COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 2127

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY BARRY G. HARDISON, M.D., LICENSE NO. 23875, 222 PHILLIP STONE WAY, CENTRAL CITY, KENTUCKY 42330

FINAL ORDER OF REVOCATION

Pursuant to KRS 311.591(7) and KRS 13B.120, at its meeting on November 21, 2024, the Kentucky Board of Medical Licensure (hereafter "the Board"), acting by and through its Hearing Panel B, took up this matter for final action. Hearing Panel B considered a memorandum, dated November 1, 2024; the Complaint, filed October 24, 2023; the Emergency Order of Restriction, filed October 24, 2023; the Final Order Overturning Emergency Order of Restriction, filed March 20, 2024; the Findings of Fact, Conclusions of Law and Recommended Order, dated October 15, 2024; the Board's Exceptions, filed October 30, 2024; and the licensee's Exceptions, filed October 30, 2024.

Having considered all the information available and being sufficiently advised, pursuant to KRS 13B.120(2) Hearing Panel B hereby MODIFIES, IN PART, the Hearing Officer's recommended order as follows:

> Conclusions of Law ¶30 is modified to read: "Based upon Dr. Hardison's prescribing practices for buprenorphine, stimulants, gabapentin and benzodiazepines, the preponderance of the evidence supports the conclusion that Dr. Hardison violated KRS 311.595(9), as illustrated by KRS 311.597(4)."

Except for the identified modification, Hearing Panel B hereby ACCEPTS AND ADOPTS all other findings of fact and conclusions of law from the hearing officer and incorporates them by reference into this Order. (Attachment)

The Panel explains the modification as follows: It is clear that Conclusion of Law ¶30 is intended to refer to Dr. Hardison and to include the additional prescribing practice for gabapentin. First, the conclusions of law pertain to the case against Dr. Hardison. Additionally, it is apparent that the Hearing Officer inadvertently placed the phrase "and gabapentin," where it should have referenced Dr. Hardison. Finally, "and gabapentin" was one of the additional medications at issue throughout this case and should be moved to the list of prescribed medications.

Having considered all statutorily available sanctions and the nature of the violations in this case - including the licensee's violation of and dismissive attitude towards multiple Board regulations, failures to exercise caution when prescribing highly addictive and frequently abused controlled substances, prescribing medically unnecessary and potentially lethal drugs, and a general disregard for basic standards of care in a manner that endangers patients and community health - the Hearing Panel has determined that revocation is the appropriate sanction. Accordingly, Hearing Panel B **ORDERS**:

1. The license to practice medicine held by Barry G. Hardison, M.D., is hereby REVOKED and he may not perform any act which constitutes the "practice of medicine," as that term is defined by KRS 311.550(10) – the diagnosis, treatment, or correction of any and all human conditions, ailments, diseases, injuries, or infirmities by any and all means, methods, devices, or instrumentalities – in the Commonwealth of Kentucky;

2. The provisions of KRS 311.607 SHALL apply to any petition for reinstatement filed by the licensee; and

3. Pursuant to KRS 311.565(1)(v), the licensee SHALL REIMBURSE the costs of these proceedings in the amount of $44,871.50, prior to filing any petition for reinstatement of his license to practice medicine in the Commonwealth of Kentucky.

SO ORDERED on this 27th day of November 2024.

DALE E. TONEY, M.D.
CHAIR, HEARING PANEL B

CERTIFICATE OF SERVICE

I certify that the original of the foregoing Final Order of Revocation was delivered to Mr. Michael S. Rodman, Executive Director, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222; a copy was mailed, first-class postage prepaid, to Thomas J. Hellmann, Esq., Hearing Officer, 810 Hickman Hill Road, Frankfort, Kentucky 40601; and copies were mailed, certified return-receipt requested, to the licensee Barry G. Hardison, M.D., License No. 23875, 3064 Pea Ridge Rd., Waddy, Kentucky 40076 and his counsel, Lisa English Hinkle, Esq., Ed Monarch, Esq., and Katy Harvey, Esq., McBrayer, PLLC, 201 East Main Street, Suite 900, Lexington, Kentucky 40507 on this 27th day of November, 2024.

Nicole A. King
Assistant General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
Louisville, Kentucky 40222
Tel. (502) 764-2615

EFFECTIVE DATE AND APPEAL RIGHTS

Pursuant to KRS 311.593(1) and 13B.120, this Order will be effective immediately on filing. It is the Panel's opinion that based upon sufficient reasonable cause, the health, welfare, and safety of Dr. Hardison's patients or the general public would be endangered by delay.

The licensee may appeal from this Order, pursuant to KRS 311.593 and 13B.140-.150, by filing a Petition for Judicial Review in Jefferson Circuit Court within thirty (30) days after this Order is mailed or delivered by personal service. Copies of the petition shall be served by the licensee upon the Board and its General Counsel or Assistant General Counsel. The Petition shall include the names and addresses of all parties to the proceeding

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FINDINGS OF FACT, CONCLUSIONS OF LAW AND RECOMMENDED ORDER

On October 24, 2023, the Kentucky Board of Medical Licensure [hereinafter "the Board"] issued the *Complaint* charging Barry G. Hardison, M.D., with violating the three statutes governing the practice of medicine, KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12). Exhibit 1, Tab C, *Complaint*, Paragraph 20, page 8. [The citations to the *Complaint* will be to their numbered paragraphs and pages without reference to Exhibit 1, Tab C]. In this action the Board requests the hearing officer to find Dr. Hardison guilty of violating those statutes and to recommend the Board take any appropriate disciplinary action against his license for the violations, including revocation of his license to practice medicine.

On the same day that the Board issued the *Complaint*, the Board also issued the *Emergency Order of Restriction* ("*Emergency Order*") against Dr. Hardison's license to practice medicine based upon the same allegations contained in the *Complaint*. [Citations to the emergency order will also be to the document's numbered paragraphs and pages without reference to Exhibit 1, Tab B]. The *Emergency Order* restricted Dr. Hardison's license to practice medicine by prohibiting him from "prescribing, dispensing, or otherwise professionally utilizing controlled substances until the Board's Hearing Panel has finally resolved the Complaint or until such further Order of the

Board." *Emergency Order*, page 10.

At the request of Dr. Hardison the undersigned hearing officer conducted an administrative hearing on the *Emergency Order*, and on March 20, 2024, he issued the *Final Order Overturning Emergency Order of Restrictions* ("*Final Order*"). He found pursuant to KRS 13B.125(3) and KRS 311.592(1), there was substantial evidence in the record to support the conclusion that Dr. Hardison engaged in conduct in violation of the Board's statutes as alleged in the *Emergency Order*. He also found, however, there was not substantial evidence in the record that Dr. Hardison's care and treatment of patients constituted an immediate danger to the health, safety, or welfare of patients or the general public. That determination was based largely upon the findings and opinions of the Board's expert, Dr. Mark Jorrisch, and upon Dr. Hardison's agreement not to prescribe certain controlled substances pending resolution of the allegations in the *Complaint*.

The hearing officer conducted the administrative hearing on the *Complaint* over eleven days in June 2024. Hon. Nicole A. King represented the Kentucky Board of Medical Licensure, and Hon. Lisa English Hinkle, Hon. Ed Monarch, and Hon. Katy Harvey represented Dr. Hardison, who also attended the hearing.

The hearing officer notes that the *Complaint* and *Emergency Order* issued in this action are similar to the *Complaint* and *Emergency Order* issued against Dr. William K. Vincent who worked in the same medical practice as Dr. Hardison. Although the factual allegations against the two physicians are not identical and involve different patients for each physician, the substance of the alleged types of misconduct are similar

in that they involved the same medical practice, the same prescribing practices, and the same alleged violations of the Board's statutes and regulations. In addition, Dr. Jorrisch served as the Board's consultant for both cases, and he reviewed the care and treatment at issue in both cases, arrived at substantially similar conclusions as to the deficiencies in the care and treatment of patients by both physicians, and drafted substantially similar reports for the physicians. The hearing officer further notes that Dr. Hardison and Dr. Vincent had similar and consistent approaches to the care of patients at issue in this action, had similar prescribing practices for the patients, and presented the same or similar defenses to the Board's allegations. In fact, the hearing officer found no disagreement between the physicians in their approach to patient care or inconsistencies between them with regard to the care that each provided to patients, which common defense was further supported by the fact the same counsel represented both physicians.

Due to the similarity of the charges against the two physicians and by agreement of the parties, the administrative hearing on the Board's *Complaint* against each physician was conducted jointly, and the record from the administrative hearings on the physicians' challenge to their respective *Emergency Orders* were incorporated by reference into the administrative hearing on the *Complaint* actions. Although there was substantial overlap in the exhibits admitted into evidence for the two physicians, they were not identical, and therefore, the parties utilized a separate numbering system for the exhibits in each physician's case. Dr. Jorrisch reviewed on behalf of the Board the medical records for sixteen of Dr. Hardison's patients and eighteen of Dr. Vincent's.

Fifty-three exhibits were admitted into evidence in Dr. Hardison's case, and seventy-seven in Dr. Vincent's.

After considering the evidence admitted at the administrative hearing and the arguments of counsel, the hearing officer finds the preponderance of the evidence supports the conclusion that Dr. Hardison violated KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12), in his care and treatment for the sixteen patients at issue in this case. For those violations the hearing officer recommends the Board take any appropriate action against Dr. Hardison's license to practice medicine. In support of that recommendation, the hearing officer submits the following Findings of Fact, Conclusions of Law, and Recommended Order:

FINDINGS OF FACT

1. On October 24, 2023, the Board issued the *Complaint* and *Emergency Order* in support of the allegation that Dr. Hardison violated KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12). *Complaint*, pages 1-8: *Emergency Order*, pages 2-8.

2. By agreement of the parties at the administrative hearing in this action, the record of the administrative hearing on the *Emergency Order* was adopted and incorporated into the record of this action, and the hearing officer adopts and incorporates by reference into this recommendation the Findings of Fact and Conclusions of Law from the *Final Order* that he issued on the *Emergency Order*.

3. The allegations of misconduct against Dr. Hardison focused on his care and treatment of patients at "A New Start" ("ANS"), a medical practice in Central City,

Kentucky, that specializes in the treatment of Opiate Use Disorder ("OUD"), Substance Use Disorder ("SUD"), and Stimulant Use Disorder ("StUD"). *Emergency Order*, pages 2-7; *Complaint*, pages 2-7; Exhibit 1, marked pages 311-320, 466-491, and 509-591.

4. The Board asserts that Dr. Hardison failed to follow the Board's statutes and regulations in his treatment and prescribing practices related to buprenorphine products for the treatment of OUD; with his prescribing practices related to benzodiazepines, such as Xanax and Klonopin, and other controlled substances, such as gabapentin; and with his prescribing of stimulants such as Adderall and Ritalin for StUD.

5. A physician is subject to discipline under KRS 311.595(9), as illustrated by KRS 311.597(4), if he engages in "conduct which is calculated or has the effect of bringing the medical profession into disrepute, including but not limited to any departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky . . . ."

6. Under KRS 311.595(12), a physician is subject to discipline if he has "violated or attempted to violate, directly or indirectly, or assisted in or abetted the violation of, or conspired to violate any provision or term of any medical practice act, including but not limited to the code of conduct promulgated by the board under KRS 311.601 or any other valid regulation of the board."

7. Since the Board has specific regulations governing the prescribing of controlled substances generally, and buprenorphine and amphetamines in particular, the hearing officer's review of the alleged statutory violations will necessarily focus on

Dr. Hardison's prescribing practices related to those controlled substances and on his compliance with the above-cited statutes and the applicable regulations: 201 KAR 9:016, 201 KAR 9:260, and 201 KAR 9:270.

8. An analysis of whether Dr. Hardison's prescribing practices under 201 KAR 9:270 violates the "standards of acceptable and prevailing medical practices" in Kentucky under KRS 311.595(9), as illustrated by KRS 311.597(4), must begin with a consideration of Section 5 of the regulation, which states the "failure to comply with or a violation of the professional standards established in Sections 2, 3, and 4 of this administrative regulation shall constitute a 'departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky,' in violation of KRS 311.850(1)(p) and (s), KRS 311.595(12) and (9), as illustrative by KRS 311.597(4), . . . subjecting a licensee to sanctions authorized by KRS 311.595 and 311.850."

9. To the extent the licensee and his expert witnesses assert a violation of 201 KAR 9:270, Sections 2, 3, or 4, does not constitute a violation of the standards of acceptable and prevailing medical practice in Kentucky, in light of the provision of 201 KAR 9:270, Section 5, to the contrary, such assertions carry no weight.

10. The analysis of the propriety of the prescribing of Adderall and Ritalin to patients is governed by the provisions of 201 KAR 9:016, which states in Section 2 that prior to prescribing an amphetamine a "licensee shall take into account" five factors, including the potential for abuse, dependence, misuse, and diversion of the prescribed stimulant.

