO PETITION FOR JUDICIAL REVIEW**

Pursuant to Md. Code Ann., Health Occ. § 14-408(a), Dr. Rosen has the right to seek judicial review of this Final Decision and Order. Any petition for judicial review shall be filed within thirty (30) days from the date of mailing of this Final Decision and Order. The cover letter accompanying this final decision and order indicates the date the decision is mailed. Any petition for judicial review shall be made as provided for in the Administrative Procedure Act, Md. Code Ann., State Gov't § 10-222 and Title 7, Chapter 200 of the Maryland Rules of Procedure.

If Dr. Rosen files a petition for judicial review, the Board is a party and should be served with the court's process at the following address:

**Maryland State Board of Physicians**
**Christine A. Farrelly, Executive Director**
**4201 Patterson Avenue**
**Baltimore, Maryland 21215**

Notice of any petition should also be sent to the Board's counsel at the following address:

**Noreen M. Rubin**
**Assistant Attorney General**
**Department of Health and Mental Hygiene**
**300 West Preston Street, Suite 302**
**Baltimore, Maryland 21201**