11. Under 201 KAR 9:016, Section 3, the patient record "shall denote the diagnosis that justifies treatment with a Schedule II amphetamine" and the controlled substance "shall be used to treat only" six medical conditions, a single one of which is relevant to this action, "attention deficit/hyperactive disorder."

12. Pursuant to 201 KAR 9:016, Section 6(1), the "failure to comply with the requirements of this administrative regulation shall constitute dishonorable, unethical, or unprofessional conduct by a licensee, which is apt to deceive, defraud, or harm the public under KRS 311.595(9) and KRS 311.597."

13. Thus, to the extent the licensee and his expert witnesses assert a violation 201 KAR 9:016 does not constitute a violation of KRS 311.595(9) and KRS 311.597, in spite of the provision of the regulation to the contrary, such assertions carry no weight.

14. For the prescribing of any controlled substance in Kentucky the physician "shall comply" with the provisions of 201 KAR 9:260, which establishes "the standards of acceptable and prevailing medical practice for prescribing, dispensing, or administering a controlled substance" for the treatment of pain or other medical conditions. 201 KAR 9:260, Section 1(1).

15. The standards require that prior to prescribing the controlled substance the physician to "obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the licensee is conforming to professional standards for prescribing controlled substances, which shall include, among other relevant information, the patient's medical history; physical or mental health examination; evaluations and consultations; treatment

objectives; discussions of risks, benefits, and limitations of treatment; medications, including date, type, dosage, and quantity prescribed; and instructions and agreements. 201 KAR 9:260, Sections 2, 3, and 6.

16. To the extent the licensee and his expert witnesses assert a violation of the provisions of 201 KAR 9:260 does not constitute a departure from or failure to conform to the standards of acceptable and prevailing medical practice in Kentucky such assertions carry no weight.

17. Dr. Hardison graduated from University of Louisville School of Medicine in 1984 and returned to his home in Muhlenberg County, Kentucky, where he practiced medicine for thirty-one years. Exhibit 1, marked page 405; EH 1, 9:48 a.m. (The administrative hearing on the emergency order for Dr. Hardison was conducted over four days, and citations to the recordings of the emergency hearing for Dr. Hardison are represented by "EH" (Emergency Hardison) followed by a number representing the sequential day of the hearing and the time stamp on the video recording. The citations to the recording of the emergency hearing for Dr. Vincent's case will use a similar format but that hearing will be represented by "EV" (Emergency Vincent). Citations to the recordings of the combined administrative hearing on the Complaint actions will be represented by "CH" (Complaint Hearing) followed by a number representing the sequential day of the hearing and the time stamp on the recording.)

18. Dr. Hardison has been licensed to practice medicine in Kentucky since 1985. He was certified by the American Board of Internal Medicine in 1987 and by the American Board of Preventative Medicine, Addictionology, in 2018. He is a member of

the American Society of Addiction Medicine. Exhibit 1, marked page 405; CH 5, 2:55-2:56 p.m.

19. He became Board Certified in Addiction Medicine in 2018 and has not practiced internal medicine since that time. Exhibit 1, page 405; CH 1, 10:18 a.m.

20. Dr. Hardison has been in recovery for alcohol use for thirty years and has never had a relapse. CH 1, 10:02 a.m. and 10:18 a.m.

21. In his view, a patient's addiction is difficult to understand by anyone who has not suffered from an addiction, and that view reflects his own passion and commitment to help those individuals. EH 1, 10:01 a.m.

22. It was clear from his extensive testimony on the care and treatment he provided to patients that Dr. Hardison has a high degree of empathy for them and for the physical, emotional, social, and economic burdens they face due to their addiction.

23. His commitment is reflected in the fact Dr. Hardison has dedicated his career to helping his patients' return to good health and to being fully functioning and productive adults.

24. It was also clear from the testimony that Dr. Hardison's patients had complicated and difficult addiction issues, and he worked closely with them to manage their care and to encourage them to stay on a course of sobriety while also addressing setbacks, relapses, and obstacles to recovery. EH 2, 2:36 and 3:17 p.m.

25. In response to the release of the medication Suboxone in 2010 for the treatment of opiate use disorders, in 2013 Dr. Hardison opened ANS a half day a week in Central City, Kentucky, for the treatment of those patients. EH 1, 9:49-9:50 a.m.;

Exhibit 1, marked page 405-406.

26. ANS is certified by the Commission on Accreditation of Rehabilitation Facilities for the treatment of SUD in combination with mental health services for those patients. Exhibit 12.

27. Within three months of opening the clinic Dr. Hardison reported that he witnessed "almost miracles" with opiate addicted patients who previously had nothing to live for get their lives back as a result of treatment with Suboxone. EH 1, 9:50 a.m.

28. Suboxone is a combination of buprenorphine and naloxone that knocks opiates, such as heroin, off the receptors in the brain and block its effect, and the combined medication controls the cravings for an opiate while also decreasing the likelihood of abuse. EV 1, 9:29-9:31 a.m. and 11:38-11:42 a.m.

29. Subutex is known as a "mono product" that consists only of buprenorphine and while still blocking the receptors, it gives a partial euphoric effect, which gives it a higher potential for abuse and is subject to diversion, although it is not the drug of choice for persons with OUD. EV I, 11:41-11:42 a.m.; CH 1, 10:13 a.m.

30. Therefore, by regulation the mono product "shall not be prescribed" except in limited, specific circumstances, the most relevant of which for this action is "to a patient with demonstrated hypersensitivity to naloxone." 201 KAR 9:270, Section 2(2).

31. Sublocade is the injectable form of the mono product CH 2, 1:01-1:04 p.m.

32. Because Muhlenberg County is a poor community Dr. Hardison wanted to bring all aspects of patient care under one roof at ANS. EH 1, 9:51 a.m.

33. Affiliated with ANS is the primary care practice, Care Now, that is located

in the same building as ANS. EH 1, 10:05-10:06 a.m.

34. Care Now was established for patients of ANS in order that they may have a primary care facility available to treat their other healthcare needs, including mental health treatment. EH 1, 10:05-10:06 a.m.

35. Dr. Hardison reported that prior to the start of the COVID pandemic in 2020, the program at ANS had been very successful, with 70% of patients having clean urine drug screens ("UDS") for the use of opiates and other unprescribed controlled substances, but with drug cartels synthesizing methamphetamine ("meth") and manufacturing fentanyl, the increase in drug use has been a "catastrophe" and a "disaster" for the community. EH 1, 9:51-9:52 a.m.

36. The clinic has various policies and procedures in place for the treatment of patients with SUD and has a specific organizational chart and several categories of specialists to assist patients, including peer support specialists who have overcome addiction issues themselves, targeted case managers who assist patients with issues such as food assistance and housing, and a mental health nurse practitioner who addresses the mental health issues associated with a person's addiction. Exhibit 1, marked pages 372-387 and 466-491.

37. Although the Board's expert, Dr. Mark Jorrisch, found many deficiencies in Dr. Hardison's addiction medicine practice, he never suggested in his report or in his testimony at either the *Complaint* or emergency hearings for Dr. Hardison and Dr. Vincent that their medical practice was a "pill mill" in which patients are prescribed controlled substances with little regard for the their general health, actual medical

conditions, and overall well-being. Exhibit 1, marked pages 509-515.

38. Thus, there is no dispute that ANS is a legitimate, fully operational opioid treatment facility which is reflected by the fact the facility is well respected by officials in the local community. CH 10, 1:45-2:00 p.m.; Exhibit 13.

39. Dr. Hardison stated many patients are currently doing well in their recovery from SUD and that half of the sixteen patients whose care Dr. Jorrisch reviewed are now sober and have jobs. EH 2, 3:16 and 3:19 p.m.; EH 1, 3:37 p.m.

40. Dr. Hardison asserts that he has provided excellent care to his patients and has never had a patient overdose in his ten years practicing addiction medicine. EH 2, 2:35-2:36 p.m.

41. Dr. Hardison understandably takes great pride in the help he has provided to patients, and he stated that at a minimum, his goal is to keep them safe and to reduce the level of harm they may be exposed to as a result of their addiction and drug-seeking behavior. CH 1, 10:10-10:13 a.m.

42. In spite of the current disciplinary action against him and reflective of his commitment to treating patients with SUD, at the time of the administrative hearing Dr. Hardison was in the process of opening a mental health and addiction medicine clinic with his ex-wife in Lawrenceburg, Kentucky, at which he plans to focus on behavioral health and to prescribe Suboxone for the treatment of patients with OUD. EH 1, 10:18 a.m.; EH 3, 4:10-4:13 p.m.; CH 1, 9:59-10:01 a.m.

43. Beginning in 2015 Dr. Hardison saw on average twenty-eight patients per nine-hour work day at ANS. EH 1, 10:15 a.m.

44. Fifty percent of patients at ANS are treated for opiate addiction and thirty percent for meth addiction. CH 5, 3:07 p.m.

45. At ANS Dr. Hardison and Dr. Vincent handle many patients with difficult and complex addiction issues. EH 3, 3:11 p.m.; CH 7, 3:58 p.m.; CH 8, 2:40-2:42 p.m.; CH 10, 11:26 a.m.

46. The parties do not dispute that Dr. Hardison is qualified and authorized to prescribe, dispense, and administer buprenorphine, stimulant medications, and other controlled substances. EH 1, 9:52 a.m.

47. Dr. Hardison and ANS came to the attention of the Board as a result of a grievance filed by a Social Services Clinician in the Department of Corrections who was concerned that Dr. Hardison and Dr. Vincent may be over prescribing controlled substances at ANS. Exhibit 1, marked page 314.

48. At the Board's request, the Cabinet for Health and Family Services, Office of Inspector General, reviewed Dr. Hardison's KASPER records and identified sixteen patients whose records were consistent with the concerns for his prescribing practices found by the Social Services Clinician. Exhibit 1, marked pages 315-320; CH 9, 1:02-1:20 p.m.

49. The Board obtained from ANS copies of its medical records for the sixteen patients and provided them to Dr. Jorrisch for review. EH 3, 9:06 a.m.

50. He found deviations from the standards of acceptable and prevailing medical practices in the care and treatment of fifteen of those patients. Exhibit 1, marked pages 310-311 and 509-591.

51. Dr. Jorrisch testified at the administrative hearing that unless stated otherwise in his testimony, the opinions he expressed in his report and in his testimony at the administrative hearing were based upon the standards of acceptable and prevailing medical practice in Kentucky at the time of the care provided by Dr. Hardison in this action. CH 3, 9:06 a.m.

52. Dr. Jorrisch has been a consultant with the Board since 2005, and he was qualified as an expert in medicine generally and specifically in the prescribing of controlled substances and in the treatment and management of substance use disorders. EH 3, 9:05-9:06; CH 3, 9:05 a.m. Exhibit 15.

53. In 1980 Dr. Jorrisch began practicing internal medicine, and he became certified in addiction medicine that same year. Exhibit 15; EH 3, 9:04 a.m.

54. He is the Director of the Moore Center, an opiate rehabilitation facility in Louisville, Kentucky, and has administered methadone through that facility since 1990. EH 3, 9:04-9:05 a.m.

55. For the past eight years he has practiced exclusively in the field of addiction medicine, and he has prescribed Suboxone through his medical practice since 2018. EH 3, 9:04-9:05 a.m.

56. Dr. Jorrisch testified he rarely prescribed controlled substances in his previous internal medicine practice, but he did so on occasion when a patient needed an opiate or a benzodiazepine, but only prescribed them for short periods of time. EH 3, 9:05 a.m.

57. Dr. Jorrisch and Dr. Hardison treat similar patient populations, and Dr.

Jorrisch has practiced in a rural area. EH I3, 11:30 a.m.; CH 3, 1:50 p.m.

58. Since ANS did not have a medical record for Patient 11, who was Dr. Hardison's sister but was not a patient of the clinic and was not treated by him for a substance use disorder, Dr. Jorrisch did not prepare a separate "Expert Review Worksheet" for her, but he did for the other fifteen patients whose care is at issue in this action. Exhibit 1, marked pages 509-591.

59. In those worksheets he addressed whether the diagnosis, treatment, and records for each patient met the minimum standards expected of a physician, and Dr. Jorrisch attached to the worksheet for each patient an extensive narrative explaining the basis for his opinions for the four categories of diagnosis, treatment, records, and overall opinion applicable to the care provided to the patient. Exhibit 1, marked pages 509-591.

60. Dr. Jorrisch estimated that he spent more than twenty hours reviewing the medical records and other information provided by the Board, which included the information submitted by Dr. Hardison's expert consultants, and preparing his own report. EH 3, 9:08-9:09 a.m.; Exhibit 1, marked pages 509-591.

61. The fifteen patients treated by Dr. Hardison for OUD, SUD, and/or StUD had various other medical and health conditions. Exhibit 1, marked pages 509-591.

62. In his cover letter dated March 18, 2023, that accompanied the worksheets, Dr. Jorrisch provided a general summary of his findings, conclusions, and opinions regarding the care and treatment provided by Dr. Hardison to the fifteen patients. Exhibit 1, marked pages 509-515.

63. Dr. Jorrisch found that Dr. Hardison's care fell below the minimum

standards for the diagnosis of nine patients and for the treatment and records for fourteen of the fifteen patients. Exhibit 1, marked pages 509-591.

64. For fourteen of the fifteen patients Dr. Jorrisch's "overall opinion" was that Dr. Hardison's care and treatment was "clearly below minimum standards." Exhibit 1, marked pages 509-591.

65. Dr. Jorrisch found that Dr. Hardison met the minimum standards for the diagnosis, treatment, and records for only one of the fifteen patients, Patient 16, and the "overall opinion" for the care provided for that patient was "borderline." Exhibit 1, marked pages 588-591.

66. The hearing officer notes that in spite of Dr. Jorrisch reviewing separate sets of patients for Dr. Hardison and Dr. Vincent, his findings and conclusions set forth in his multi-page cover letters to his reports for each physician are substantially identical both in form and content, and Dr. Jorrisch's opinions are substantially the same regarding violations of the applicable standards for the care each physician provided to the patients.

67. In spite of the similarities between the reports, the hearing officer finds based upon Dr. Jorrisch's testimony at the hearings on the *Emergency Order* and *Complaint*, he performed a rigorous and detailed review of each physician's care and treatment of his patients. The individual Expert Review Worksheets show similar deficiencies by the physicians in their care and treatment of their individual patients, which is not surprising to the extent the similarities are consistent with the "team approach" adopted by the practice for the care and treatment of patients with OUD,

SUD, and StUD. Exhibit 1, marked page 510.

68. In his cover letter to the Board Dr. Jorrisch concluded that Dr. Hardison violated "Prescribing" standards, rendered "Substandard Care," and violated standards related to "prescribing, management of medical records, patient evaluation and treatment," which conduct departed from or failed to conform to the standards of acceptable and prevailing medical practice in Kentucky. Exhibit 1, marked pages 509-510.

69. Dr. Jorrisch supported the conclusions in his cover letter by listing several pages of the types of deficiencies found in his review of Dr. Hardison's patient records. Exhibit 1, marked pages 512-515.

70. Those deficiencies included Dr. Hardison's failure to follow the standards for prescribing buprenorphine, treating patients with stimulants who had a diagnosis of a meth addiction, treating patients with benzodiazepines who had been diagnosed with a substance use disorder, and prescribing to patients with OUD medications such as promethazine, hydroxyzine, and gabapentin since those medications are often misused by such patients. Exhibit 1, marked page 512-515.

71. As for Dr. Hardison's practice of prescribing stimulants for the treatment of a StUD, Dr. Jorrisch stated, "treatment of Stimulant Use Disorder continues to be a purely behavioral approach albeit difficult and with limited success." Exhibit 1, marked page 511.

72. The hearing officer notes that Dr. Jorrisch's opinion is consistent with the provisions of 201 KAR 9:016, Section 3(2).

73. Dr. Jorrisch identified several other specific practices of Dr. Hardison that fell below the applicable standards of care, including his failure to record a clear history of past treatment and a History of Present Illness ("HPI") and his failure to obtain the patient's past medical records of treatment for OUD. Exhibit 1, marked pages 512.

74. Dr. Jorrisch also identified several other categories of care in which Dr. Hardison's medical practice fell below the applicable standards of care for OUD due to his failure: to provide "clear indication of past treatment episodes;" to provide a complete history of present illness; to follow the appropriate protocol to initiate treatment for OUD, including those for induction dosing; failure to identify the necessity for use of Buprenorphine mono product; to set forth for all patient visits the actual conclusion and plan of action, particularly for struggling patients; to provide clear prescriptions, changes in medications, or dosing; to document efforts to taper controlled substances; to identify alcohol use by patients; to address drug screens that were inconsistent with the prescribed medications; to adequately address mental health concerns; to refer patients to a higher level of care; and to address non-opiate related medical issues revealed through a patient examination or testing. Id, marked pages 512-515.

75. Dr. Jorrisch also noted in the cover letter that his "critical concern" was "the prescribing habits and routines of Dr. Hardison" and the risks related to the prescribing of "potentially addicting substance" to "patients with a diagnosis of Substance Use Disorder." Id., marked page 514.

76. Dr. Jorrisch summarized his findings and conclusions in his report by

stating, "Dr. Hardison's practice [is] definitely outside the standards for treatment in the Commonwealth of Kentucky, dangerous to his patients, and dangerous to the community. Major concerns exist for evaluation of patients, for identification of active diagnoses, for documentation in the medical record and in prescribing." Id., marked page 515.

77. Dr. Jorrisch also identified several other categories of care in which Dr. Hardison's medical practice fell below the applicable standards of care for OUD due to his failure: to provide "clear indication of past treatment episodes;" to provide a complete history of present illness; to follow the appropriate protocol to initiate treatment for OUD, including those for induction dosing; failure to identify the necessity for use of Buprenorphine mono product; to set forth for all patient visits the actual conclusion and plan of action, particularly for struggling patients; to provide clear prescriptions, changes in medications, or dosing; to document efforts to taper controlled substances; to identify alcohol use by patients; to address drug screens that were inconsistent with the prescribed medications; to adequately address mental health concerns; to refer patients to a higher level of care; and to address non-opiate related medical issues revealed through a patient examination or testing. Id, marked pages 1710-1714.

78. Many of the standards that Dr. Jorrisch found Dr. Hardison failed to meet in his medical practice are specifically required under the regulations governing the prescribing of controlled substances, stimulant medications, and buprenorphine.

79. In his individual report for each of the fifteen patients, Dr. Jorrisch set

forth the specific findings that supported his general findings and conclusions in his cover letter that accompanied the Expert Review Worksheets. Exhibit 1, marked pages 509-591.

80. In response to Dr. Jorrisch's report and to the Board's allegations, Dr. Hardison provided to the Board through his counsel several letters and a substantial amount of information in support of his medical practices. Exhibit 1A, attached exhibits 3 and 5, marked pages 321-508 and 592-1145 respectively.

81. Dr. Hardison also provided the Board with written opinions from two addiction medicine specialists, Dr. Roger Starner Jones and Dr. James Patrick Murphy, who, while agreeing with some of Dr. Jorrisch's findings, found Dr. Hardison's practice of medicine fell within the applicable standards for the sixteen patients at issue in this action. Exhibit 1, marked pages 607-623 and 734-782.

82. Dr. Jorrisch submitted to the Board two written replies to the information Dr. Hardison provided to the Board and to the written reports from Dr. Jones and Dr. Murphy, and Dr. Jorrisch stated his opinions had not changed as a result of that additional information. Exhibit 1, marked pages 1146-1151.

83. At the emergency hearing Dr. Jorrisch testified that as a result of Dr. Hardison's prescribing practices, he would not be surprised to learn that any of the patients at issue in this action had died. EH 3, 11:43 a.m. and 1:59-2:00 p.m.

84. At the administrative hearing on the *Complaint*, Dr. Jones, Dr. Murphy, and an additional expert witness, Dr. Molly Rutherford, testified on behalf of Dr. Hardison, and they agreed that his treatment of the patients at issue in this action fell

within the standards of acceptable and prevailing medical practice in Kentucky and did not violate the Board's statutes and regulations.

85. Dr. Hardison testified at both the emergency hearing and the Complaint hearing about the care provided to the patients at issue, and Dr. Jorrisch also testified at both hearings and provided testimony regarding his review of the care and treatment for each of the sixteen patients.

86. Dr. Jorrisch's findings and conclusions for each patient are too extensive to review individually in this recommendation, but the hearing officer found in general Dr. Jorrisch's findings and opinions to be compelling and well supported by the record.

87. In contrast, the hearing officer did not find Dr. Hardison's or his experts' testimony to be as persuasive as Dr. Jorrisch's in light of Dr. Hardison's own admission to several shortcomings in his medical practice, his failure to challenge many of Dr. Jorrisch's factual findings in support of his opinions, and based upon the standards of acceptable and prevailing medical practice in Kentucky as established by the applicable regulations and through the experts' testimony.

88. To the extent that Dr. Hardison's expert witnesses assert he did not violate the standards of acceptable and prevailing medical practice in Kentucky in spite of his clear and repeated violations of the provisions of 201 KAR 9:270, their opinions are not credible, especially considering Section 5 of the regulation that specifically states violations of Sections 2, 3, and 4 of the regulations "shall constitute a 'departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky" and shall constitute violations of KRS

311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12), which are the specific statutes cited by the Board in support of the *Complaint*.

89. The hearing officer notes that one section of Dr. Murphy's report is titled "Buprenorphine is Effective Pain Treatment." Exhibit 1, marked page 618.

90. Yet, 201 KAR 9:270, Section 2(1)(b), states that buprenorphine products shall not be prescribed for pain unless delivered in an FDA approved form and for an FDA approved purpose, and although Dr. Jorrisch testified that some formulations of buprenorphine are approved for the treatment of pain, he also testified that Suboxone, Subutex, and Sublocade are not approved for that purpose. CH 3, 9:24-9:25 a.m.

91. In addition, Dr. Murphy testified at the Emergency Hearing for Dr. Vincent that any deviation from the regulation he found in his review of the medical records were not violations of the standard of care because the deviations were consistent with the Treatment Improvement Protocol ("TIP") 63, published by the Substance Abuse and Mental Health Services Administration ("SAMHSA"). EV 2, 10:30 a.m.; Exhibit 16.

92. Thus, Dr. Murphy does not believe a physician is bound by the requirements of the Board's regulations if there is a competing authority, even with the specific requirement that a physician explain in his medical record why he deviated from the regulation's standards. 201 KAR 9:270, Section 4(2).

93. At the administrative hearing on the emergency order Dr. Hardison acknowledged many of the deficiencies found by Dr. Jorrisch in the record keeping practices for his patients as required by 201 KAR 9:270, Section 2(4), including the failure to "obtain and record a complete and appropriate evaluation of the patient,"

which shall include a history of present illness, past medical records, and the patient's past treatment history. Exhibit 1, marked page 512-513; EH 1, 4:04-4:06 p.m.

94. Hence, to the extent Dr. Murphy or Dr. Hardison's other expert witnesses assert or suggest his prescribing practices have met the applicable standards in light of clear violations of the regulations, the obvious conclusion is the expert witnesses do not accept the Board's regulations as the governing standards for the prescribing of buprenorphine and other controlled substances. Therefore, their overall credibility is further undermined by such assertions, and their opinions carry little weight.

95. Pursuant to 201 KAR 9:270, Section 4(1) and(2), a physician is required to "obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the licensee is conforming to the professional standards for prescribing" buprenorphine, and if he is unable to obtain those records, the physician "shall document those circumstances in the patient's record." CH 3, 9:25-9:26 a.m.

96. To the extent Dr. Hardison or his expert witnesses assert or suggest a physician may ignore that requirement and others in the Board's regulation, or may ignore an established standard because the practice of addiction medicine is "evolving" or because the physician is acting in the best interest of the patient, such an approach has no basis in law and is contrary to the fundamental principle that a physician is required to follow the Board's regulations. At the least and as required by the Board's regulations, the physician shall explain in his patient records, which Dr. Hardison failed to do, the reason for his deviation from a standard and regulation, assuming such

deviation may even be authorized by the language of the regulation itself.

97. To the extent that Dr. Hardison or his experts assert he acted in the best interests of the patient and within the standards of acceptable and prevailing medical practice by deviating from the requirements of a regulation, but he has not clearly stated in the patient record as required by the Board's regulations the reasons in support of the deviation from the standard, the physicians' assertions carry little weight. 201 KAR 9:270, Section 4(1) and(2).

98. At the administrative hearings on the emergency orders and on the *Complaints*, witnesses provided extensive and detailed testimony on the effects of opiates on the human body and on the evaluation and treatment process for prescribing buprenorphine to treat OUD that was helpful in providing both the context for and an understanding of the violations at issue in this action.

99. Because there is substantial overlap regarding the allegations against Dr. Vincent and Dr. Hardison and since Dr. Vincent provided during the administrative hearing on his *Emergency Order* relevant testimony regarding the operation of ANS and an opioids' effect on the body, the hearing officer has set forth in this recommendation several Findings of Fact from the *Final Order Overturning Emergency Order of Restriction* for Dr. Vincent that are relevant to the allegations against Dr. Hardison and that provide general background information regarding opioids effect on the body and how they interfere with its functioning.

100. Opioids, such as heroin, are a full agonist that binds to receptors in the brain to give a "reward" and cause persons to seek more of the drug for the effect

produced. EV 1, 11:32-11:34 a.m.

101. Because a person builds a tolerance to the drug, requiring increasing amounts for the same effect and to prevent the person from going into withdrawal, large amounts of opioids can cause respiratory suppression that results in death. EV 1, 11:34-11:36 a.m.

102. ANS treats OUD by substituting buprenorphine for heroin or other opioids the patient may be taking. EV 1, 11:32-11:34 a.m.

103. Buprenorphine occupies the same receptors in the brain as opioids, which prevents the person from going into withdrawal and reduces the craving for the drug. EV 1, 11:34 and 11:41 a.m.; EV 2, 11:35-11:38 a.m.

104. The standards for the prescribing of buprenorphine has been evolving in the medical community in an effort to allow increased access to the medication to treat an opioid addiction. EV 1, 11:42-11:45 a.m.

105. Suboxone has an advantage over methadone because it is generally a safer medication for the treatment of OUD and does not have the side effect of respiratory suppression. EV 1, 11:56-11:58 a.m.

106. Methadone can be abused by opiate addicted patients and is susceptible to diversion, and therefore, it is also highly regulated. EV 1, 11:59 a.m.-12:01 p.m.

107. If a patient is switching from methadone to Suboxone, the person must not have taken methadone for at least seventy-two hours before induction since he can experience severe withdrawals if he still has methadone in his body. EV 3, 12:54-12:57 p.m.

108. Dr. Hardison does not prescribe methadone in his medical practice. CH 1, 4:29 p.m.

109. Dr. Hardison testified that he preferred to prescribe Suboxone over Subutex since the latter contains only buprenorphine and can be snorted and injected. EH 2, 9:58-9:59 a.m.; See also CH 3, 2:55 p.m.

110. The entire process for prescribing buprenorphine is strictly regulated by the provisions of 201 KAR 9:270.

111. In his reports for the individual patients and in his testimony reviewing the care for each patient, Dr. Jorrisch provided details related to Dr. Hardison's violations of the standards set forth in 201 KAR 9:270, Section 2(4) related to the induction process for prescribing buprenorphine and the maintenance of adequate records. Exhibit 1, marked pages 509-591.

112. In spite of the requirements of the regulation to obtain past medical records and in spite of the assertion that ANS had a standing order to obtain those records, at the administrative hearing on the *Complaint* Dr. Hardison testified that it was a "rare bird" for ANS to obtain a patient's past medical records. CH 1, 10:19-10:20 a.m.

113. In addition, Dr. Hardison testified, "I'm sure" that he hadn't documented every effort to obtain those records in spite of his requirement to do so pursuant to 201 KAR 9:270, Section 4, when prescribing buprenorphine. CH 1, 10:20 a.m.

114. Although testifying on behalf of the physicians, Dr. Jones stated he may have seen a few records from other clinics in the patients' files, but he couldn't recall

seeing documentation regarding ANS's inability to get a patient's prior medical records. CH 8, 10:51 a.m.

115. In fact, Dr. Hardison was dismissive of the regulation's documentation requirement, stating that if the regulations required a physician to document the efforts to obtain a patient's past medical records, 99% of physicians didn't do it. CH 1, 10:21 a.m.

116. Furthermore, Dr. Hardison testified that the clinic had "lots of protocols," and although he asserted it was important to follow them on each occasion, his failure to obtain the patient's medical records or to document those efforts showed that he either routinely ignored or failed to rigorously enforce the protocols for record keeping. CH 1, 10:21 a.m.

117. Dr. Hardison also asserted, however, that the record keeping system and practices at ANS have improved substantially from 2017 and 2018, but the record indicates the practices have not improved sufficiently since that time to meet the requirements of the Board's regulations. EH 2, 9:40-9:42 a.m.

118. Thus, the preponderance of evidence supports the conclusion that he failed to maintain documentation as required by 201 KAR 9:270, Section 2(4), and he failed to document that he made the requisite effort to obtain patients' prior medical records.

119. In applying the standards in the regulation on treating patients with buprenorphine, the treating physician must first identify the patient as either a new patient for treatment of OUD or a patient who is continuing treatment. CH 3, 9:15 a.m.

120. The physician is also required to include in the medical records the HPI,

which in many instances was inadequate due to the failure to include the person's current status, which would necessitate another physician to review an entire three-page office note to understand the patient's status. CH 3, 1:36 p.m.

121. Every new patient at ANS was required to have a urine drug screen ("UDS") and an evaluation to determine whether the person was in withdrawal, was currently taking opioids or methadone, and was naive to buprenorphine. EV 3, 12:42-12:46 p.m.

122. Thus, the urine drug screen is performed for patient safety and to get baseline levels of opiates and other medications the patient is taking since some medications can stay in the body for weeks. EV 3, 12:59 p.m.

123. Although Dr. Hardison generally performed an appropriate initial UDS, significant and important information was often missing in the medical records related to those drug screens. Exhibit 1, marked page 512-513.

124. Dr. Hardison also failed to adequately address diluted UDS and failed to adequately address drug screens that showed the absence of prescribed medications or additional unprescribed controlled substances. Exhibit 1, marked page 513; EH 3, 9:24 a.m.; CH 3, 12:43-12:44 p.m.

125. As part of initial patient screening, the physician must obtain a COWS score to determine whether the patient is in withdrawal, but it was not clear if the COWS evaluation was performed or if the patient was in moderate or severe withdrawal since that information was often missing from the patient record. Exhibit 1 marked page 512; 201 KAR 9:270, Section 2(4)(c)(2).

126. Dr. Hardison acknowledged the COWS score in his office notes for Patients 4 and 5 was left blank, but he asserted a COWS score was not needed for anyone addicted to an opiate in spite of the requirements of the regulation. EH 1, 11:38-11:39 a.m.; Exhibit 4, marked page 3525; CH 2, 10:17-10:19 a.m.; Exhibit 6H, marked page 6253; 201 KAR 9:270, 2(4)(c)(2).

127. In addition, a patient needs to be in moderate withdrawal, as reflected by a COWS score of twelve or above prior to the start of treatment with buprenorphine, but Dr. Hardison's APRN initiated induction for Patient 15 with a COWS score of 9, which was mild withdrawal and presents risk to the patient with that score. CH 4, 10:02-10:03 a.m. and 10:10 a.m.

128. Patient 2 had a COWS score of only 3 at the start of her treatment with buprenorphine. Exhibit 1, marked page 523.

129. In addition to obtaining a COWS score, 201 KAR 9:270, Section 2(4)(c), requires the physician to recommend and observe in-office induction or record why in-office induction did not occur, shall initiate treatment with a dose not to exceed the equivalent of four milligrams of buprenorphine, and shall not exceed sixteen milligrams on the first day of treatment.

130. If the patient is "naive" to Suboxone, in that they have no recent history of use of the medication, the induction must take place at ANS, but if the person is not naive, he can undertake the induction in his own home. EV 3, 12:42 p.m. and 12:49-12:53 p.m.

131. Pursuant to 201 KAR 9:270, Section 2(4)(c)(1)(b), the physician is required

to record why in-office induction did not occur.

132. If the patient has been seen by another provider and does not have a lapse in treatment, the new provider "shall document that fact" and may treat the patient with buprenorphine without induction at the same or lesser dosage. 201 KAR 9:270, Section 4(d).

133. Dr. Hardison initiated Patient 2's treatment with buprenorphine when she was not in withdrawal and without recording whether she had a home or office induction or why an induction did not take place. Exhibit 1, marked page 523: CH 2, 11:29-11:31 a.m., 11:37-11:38 a.m.

134. Dr. Hardison also failed to comply with the requirements of the Board's regulations to document the initial dose given to a new patient, the escalation of the dosage, and the use of home inductions in place of office inductions. Exhibit 1, marked page 512; EH 3, 9:15-9:20 a.m.; 201 KAR 270, Section 2(4).

135. New patients or patients with a lapse in treatment with buprenorphine must initiate treatment at 4 mg and have their dosage escalated to no more than 16 mg the first day of treatment in accordance with 201 KAR 9:270, Section 4(c)(3). CH 3, 9:15-9:16 a.m.

136. The great majority of patients did not need a dose greater than 16 mg, and if patients are prescribed more, the medication, especially the mono product, can be sold which presents a safety issue for the community. EH 3, 9:19-920 a.m.

137. Thus, it was both inappropriate and contrary to the provisions of 201 KAR 9:270 to initiate a new patient at 16 mg or greater of buprenorphine, especially in light

of the regulation's requirement to document the need to go beyond the requirements of the regulation. CH 3, 9:15 a.m.; EV 5, 9:31-9:33 a.m.; 201 KAR 9:270, Section 4(2).

138. Dr. Hardison failed to require a re-induction for Patient 2 in spite of her being absent from two occasions for a significant period of time. Exhibit 1, marked page 523; CH 3, 11:54-11:56 a.m.

139. If the physician can document through medical records, drug screens, and KASPER reports that the patient is not naive to buprenorphine or has not had a lapse in treatment, the patient can be started at the dosage the patient had been taking with the previous provider. CH 3, 9:15-9:17 a.m.

140. The physician, however, cannot simply rely upon the patient's assertion that he has been in a suboxone treatment program to justify classifying a patient as anything but a new patient and must start him at 4 mg and escalate to no more than 16 mg of buprenorphine on the first day in accordance with the requirements of the regulation. CH 3, 9:15-9:16 a.m.

141. A patient "simply identifying familiarity with buprenorphine does not justify admission without induction and at higher doses." Exhibit 1, marked page 512; CH 3, 9:16 a.m.

142. After induction, the physician may increase a patient's buprenorphine beyond 16 mg in the appropriate circumstances. CH 3, 9:17 a.m.

143. Dr. Hardison increased buprenorphine for Patient 2 "without rationale." Exhibit 1, marked page 523.

144. Dr. Hardison had inadequate justification for the use of Subutex in place of

Suboxone. Exhibit 1, marked page 512.

145. Because of the potential for abuse of the mono product, Subutex, a physician "shall not" prescribe it unless the patient has a "demonstrated hypersensitivity to naloxone" or other specific medical conditions not applicable to the patients in this action. 201 KAR 9:270, Section 2(2)(b). CH 1, 10:13 a.m.; CH 2, 1:32-1:34 p.m.; 201 KAR 9:270, Section 2(2).

146. In fact, Dr. Hardison prescribed the mono product to three patients, Patients 5, 6, and 7, based upon their alleged allergic reaction to naloxone.

147. Dr. Hardison treated Patient 5 with the mono product due to her documented allergic reaction to naxolone. CH 3, 2:41-2:44 p.m.: Exhibit 1, marked page 538.

148. Dr. Jorrisch did not criticize Dr. Hardison's prescription of the mono product to Patient 5. CH 3, 2:41-2:43 p.m.

149. Patients 6 and 7, however, were husband and wife and both were prescribed the mono product due to an alleged allergic reaction to naloxone. CH 2, 1:01 p.m.; CH 3, 3:02 p.m.

150. He treated Patient 6 with Subutex because that was the medication he had been receiving from his previous provider due to his alleged allergic reaction to naloxone. EH 2, 11:13-11:16 a.m.

151. When the UDS for Patient 6 was positive for naloxone on June 6, 2021, Dr. Hardison did not change the patient's prescription to the less abusable Suboxone, but instead, he continued his prescription for the mono product in spite of the evidence the

patient did not, in fact, have an allergy to naloxone. Exhibit 7H, 8633, 9071.

152. Dr. Hardison asserted simply that he didn't recall seeing the naloxone on the UDS, and nothing in the patient notes indicate he otherwise addressed the matter with the patient, including where the patient obtained Suboxone, or had him tested for an allergy to naloxone, which he asserted an allergist could do. EH 2, 11:15 a.m.; Exhibit 7H, 8632-8654.

153. Dr. Hardison continued Patient 7 on the mono product based upon a previous provider's prescriptions, but the medical records do not show that Dr. Hardison documented the necessity for the mono product by obtaining the previous provider's medical records. Exhibit 1, marked page 548; Exhibit 32H.

154. Hence, in spite of the facts that Patients 6 and 7 were married and both tested positive for naloxone in their UDS, Dr. Hardison seemed to dismiss or discount the possibility of their diverting the mono product, and he made no effort in his patient notes to justify continuing the prescriptions for Subutex. Exhibit 32, last page. CH 2, 1:10-1:11 p.m.; CH 3, 3:02-3:04 p.m. and 3:21 p.m.

155. The standard of care required the physician to obtain the patient's medical records from the previous provider before issuing the second or third prescription for the mono product to verify the truthfulness of the patient's assertion of an allergic reaction to naloxone. CH 3, 2:50-2:51 p.m.

156. Dr. Hardison's patient records do not suggest Dr. Vincent made the requisite effort to comply with that requirement.

157. In spite of Dr. Hardison having three of the fifteen patients whose records

Dr. Jorrisch reviewed allegedly being allergic to naloxone, Dr. Jones testified he has never seen a patient with a naloxone allergy, describing the occurrence as "vanishingly rare." CH 8, 10:49 a.m. and 10:56 a.m.

158. Due to the requirements of the Board's regulation, Dr. Jones stated he expected a physician to state his clinical reasoning for continuing the mono product for a patient, stating a physician cannot simply take a patient's word on an allergy because of the risk of diversion. CH 8, 10:53-10:54 a.m.

159. Despite those requirements, however, Dr. Jones did not see that reasoning in Dr. Hardison's medical records. CH 8, 10:57 a.m.

160. Hence, Dr. Hardison failed to comply with the requirements of the regulation for prescribing the mono product, failed to document its necessity, and dismissed the possibility that his patients may be diverting the mono product and taking the buprenorphine/naloxone product in its place.

161. An initial dose of buprenorphine at 16 mg and above can precipitate withdrawal, which is unsafe, and dose escalation by the physician beyond 16 mg, which occupies 90-94% of the receptors in the brain, within the first two to three weeks of treatment is excessive. EH 3, 9:18-9:19 a.m.

162. The treating physician has to be aware that a patient is unlikely to have withdrawal at 16 mg of buprenorphine and that other interventions are appropriate over increasing buprenorphine, especially in patients who may be looking for the same effect they received from street drugs. EH 3, 9:19 a.m.; CH 3, 10:15 a.m.

163. The escalation of buprenorphine above 16 mg must be done in a measured

and safe way and must be supported in the record, which Dr. Jorrisch did not see in Dr. Hardison's records. EH 3, 9:20 a.m.; CH 3, 915-9:16 a.m. and 10:15-10:17 a.m.

164. Another concern for escalating Buprenorphine above 16 mg is the possibility that the patient may seek to divert any excess medication, and although Dr. Jorrisch recognized that some patients may benefit from a higher dose, that need must be documented, which he didn't see in the medical records. EH 3, 9:19-9:20 a.m. and 3:15 p.m.; CH 3, 10:15-10:17 a.m.

165. The patient records showed that Dr. Hardison initiated and/or continued treatment of many patients with buprenorphine at 16 mg or greater without adequately documenting the need for that treatment contrary to the provisions of 201 KAR 9:270, Section 4(c)(3). See Exhibit 1, pages 516-587, Patients 1, 5, 6, 7, 12, 13, 14, and 15.

166. While Dr. Hardison did not disagree with the substantial majority of Dr. Jorrisch's factual findings related to the failure to follow the requirements of the regulation, he and his experts offered various rationales justifying his prescribing practices, including his own expertise in treating OUD patients, the evolving nature of the understanding of OUDs, and the potency of opiates such as fentanyl, and harm reduction. See Exhibit 1, marked pages 509-591; CH 1, 10:22-10:27 a.m.; CH 7, 10:38-10:42 a.m.

167. Dr. Hardison failed to incorporate abnormal KASPER findings into appropriate clinical reasoning to support the continuation or modification of treatment and failed to accurately document the same in the patient record, as required by 201 KAR 9:270, Section 2(4)(e)(5)(a). See for example, Exhibit 1, marked page 548; CH 2,

2:10-2:13 p.m.

168. Dr. Hardison failed to incorporate abnormal drug screens into appropriate clinical reasoning to support the continuation or modification of treatment and failed to accurately document the same in the patient record, as required by 201 KAR 9:270, Section 2(4)(e)(5)(f)(ii). Exhibit 1, marked page 513 and 533; CH 2, 1:31-1:32 p.m.

169. Patient 4 had three benzodiazepines in his drug screen at the time Dr. Hardison restarted the patient on Xanax after having been in rehabilitation to wean him from that medication, and he provided no explanation for that prescribing practice. CH 2, 10:08-10:09 a.m.

170. Dr. Jorrisch stated it was not within standard of care to continue to prescribe benzodiazepines to Patient 4 in that situation, which presented a strong safety issue. CH 3 1:31-132 p.m.

171. If a physician decides to veer from the standard of care, there needs to be clear documentation in the record to go in another direction. CH 3, 1:42 p.m.

172. If the patient is stable and in treatment for OUD and wants to continue treatment of suboxone at the present dosage, it's within the standard of care not to push the patient to decrease their dosage. CH 3, 9:19 a.m.

173. Several patients had a lapse in treatment but Dr. Hardison did not repeat the induction process as he was required to do for the safety of the patient. CH 3, 9:16 a.m.; See, e.g., CH 3, 11:53-11:55 a.m.; Exhibit 1, marked page 512.

174. In addition to finding that Dr Hardison's care and treatment related to a patient's opiate use disorder failed to meet the standard of care in violation of the

Board's statutes and regulations, Dr. Jorrisch also found Dr. Hardison's care and treatment of patients with StUD, often as a result of their addiction to methamphetamine, violated the Board's statutes and regulations by his prescribing stimulants and other medications to those patients under the guise of treating them for ADHD and ADD.

175. Dr. Hardison described the difference between persons with StUD to those with OUD as the former chasing the high while the latter is attempting to prevent withdrawal. EH 1, 1:33-1:34 p.m.

176. He also characterized methamphetamine as "the most destructive drug on the planet" due to the organ damage, paranoia, violence, and number of deaths attributed to the drug. EH 1, 9:52 a.m.

177. The drug destroys the ability to produce dopamine, serotonin, and norepinephrine, and neural pathways must be redeveloped over the course of years for the person to have a good and productive life. EH 1, 9:54-9:56 a.m.

178. Hence, Dr. Hardison asserted meth addicted patients must be placed in a structured program, given low levels of Klonopin in place of the meth, and they must be allowed time to develop new neural pathways for the production of dopamine in order to facilitate harm reduction for the patient. Id.

179. Suboxone is not used to treat a meth addiction but is used in combination with other medications for patients diagnosed with both OUD and StUD. CH 1, 10:28-10:29 a.m.

180. StUD patients experience fatigue, lack of concentration, and difficulty

completing tasks and will turn to illicit drugs to obtain symptom relief. EV 1, 1:38 p.m.

181. Therefore, controlled substances are not an effective tool for treating StUD, and instead, cognitive therapy and twelve-step type programs are used for treatment. EV 1, 1:35 p.m.

182. Dr. Jorrisch testified that the "great majority" of physicians acknowledge the standard of care for the treatment of StUD is not to prescribe stimulants for the condition. CH 3, 1:43 p.m.

183. Dr. Hardison acknowledged that no drugs, including stimulants, are routinely recommended for treatment of StUD, or meth addiction specifically, and that behavioral therapy and contingency management are the only treatments proven to work for those patients. CH 4, 10:06 a.m.; Exhibit 1, marked page 869.

184. Dr. Murphy acknowledged in his own testimony that he did not prescribe stimulants for his own patients suffering from StUD. CH 11, 10:12 a.m.

185. Persons with Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder, however, have symptoms similar to persons with StUD. EV 1, 1:39 p.m.

186. Therefore, there has been some discussion among addiction specialists and studies published concerning the treatment of StUD patients with stimulants such as Adderall, but that is irrelevant to the issue of whether Dr. Hardison has complied with the Board's statutes and regulations since they do not authorize the use of stimulant medications for the treatment of StUD. EV 1, 1:39-1:44 p.m.

187. Since Adderall and Ritalin are Schedule II amphetamine or amphetamine-like controlled substances, the prescribing of those medications are governed by the

provisions of 201 KAR 9:016, Section 3(2)(a)-(f), which authorizes the use of stimulants for the treatment of certain specific medical conditions that include ADHD but not StUD.

188. Dr. Jorrisch testified that while it is completely appropriate to treat ADHD in children with Adderall, it is not within the standard of acceptable and prevailing medical practice in Kentucky to prescribe Adderall to an adult who has StUD unless that person had a documented diagnosis of ADHD. CH 3, 9:17 a.m.

189. Thus, Dr. Jorrisch's opinion is simply a recognition and application of the requirements of 201 KAR 9:016, Section 3(2)(a)-(f) that represent the standards of acceptable and prevailing medical practice in Kentucky.

190. Furthermore, even without the strict provisions of 201 KAR 9:016, Section 3(2)(a)-(f), Dr. Jorrisch noted that since there currently is not good support for the use of medications for the treatment of StUD, the danger of prescribing stimulants to the patient already suffering from StUD is always highlighted in the studies that advocate for the use of those medications. EH 3, 9:40 a.m.

191. Thus, even without the specific prohibition in the Board's regulation, Dr. Hardison would have been expected under the requirements of the Board's regulation to provide in his patient notes a clear and detailed explanation for the prescribing of stimulants to such patients, which he did not do.

192. Even if Dr. Hardison were qualified to diagnose a patient's ADHD, the Board asserts that Dr. Hardison and Dr. Vincent improperly prescribed Ritalin and Adderall for the treatment of patients' StUD under the guise of a diagnosis of ADHD and

ADD when there was not adequate support and justification in the patients' medical records for such diagnoses.

193. Dr. Hardison justified the treatment of Patient 4 with stimulants for ADHD based upon the patient's statement, "think I had ADHD as a child." Exhibit 1, marked page 533.

194. Yet, Dr. Hardison admitted that he prescribed Adderall to Patient 4 not for a diagnosis of ADHD but for his "terrible meth addiction" which is an admission of a violation of 201 KAR 9:016. CH 1, 3:49 p.m.

195. Dr. Hardison justified his treatment of Patient 6's ADHD with stimulants not after making a formal and rigorous review and diagnosis of the condition that is set forth in the patient's record but merely based upon his statement "patient has evidence of ADHD." Exhibit 1, marked page 543.

196. Dr. Hardison treated Patient 13 with stimulants for ADHD based upon the patient's assertion, "I think I have ADHD." Exhibit 1H, marked page 574.

197. As Dr. Jorrisch stated, making diagnosis quickly and based upon such limited information "just doesn't cut it" under the applicable professional standards, and a physician prescribing stimulants to a patient with StUD in such circumstances represents a danger to the patient. EH 3, 9:31-9:33 a.m.

198. Dr. Hardison also admitted that he should have, but did not, send Patient 15 for a diagnosis of ADHD, which is an admission and confirmation that he had prescribed Adderall for meth addiction, which is an inappropriate use of the medication. Exhibit 1, marked page 870; CH 4, 10:06-10:07 a.m.

199. Dr. Hardison's comment about referring Patient 15 to another physician for a diagnosis of ADHD was a tacit admission that he was not qualified to make such a diagnosis for any patient for whom he prescribed Adderall and shows that he was actually using ADHD as an excuse to prescribe the medication for his patients' meth addiction in recognition that such prescriptions were not authorized for StUD under the Board's regulation.

200. Dr. Hardison prescribed controlled substances that are often misused by patients with OUD, such as promethazine, hydroxyzine, and gabapentin, but he "did not show clear rationale [for medications that] carried inherent dangers." Exhibit 1, marked page 514.

201. Among persons with OUD, Dr. Jorrisch stated that "in particular gabapentin, a controlled substance, is widely misused [and is] dangerous with its sedative properties," and therefore, "its prescription by Dr. Hardison in his patients necessitated clear rationale for an FDA approved purpose to be acceptable," which he failed to do in his patient notes. Exhibit 1, marked pages 514-515; CH 3, 9:18-9:19 a.m.

202. Since it's "well known" that patients with OUD misuse gabapentin, a physician should avoid prescribing that medication. CH 3, 9:18 a.m.

203. Although gabapentin is approved for specific uses, it is not approved for the treatment of pain, anxiety, or other mental health issues. EH 3, 9:35-9:36 a.m.

204. Dr. Hardison, however, prescribed gabapentin for those conditions. Id.

205. The hearing officer notes that Dr. Hardison asserted that because he was prescribing gabopentin "off label," which meant it was not prescribed for an FDA

approved use, he was authorized to prescribe the medication for any reason, but at the same time, he asserted he was under no obligation to state specifically in the patient notes, in spite of the requirements of the applicable regulations to the contrary, the diagnosis and the justification for prescribing gabopentin to the patient, and more importantly for the patients at issue in this action, the justification for prescribing to a patient who is being treated for SUD. 201 KAR 9:260, Section 2.

206. In addition to misusing gabapentin, OUD patients are also "well known to misuse benzodiazepines" and therefore, benzodiazepines are generally to be avoided and are contraindicated for those patients. CH 3, 9:20 and 9:22 a.m.

207. Dr. Jorrisch noted a physician must be concerned that a patient who is being treated with buprenorphine is also using sedative-hypnotic medications, including include benzodiazepines generally, and Xanax specifically, particularly from the standpoint of sedation and possible respiratory suppression, overdose, and death. CH 3, 1:31 p.m.

208. The benefit to the patient in prescribing benzodiazepines must be greater than the risk, especially for a patient who may not only be misusing his prescribed medication but is also taking unprescribed benzodiazepines. CH 3, 1:31 p.m.

209. Taking unprescribed benzodiazepines presents a strong safety issue, and it's not within the standard of care to prescribe them in such a circumstance. CH 3, 1:32 p.m.

210. Benzodiazepines could be used, however, in an "urgent situation" to allow a patient to detox and avoid withdrawal as the patient enters treatment, but it would be

"foolhardy" to prescribe them PRN ["as needed"] rather than in a "specific, guided course" since such patients cannot manage withdrawal on their own. CH 3, 9:21 a.m.

211. The gradual withdrawal from benzodiazepines represented the standard of care, and a safe withdrawal course of treatment may extend over a couple of weeks, but a month or more would be excessive. CH 1, 4:14 p.m.; CH 3, 9:21 a.m.

212. The fact that patients are rarely able to taper their benzodiazepine use is not a reason to continue prescribing the medication but is a reason to have them enter a higher level of care due to the danger of the continued use of benzodiazepines with OUD. CH 3, 9:22-9:23 a.m.

213. In response to Dr. Jorrisch's criticism of his prescribing practice related to benzodiazepines, Dr. Hardison asserts that by continuing to prescribe benzodiazepines such as Xanax, he's engaging in "harm reduction" by maintaining them on the medication with their underlying emotional problems, which will also help in maintaining the patient on the treatment for OUD. CH 1, 10:11-10:12 a.m. and 12:16 a.m., 3:51 p.m., 3:54-3:55 p.m.

214. While harm reduction is a legitimate goal and necessary for some patients, the physicians' discretion in treating patients is not unlimited, especially when the patient continues to misuse controlled substances, and Dr. Hardison was required to follow the Board's statutes and regulations in exercising his discretion. CH 3, 2:22-2:23 p.m. and 2:27-2:28 p.m.

215. Dr. Hardison asserted that many patients with OUD also have anxiety issues and placing them on a long-acting, low dose benzodiazepine while being treated

with buprenorphine for their OUD helps to keep them in the recovery program and helps to keep them from seeking benzodiazepines illicitly. CH 1, 4:27-4:30 p.m.

216. In addition, Dr. Hardison asserted that more patients die if you take them off benzodiazepine than if you keep them on the medication while treating their OUD with buprenorphine. CH 1, 4:22-4:24 p.m.

217. Whether the patient suffers from OUD or StUD, Dr. Hardison characterized his overall goal for patient treatment is to prevent relapse and keep them in recovery since patients may die if they relapse. CH 1, 10:29-1031 a.m.

218. If the physician believes the prescribing of benzodiazepines is necessary for a patient with OUD, the reasons for its use must be well documented, and the physician must have the experience and training in treating the panic, anxiety, or other associated conditions for which that medication has been prescribed. CH 3, 9:23 a.m.

219. Dr. Jorrisch noted that benzodiazepine prescriptions for patients with a diagnosis of StUD or of a sedative-hypnotic use disorder may be appropriate in some circumstances, but the physician's reasoning must be well documented, which the records indicate Dr. Hardison did not do. CH 3, 9:23 a.m.; CH 4, 11:48 a.m.

220. In addition, there are other medications and other methods, including behavioral techniques, to manage the patient's mental health problems, which should be the first course of treatment. CH 3, 9:23 a.m.

221. ANS did not have a taper protocol for benzodiazepines prior to January 2023, which suggests the facility did not prioritize the need to wean patients from the medication. CH 5, 4:10-4:12 p.m.

222. Even when prescribing to a patient addicted to benzodiazepines, the standard of care is to switch the patient from Xanax to longer acting Klonopin and to prescribe for a short course of treatment not extending beyond a couple of weeks since a longer period of time is excessive. CH 3, 9:21 a.m.; CH 7, 10:43-10:45 a.m.

223. For example, Patient 4 was placed on Klonopin but switched back to Xanax and continued on that medication even with clear evidence of misuse. EH 1, 12:14 p.m.; EH 3, 10:08-10:12 am.; CH 3, 1:31-1:32 p.m.

224. Although patients with addiction issues frequently have mental health issues that also must be addressed, Dr. Hardison failed to consider whether the patients needed a higher level of care than could be provided through his own medical practice. Exhibit 1, marked page 513-514; EH 3, 9:28-9:30 a.m.

225. While Dr. Hardison had some experience and training to address mental health issues, he doesn't have the training and expertise for full treatment of mental health disorders, such as a three-year psychiatry residency, and some of his patients with mental health disorders associated with their addictions needed referral to a higher level of psychiatric care, which they did not receive. EH 3, 9:26 a.m.; CH 3, 11:21-11:22 a.m.; CH 4, 9:44-9:45 a.m.

226. In addition, there's no evidence in his patient records that Dr. Hardison was providing psychiatric care, much less a higher level of care that can be provided by a trained psychiatrist, for his patients' mental health disorders.

227. There is not a strict contraindication for a patient with SUD to be prescribed benzodiazepines, but that has to be done under the right circumstances and

in consultation with an expert, such as a psychiatrist. CH 3, 2:05 p.m.; Exhibit 1, marked page 514.

228. Thus, the issue in this action is not whether Dr. Hardison is qualified to diagnose and treat a person with an addiction to benzodiazepines, but whether, as Dr. Jorrisch found, he placed too much reliance on continuing benzodiazepine prescriptions, had inadequate justification for the medication in the patient records, and should have referred the patient to a higher level of care when his treatment was not successful.

229. As Dr. Jorrisch summarized in his report, "there are alternative medications to BZD's [benzodiazepines] to help manage [anxiety.] Psychiatry expertise would be helpful. But definitely in patients with identified sedative hypnotic use disorder, in those known to be misusing sedative hypnotics (including alcohol), being treated with medications that cause sedation, the risks may be too high to consider the use of BZD's." Exhibit 1, marked page 514.

230. For example, Dr. Jorrisch stated for Dr. Hardison's care and treatment of Patient 4, "Prescribing of BZD's for a patient with identified sedative-hypnotic use d/o [disorder], with obvious misuse of prescribed BZD's identified by DS [Drug Screen] results, was contraindicated. Use of alternative, non-BZD anxiolytics was indicated." Exhibit 1, marked page 533.

231. Thus, while prescribing benzodiazepines in some situations may be necessary, Dr. Hardison did not comply with the standards in 201 KAR 9:260, Section 2, by providing in his patient notes a clear diagnosis, starting with safer medications,

documenting his reasoning for continuing the medications over a long course of treatment, and referring such patients to a psychiatrist with experience and credentials in treating anxiety, panic disorders, and other associated diagnoses. EH 3, 9:33-9:34 a.m.; See for example, the care and treatment provided to Patient 4 and Dr. Jorrisch's report on that patient in Exhibit 1, marked page 533.

232. There is no requirement that a physician continue stimulant or sedative-hypnotic medications if the patient had been prescribed them by an earlier provider, but instead, the new physician must contact the previous provider for the patient's medical records and must document the reasons for continuing those medications. Dr. Hardison did not follow those guidelines and standards of care. CH 3, 9:28 a.m.

233. The off-label use of gabapentin is not a better course of treatment for patients treated with benzodiazepines who suffer from anxiety, panic disorders or other associated mental health conditions and is not approved by the FDA for that purpose. CH 3, 9:24 a.m.

234. Therefore, Dr. Hardison violated the applicable standards for prescribing gabapentin for treatment of those conditions.

235. In this recommendation the hearing officer will review the care and treatment of Patient 4 as representative of many of the violations alleged in the *Complaint*, of Dr. Hardison's approach to patient care and record keeping, and of Dr. Jorrisch's findings and opinions related to the fifteen patients whose records he reviewed and for whom Dr. Jorrisch found similar and consistent shortcomings and violations of the applicable standards.

236. Patient 4 started treatment at ANS on April 18, 2017, and continued treatment there periodically through August 2022 at which point he dropped out of the program after he was taken off Adderall and was no longer under the care of ANS. CH 1, 10:02-10:03; Exhibit 3, pages 4996 and 4769.

237. At the beginning of his treatment Patient 4 was thirty-five years old and had a long history of opiate, heroin, methamphetamine, benzodiazepine, and marijuana abuse. EH 1, 1:29 p.m.

238. Dr. Hardison characterized Patient 4 as having substantial stress in his life resulting from many sources, including his mother who suffered from ALS and died from that condition. EH 1, 1:30 p.m.

239. Patient 4 was being treated at ANS for OUD, benzodiazepine misuse, and StUD. EH 1, 1:29 p.m.

240. His opiate use was well controlled with Suboxone and he was prescribed Adderall for his meth addiction, which Dr. Hardison characterized as successful for periods of times. EH 1, 1:32 p.m.

241. At his initial patient encounter at ANS, Patient 4 announced he would almost rather stop taking Suboxone than give up Xanax. Exhibit 3H, marked page 3455.

242. Thus, by Patient 4's own tacit admission Xanax was his most powerful addiction, and although Dr. Hardison attempted to substitute Klonopin for the Xanax, Patient 4 was never able to completely wean himself from Xanax. EH 1, 1:32-1:34 p.m.

243. Dr. Hardison prescribed Adderall for what he described as Patient 4's "terrible" meth addiction. CH 1, 3:49 p.m.

244. Thus, there can be no dispute that Patient 4 presented many challenges for the treatment of his drug addictions and would be a difficult patient to treat successfully.

245. Patient 4's medical records provided a clear example in support of Dr. Jorrisch's assertion that Dr. Hardison's patient records were "in general excessive, repetitive, conflictual, and difficult to follow;" that it was difficult "to discern from any patient visit the actual conclusion and plan of action particularly for struggling patients;" that the records failed to provide in the HPI "important patient information visit to visit (e.g. RX changes, other practitioner visits and interventions)," and that they lacked documentation to show that a "taper had actually occurred." Exhibit 1, pages 512-513.

246. Patient 4 was compliant with his treatment for OUD and had done well on Suboxone throughout the time period at issue.

247. During the period that Patient 4 received care at ANS, he was in rehabilitation once and possibly twice for his methamphetamine and benzodiazepine addictions. CH 1, 3:49 p.m.

248. Dr. Hardison reported that over time, Patient 4 was doing better than when he started with the ANS program and was sober for six to eight months at one point. EH 1, 1:33 p.m.

249. Dr. Hardison reported that if Patient 4 stayed with ANS, there was a good chance that he could get sober, but if he was dismissed, he was likely to go back to opioids and die. EH 1, 1:34-1:36 p.m.

250. Thus, Dr. Hardison characterized his approach to the care of patients addicted to benzodiazepine to be that of harm reduction, by which he attempts to keep them safe by continuing to write prescriptions for the lowest possible dose in a controlled amount to keep them away from street drugs and to the reversion to more potent drugs that may kill them. EH 1, 10:10-10:11 a.m.

251. At his initial patient encounter, Dr. Hardison informed Patient 4 that he would need to be tapered from Xanax starting at 2.5 mg per day due to the side effects of "increased anxiety and rebound depression" as a result of his history of using three mg of Xanax per day "for years." Exhibit 3, marked page 3455.

252. On August 9, 2017, Dr. Hardison also prescribed Patient 4 Celexa for depression and substituted Klonopin for Xanax because Klonopin as a long-acting benzodiazepine is a safer medication. EH 1, 11:18-11:19 a.m.; Exhibit 3H, marked page 3466.

253. The next office note dated August 23, 2017, states Patient 4 reported that he had been in a fight that resulted in a broken jaw, and Dr. Hardison wrote that he planned to taper Patient 4's Xanax on the next visit. Exhibit 3H, marked page 3470.

254. Dr. Hardison acknowledged the note is confusing since at that point he had prescribed Klonopin in place of Xanax. EH 1, 11:20 a.m.

255. Dr. Hardison's office note dated October 18, 2017, states that Patient 4's last successful taper for Suboxone was on April 25, 2017, but Dr. Hardison acknowledged at the administrative hearing the KASPER report reflects there was no decrease in his prescriptions for that medication. Exhibit 3H, pages 3494; Exhibit 26H,

page 1; CH 1, 3:45 p.m.

256. Dr. Hardison then asserted during his testimony that the notation actually refers not to the tapering of Suboxone but of the patient's Xanax prescription, but the KASPER shows that a provider other than Dr. Hardison was prescribing Xanax to Patient 4 in April 2017 and had not decreased the medication. CH 1, 3:46 p.m.; Exhibit 26H, page 1.

257. Thus, Dr. Hardison's assertion is not credible.

258. On several occasions during the administrative hearing on the *Emergency Order*, Dr. Hardison asserted he had not been the provider who had seen Patient 4 on the date of the patient note, in spite of his electronic signature at the bottom of the note. See e.g., EH 1, 11:25 a.m.; Exhibit 3, marked page 3494.

259. Dr. Hardison acknowledged that the practice at ANS was for the provider who saw the patient to sign off on the office note. EH 1, 11:30 a.m.

260. Thus, the hearing officer assumes that Dr. Hardison saw the patient since there was no testimony that other providers ever signed patient notes on behalf of other providers.

261. A lab report for the UDS taken during his office visit on October 18, 2017, showed that Patient 4 was positive for three different benzodiazepines, which Dr. Hardison stated reflected that Patient 4 was "taking everything." CH 1, 3:47-3:48 p.m.; EH 1, 11:20 a.m.; Exhibit 3, marked page 4996.

262. Dr. Hardison acknowledged, however, that his office note failed to address Patient 4's use of unprescribed benzodiazepines as revealed in his UDS. EH 1, 11:22

a.m.; Exhibit 3, marked page 4996.

263. His treatment note for that date states that Patient 4 was experiencing some withdrawal from Xanax, which would require increasing the medication, but it would be reduced at the next appointment. Exhibit 3, marked page 3495.

264. At the emergency hearing Dr. Hardison stated that he'd have to refer to the KASPER report to know for certain whether he had prescribed Patient 4 Xanax rather than Klonopin on that date, and although he asserted he had counseled the patient on his taking unprescribed benzodiazepines, he acknowledged the patient notes don't reflect that, stating, "I should have noted it." EH 1, 11:21-11:23 a.m. 11:22-11:23 a.m.

265. Later, at the complaint hearing Dr. Hardison acknowledged that he placed Patient 4 back on Xanax in response to the UDS that showed he was taking three benzodiazepines. CH 2, 10:08-10:09 a.m.

266. He admitted that his patient notes do not reflect his reasoning for restarting Xanax but asserted his J-Section notes, which were never offered into evidence, would explain what he did. CH 2, 10:09 a.m.

267. The next office visit note for December 20, 2017, states in the HPI that it was "for routine F/U [Follow Up] of medication efficacy. Doing well. No new issues/concerns." Exhibit 3H, marked page 3507.

268. Again, in spite of his electronic signature on the note, Dr. Hardison was unsure whether he saw the patient on that date and was unsure whether this was the patient's first visit after his time in rehabilitation to come off Xanax that was referenced in the note. Exhibit 3H, marked pages 3507 and 3509. EH 1, 11:28-11:30 a.m.

269. The note also states Patient 4 was "Doing well. No new issues/concerns" in spite of his recent return from a drug rehabilitation clinic, and the note states further, "Xanax-tapering off, will continue same dose and Dr. Hardison will address next visit." Exhibit 3H, marked page 3509.

270. Dr. Hardison testified that he was unsure why, or if, he put Patient 4 back on Xanax and stated he was unsure of the note's meaning. EH 1, 11:31 a.m.

271. Later during the hearing, he acknowledge he had placed the patient back on Xanax and stated his reasons for doing so could be discerned by looking at the UDS that had been positive for multiple benzodiazepines. CH 2, 10:09 a.m.; Exhibit 3H, marked page 4996.

272. On several occasions during the course of his testimony Dr. Hardison offered similar explanations for how a practitioner could follow his reasoning and plan of care. He stated that while he may not have noted directly in his patient notes why he took any particular action, one only had to review the entire note in order to piece together and understand his reasoning and plan of care.

273. After Dr. Hardison expressed confusion at the administrative hearing as to whether he had actually put the patient back on Xanax, and in response to the question whether the note is "a little confusing," Dr. Hardison responded, "Why sure it is," which confirmed Dr. Jorrisch's own assessment of the inadequacy of his patient notes and refuted Dr. Hardison's assertion that by merely reviewing his notes a practitioner could understand his actions and plan of care. EH 1, 11:32 a.m.

274. The inadequacy of Dr. Hardison's patient notes continued through his

course of treatment of Patient 4.

275. The note dated January 5, 2022 lists Vraylar, an anti-depressant, as one of Patient 4's "Current Medication," and although it was just added that visit, and Dr. Hardison answered "No" to the question on the form asking whether "Any new medications added?" EH 1, 12:10-12:11 p.m.; Exhibit 3, marked page 4128-4129.

276. Dr. Hardison described that failure simply as an "oversight." EH 1, 12:11 p.m.

277. The patient note itself provides no explanation for why that medication was added. Exhibit 3H, marked pages 4128-4129.

278. When it was pointed out to Dr. Hardison at the administrative hearing that Patient 4's prescriptions for Adderall and Klonopin were not included in his list of "Current Medications, Dr. Hardison explained, "that wasn't written down right." EH 1, 12:10 p.m.

279. The next patient note for January 12, 2022, states Patient 4 is "doing much better. No meth in 2 weeks." Exhibit 3, marked page 4168.

280. When Dr. Hardison was informed at the administrative hearing that the note on that date did, in fact, list all of Patient 4's current medications, Dr. Hardison laughed and stated, "finally." Exhibit 3H, marked page 4169; EH 1, 12:11 p.m.

281. The patient note concludes with the statement that Patient 4 "wanted to change Klonopin to Xanax, which I did." Exhibit 3H, marked page 4170.

282. At the administrative hearing Dr. Hardison stated that Patient 4's medication was changed because he was always relapsing but admitted an explanation

for the change should have been included in the note. EH 1, 12:12 p.m.

283. Dr. Hardison also stated, however, that if Patient 4 had not been on Xanax for the last three to four weeks the patient's request would have been a "poor excuse" to put him back on the medication. EH 1, 12:14 p.m.

284. Thus, by Dr. Hardison's own admission his decision to prescribe Xanax is not supported by his medical records and can't be justified under the standards of acceptable and prevailing medical practice in Kentucky.

285. Dr. Hardison admitted the patient records do not support the conclusion that Patient 4 had been taking Xanax during the time period immediately prior to the date of the office note. EH 1, 12:15 p.m.

286. Near the conclusion of the series of questions at the administrative hearing regarding his patient notes during that time period, Dr. Hardison testified he thought he had extensive notes on the patient's care, and "I didn't know these notes were like this," which again is a tacit admission as to the inadequacy of notes generally, and specifically, for Patient 4. EH 1, 12:14 p.m.

287. In addition, the patient notes confirm Dr. Jorrisch's assessment of the inadequacy of care and treatment provided to Patient 4, including the lack of sufficient patient notes, the reasoning for the care provided, and the over-prescribing of controlled substances.

288. Adequate documentation is "critical" to know what's happening with a patient, and the provider needs to have clarity in the records if another provider is seeing the patient in a short office visit, especially in a medical practice like ANS where

multiple providers are caring for patients. EH 3, 9:57-9:58 a.m.; Ch 11, 10:13-10:14 a.m.

289. Dr. James Murphy testified on behalf of Dr. Hardison that clear documentation is always helpful and needs to be as clear as the provider can make it, further suggesting the inadequacy of Dr. Hardison's patient notes. CH 11, 10:13-10:14 a.m.

290. Testifying on behalf of Dr. Hardison, Dr. Jones stated he could follow Dr. Hardison's reasoning in the medical records and asserted they fell within the standard of care. CH 8, 11:54-11:56 a.m.

291. He added, however, that Dr. Hardison could have provided better documentation on the care and treatment of Patient 4 but asserted that was a common failing of many providers. CH 8, 11:29 a.m.

292. The hearing officer notes that Dr. Jones had been working part-time at ANS for several months and could be expected to have gained a level of familiarity with Dr. Hardison's practice and his system for recording patient information that was greater than someone outside the practice who was reviewing the medical records, and as an employee of ANS, Dr. Jones could be expected to have some degree of bias, whether knowing or not, in favor of a physician and medical practice that he chose to join. Thus, Dr. Jones' positive assessment of Dr. Hardison's notes and medical practices carry little weight. CH 8, 10:33 a.m.

293. Certainly, Dr. Hardison's own testimony showed he failed to provide adequate or sufficient documentation of the care and treatment of his patients in light of the fact he couldn't understand or follow his own records.

294. When questioned about another patient note that stated Patient 4 did not have a mental health provider at ANS, Dr. Hardison reported that he was sure the patient had a mental health provider. CH 2, 10:10 a.m.

295. Dr. Hardison then asserted that as a board certified addictionologist, he himself was "probably" the mental health provider for Patient 4. CH 2, 10:10 a.m.

296. Again, Dr. Hardison only highlighted the confusing and inadequate nature of his patient notes.

297. Dr. Hardison asserted that he attempted to get the medical records for a patient's time spent in drug rehabilitation but stated it's almost impossible to do since such facilities are "like Ft. Knox." EH 1, 11:32 a.m.; CH 1, 3:48-3:49 p.m.

298. Dr. Hardison admitted he didn't document in the patient notes his efforts to obtain patient records. CH 1, 3:48 p.m.

299. Dr. Hardison was further confused by his own records dated two weeks later.

300. The "Adult History Intake" form for Patient 4 dated January 3, 2018, that includes the Prior Induction - Clinical Opiate Withdrawal Scale (COWS)" on one page and the "Post Induction - Clinical Opiate Withdrawal Scale (COWS) form on the next page, were left blank. Exhibit 3H, marked pages 3521-3526.

301. In spite of his signature on the form Dr. Hardison was unsure whether he performed an induction on Patient 4 but seemed to justify his failure to complete the forms by asserting induction is "not a problem" for anyone who is opiate addicted. EH 1, 11:36-11:41 a.m.

302. Dr. Hardison stated the only problem he experienced with a patient's induction in his ten years of addiction practice was early in his practice when one patient experienced acute withdrawal while on methadone. EH 1, 11:42-11:43 p.m.

303. Thus, Dr. Hardison tacitly admitted that he's dismissive of the need to perform an induction in accordance with the applicable Board regulation and to have adequate patient records to document his compliance.

304. The HPI in the patient note dated June 23, 2021, states Patient 4 had been back for three weeks as a participant in ANS's substance abuse program, and the patient note states he had been having "meth cravings." Exhibit 3H, marked page 3676.

305. The note also asked Dr. Hardison "to evaluate for adderall. Pt thinks he had ADD as a child. Still has focus problem." Exhibit 3H, marked page 3677.

306. There's nothing in the patient note suggesting Dr. Hardison performed such an evaluation. Exhibit 3H, marked pages 3676-3678.

307. On that date, however, Dr. Hardison increased Patient 4's suboxone to 24 mg per day, added 30 mg adderall twice a day for the meth cravings, and 150 mg Wellbutrin twice a day for ADD. Exhibit 3, marked pages 3677-3678; EH 1, 11:57 a.m.; CH 1, 3:49 p.m.

308. In spite of the note stating the patient had no primary care or mental health provider, Dr. Hardison testified Patient 4 had both. Exhibit 3H, marked page 3676.

309. Dr. Hardison explained that by viewing ANS's electronic medical records it would have been easy for him to see the patient had both providers, unlike a review of the paper copies of the medical records by Dr. Jorrisch that were admitted into evidence

at the Board's hearings. EH 1, 11:58.

310. The hearing officer notes that at various times through the course of the administrative hearings, Dr. Hardison asserted that the Board did not have all of ANS's medical records for the patients at issue and that various missing records could be found in the "J-Section" of ANS's electronic patient records.

311. Dr. Jones reviewed the patient records at issue in this action, and although working part-time at ANS, he could not recall ever seeing the J-Section of notes for any of the patients at issue in this action. CH 8, 11:30 a.m.

312. There was no dispute at the administrative hearing that the Board subpoenaed all relevant patient records, that Dr. Hardison produced documents in response to the subpoena, and that he never previously asserted there were relevant but undisclosed patient records in ANS's electronic medical record system.

313. In addition, in spite of the hearing officer granting Dr. Hardison the opportunity during the course of the administrative hearing to produce such missing, but allegedly relevant patient records, no such documents were ever produced or offered into evidence.

314. Hence, the hearing officer gives no credence to Dr. Hardison's assertion that relevant documents, such as J-Section notes, had been prepared by him for patients and were available but undisclosed to the Board during the administrative hearing process.

315. On the next patient visit dated June 30, 2021, the patient note states Patient 4 "just started ANS program 2 weeks" and that "PT doing well other than

cravings. I will increase Suboxone to 2½ per day [20 mg]." Exhibit 3H, marked page 3685 and 3687.

316. Dr. Hardison conceded at the administrative hearing that at the previous patient visit, he had increased Patient 4's suboxone to 24 mg per day, and as a result, it was hard to know what the patient was prescribed and taking based on Dr. Hardison's patient records. Exhibit 3H, page 3678; EH 1, 12:01 p.m.

317. Throughout the course of the administrative hearing the Board highlighted the fact that a patient's vital signs remained the same for one office visit to another. EH 1, 12:00 and 12:05 p.m.

318. Dr. Hardison himself noted the unexpected consistency of some vital signs over the course of his treatment, and he stated the need to address that with staff, noting that with addiction, it's wise to check vital signs such as a patient's weight regularly. EH 1, 12:05 p.m.

319. The Board suggested the consistency over the course of multiple patient visits reflected an effort to fabricate patients' vital signs, but the hearing officer finds the consistency more likely indicates the clinic's habit of cutting and pasting previous records to the current one and reflects generally the lack of rigor and focus by the medical practice on having accurate and sufficient patient notes.

320. On two consecutive office visits Dr. Hardison stated Patient 4 had relapsed on meth, and on each occasion wrote "See above for details and plan of care," but there was no explanatory details or plan of care set forth anywhere in the patient note, which Dr. Hardison admitted "wasn't right." Exhibit 3H, marked pages 3809, 3811, 4045, and

4047; EH 1, 12:07 p.m.

321. Dr. Jorrisch noted that adequate documentation is especially critical in a medical practice such as Dr. Hardison's in which multiple providers can be treating the same patient and reviewing the record of care. EH 3, 9:57-9:58 a.m.

322. During a short office visit, the physician needs clarity as to what is happening with the patient in order to adequately treat the patient. EH 3, 9:58 a.m.

323. Dr. Hardison's patient notes simply did not meet that standard, and the preponderance of evidence supports the conclusion that Dr. Hardison's patient notes and medical records were simply inadequate for him, as well as for fellow healthcare professionals, for a clear understanding of the care and treatment being provided to patients.

324. The Board also alleges in the *Complaint* that Dr. Hardison violated the applicable ethical standards by treating his sister, Patient 11, with a sleep medication. *Complaint*, Paragraph 12, page 7; EH 3, 9:11 a.m..

325. Patient 11 has anxiety and insomnia, and Dr. Hardison prescribed her fifteen Lunesta tablets to treat those conditions. CH 1, 10:14 a.m.

326. It is undisputed that Dr. Hardison did not have a patient chart for Patient 11, that she was not a patient in his addiction practice, and that she did not have medical problems associated with addiction. EH 3, 10:40 a.m.

327. Dr. Hardison and his expert witness Dr. Jones acknowledged that prescribing to his sister the medication Lunesta, which was described as a generally safe, short-acting sleep medication, was not within the standard of care, and although

he had been prescribing the medication to her for two years, he stopped after being alerted to the ethical issue of prescribing to a family member. EH 2, 2:53-2:55 p.m; EH 3, 9:11 a.m.; Exhibit 1, marked page 790.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this action pursuant to KRS 311.591 and KRS 311.595.

2. The administrative hearing was conducted in accordance with the provisions of KRS Chapter 13B and KRS 311.591.

3. Under KRS 13B.090(7), the Board had the burden to prove by a preponderance of the evidence the allegations against Dr. Hardison.

4. The Board has met its burden to prove Dr. Hardison violated KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12).

5. Dr. Hardison violated the AMA Code of Medical Ethics Opinion 1.2.1 and KRS 311.595(9), as illustrated by KRS 311.597(4), by failing to create and maintain a record of his treatment for Patient 11 and by providing a controlled substance to her in circumstances that were not an emergency situation or in circumstances that addressed a short-term, minor problem.

6. The testimony and exhibits admitted into evidence at the administrative hearing support the conclusion that Dr. Hardison violated three of the Board's regulations governing the prescribing of controlled substances, and as a result his conduct violated KRS 311.595(9), as illustrated by KRS 311.597(4), by failing to conform to the standard of acceptable and prevailing medical practice in Kentucky, and he

violated KRS 311.595(12), by failing to comply with the standards set forth in the Board's regulations governing controlled substances.

7. Under 201 KAR 9:016, Section 6, a violation of the standards established in the regulation for the use of amphetamine and amphetamine-like anorectic controlled substances shall constitute a violation of KRS 311.595(9) and KRS 311.597.

8. Dr. Hardison violated 201 KAR 9:016, Section 3, by prescribing amphetamine and amphetamine-like controlled substances to treat medical conditions that are not included in Section 3(2)(a)-(f) of the regulation.

9. Under 201 KAR 9:260, Section 9, a violation of the standards established in the regulation for the prescribing of controlled substances shall constitute a violation of KRS 311.595(9) and (12).

10. Dr. Hardison violated 201 KAR 9:260, Section 2(1)(a)-(I), by failing to have adequate documentation to support the prescribing of controlled substances and violated Section 2(2) by failing to have adequate documentation to support and justify not complying with the professional standards for prescribing controlled substances, such as benzodiazepines and gabapentin.

11. Dr. Hardison violated 201 KAR 9:260, Section 2(2) by increasing doses of controlled substances without providing adequate justification for the increase.

12. Since the preponderance of the evidence supports the conclusion that Dr. Hardison failed to apply and follow all of the requirements of 201 KAR 9:016 and 201 KAR 9:260 for prescribing stimulants and other controlled substances, by his conduct he violated KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12).

13. The evidence showed that while Dr. Hardison complied with some of the guidelines and requirements in 201 KAR 9:270 for the prescribing of buprenorphine in the treatment of Opioid Use Disorder, the preponderance of the evidence shows he failed to apply and follow all of the requirements of Sections 2 and 4 of the regulation and failed to properly document in his medical records all of the relevant information related to his prescribing practices in sufficient detail to determine that he complied with the professional standards for administering the medication.

14. Dr. Hardison violated numerous provisions of 201 KAR 9:270, Sections 2 and 4, as set forth in the Findings of Fact above, including prescribing the mono product to patients who did not have a documented allergy to naloxone and continuing to prescribe the mono product to an individual even after their drug screen was positive for Suboxone without questioning the patient or documenting the need to continue prescribing the mono product.

15. Dr. Hardison failed to obtain a complete patient history and failed to obtain past treatment records, or failed to document efforts to obtain those records when treating a patient with buprenorphine as required by 201 KAR 9:270, Section 2(4)(a)(2)(b).

16. He failed to obtain COWS scores or to document the reason not to perform an in-office induction or document reasons why it wasn't performed as required by 201 KAR 9:270, Section 2(4)(c).

17. Dr. Hardison initiated induction at greater than 4 mg of buprenorphine and exceeded 16 mg on the first day of treatment in violation of 201 KAR 9:270, Section

2(4)(c)(3).

18. Dr. Hardison failed to initiate re-induction for patients who had a lapse in treatment in violation of 201 KAR 9:270, Section 2(4)(d).

19. Dr. Hardison violated 201 KAR 9:270, Section 2(4)(e)(5)(a), by failing to document abnormal KASPER findings and incorporating them into appropriate clinical reasoning to support continuation or modification of treatment.

20. Dr. Hardison violated 201 KAR 9:270, Section 2(4)(e)(5)(f)(ii), by failing to document abnormal drug tests and his clinical reasoning for continuing the treatment with controlled substances.

21. Dr. Hardison violated 201 KAR 9:270, Section 4(1) by failing to document in sufficient detail all relevant information to enable the Board to determine whether he has conformed to the professional standards for administering buprenorphine.

22. Dr. Hardison violated 201 KAR 9:270, Section 4(2), by failing to document his professional determination not to comply with the Board's standards in the regulation and failing to provide the facts in support of the deviation from the standard.

23. Under 201 KAR 9:270, Section 5, any violations of Sections 2, 3, ane 4 of the regulation "shall constitute" violations of KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12). Therefore, by his conduct, Dr. Hardison violated the 201 KAR 9:270, Sections 2 and 4, and violated KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12).

24. To the extent Dr. Hardison or his expert witnesses assert a violation of those regulations does not constitute a departure from or a failure to conform to the

standards of acceptable and prevailing medical practice in Kentucky in violation of KRS 311.595(9), as illustrated by KRS 311.597(4), such assertions carry no weight because they are contrary to the very language of the applicable regulations themselves.

25. In addition, the general credibility of the expert witnesses and the reliability of their opinions are greatly diminished and called into question when the expert offers opinions that are contrary to the provisions of the applicable regulations.

26. Dr. Hardison asserts that Dr. Jorrisch is not qualified to evaluate his medical practice because Dr. Jorrisch does not have the same psychiatric qualifications as Dr. Hardison as reflected by his certification in Addictionology through the American Board of Preventative Medicine.

27. The hearing officer finds Dr. Jorrisch was fully qualified to offer expert opinions on the care and treatment of patients with SUD, OUD, or StUD. In addition, Dr. Jorrisch is presumptively qualified under the provisions of 201 KAR 9:240, Section 5(5). The hearing officer finds that Dr. Jorrisch was fully qualified by background, training, and experience to conduct the review and to offer expert opinions on the issues in this action. His alleged lack of comparable expertise related mostly to Dr. Jorrisch's opinions on the necessity of Dr. Hardison referring patients to a higher level of psychiatric care when the patient was not compliant with the current treatment program. Dr. Jorrisch stated generally that such a referral was necessary because the care Dr. Hardison provided was not working, and Dr. Jorrisch has the training and expertise to know whether that was true and to offer his opinion on what needed to be done. In addition, there's been no evidence presented that Dr. Hardison was offering

psychiatric care to his patients that would constitute the necessary higher level of care. Irrespective of Dr. Hardison's qualifications and certifications, someone with a higher level of psychiatric expertise than his own was needed for a consultation regarding the patient's care, and Dr. Hardison's failure to refer those patients to a higher level of care was the basis for Dr. Jorrisch's opinion regarding a violation of the standard of care. Such an opinion was well within Dr. Jorrisch's expertise and appropriate for the hearing officer to consider in issuing this recommendation.

28. Dr. Hardison violated KRS 311.595(9), as illustrated by KRS 311.597(4), due to his failure to refer patients to a higher level of care and to a physician with more expertise when his treatment of patients for OUD and StUD who were having relapses and continuing to use illicit controlled substances and who had psychiatric conditions that required a higher level of expertise in light of the patients' lack of progress under Dr. Hardison's care for issues related to their addiction.

29. After the close of the proof at the administrative hearing Dr. Vincent filed in his case a motion to supplement the record and to dismiss the Board's *Complaint* action. *Motion to Supplement the Evidence and to Recommend Dismissal Based Upon Ongoing Developments in the Amendment of 201 KAR 9:270*. In light of the joint hearings on the *Complaint* actions against both Dr. Hardison and Dr. Vincent, the hearing officer will assume the motion applies to both licensees. Initially, the hearing officer notes he has no authority to set aside a Board regulation, and the allegations in this action go beyond the violations of a single regulation. In addition, all of the violations found in this action relate to the statutes and regulations that were in effect at

the time of the misconduct at issue in the case. Furthermore, to the extent Dr. Hardison asserts the standards for the care and treatment of patients addicted to controlled substances are "evolving" and that the current regulations are "out of step with current acceptable standards of practice," the Board's regulations allow a physician a degree of latitude in his care and treatment of patients outside the specific provisions of the applicable regulations, but the physician is required to document the reasons for acting outside the requirements of the regulation, which Dr. Hardison did not do. 201 KAR 9:260, Section 2(2); 201 KAR 9:270, Section 4(2). Hence, the assertion that somehow the licensees rights to due process have been violated by his failure to comply with the provisions of the regulation is without merit. At most, Dr. Hardison's assertion as to the evolving treatment of SUD set forth in the motion relate to the appropriate disciplinary action that the Board may take against the licensee for his violation of the Board's regulation. The licensee may raise that argument directly with the Board in his exceptions to this recommendation. There can be no question, however, that the licensee was in violation of multiple provisions of the applicable regulations, in addition to the requirement that he explain his reasoning for any deviations from the standards set forth in the regulations.

30. Based upon Dr. Vincent's prescribing practices for buprenorphine, stimulants, and benzodiazepines, the preponderance of the evidence supports the conclusion that and gabapentin violated KRS 311.595(9), as illustrated by KRS 311.597(4).

31. The preponderance of the evidence also supports the conclusion that Dr.

Hardison violated KRS 311.595(12) based upon his violation of more than one "valid regulation of the board," including 201 KAR 9:016, 201 KAR 9:260, and 201 KAR 9:270.

RECOMMENDED ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, the hearing officer recommends the Board find Dr. Barry G. Hardison in violation of KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311. 595(12), and for those violations, the hearing officer recommends the Board take any appropriate action against Dr. Hardison's license to practice medicine in Kentucky.

NOTICE OF EXCEPTION AND APPEAL RIGHTS

Pursuant to KRS 13B.110(4) a party has the right to file exceptions to this recommended decision:

> A copy of the hearing officer's recommended order shall also be sent to each party in the hearing and each party shall have fifteen (15) days from the date the recommended order is mailed within which to file exceptions to the recommendations with the agency head.

A party also has a right to appeal the Final Order of the agency pursuant to KRS 13B.140(1) which states:

> All final orders of an agency shall be subject to judicial review in accordance with the provisions of this chapter. A party shall institute an appeal by filing a petition in the Circuit Court of venue, as provided in the agency's enabling statutes, within thirty (30) days after the final order of the agency is mailed or delivered by personal service. If venue for appeal is not stated in the enabling statutes, a party may appeal to Franklin Circuit Court or the Circuit Court of the county in which the appealing party resides or operates a place of business. Copies of the petition shall be served by the petitioner upon the agency and all parties of record. The petition shall include the names and addresses of all parties

> to the proceeding and the agency involved, and a statement of the grounds on which the review is requested. The petition shall be accompanied by a copy of the final order.

Pursuant to KRS 23A.010(4), "Such review [by the circuit court] shall not constitute an appeal but an original action." Some courts have interpreted this language to mean that summons must be served upon filing an appeal in circuit court.

SO RECOMMENDED this 15th day of October, 2024.

Thomas J. Hellmann

THOMAS J. HELLMANN
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CERTIFICATE OF SERVICE

I hereby certify that this Recommended Order was sent by email this 15th day of October, 2024, to:

JILL LUN
KY BOARD OF MEDICAL LICENSURE
HURSTBOURNE OFFICE PARK STE 1B
310 WHITTINGTON PKWY
LOUISVILLE KY 40222

for filing; and a true copy was also sent by email on the same date to:

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