COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 2127-E

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 OVERTURNING EMERGENCY ORDER OF RESTRICTION

This action was instituted as the administrative appeal of Barry G. Hardison, M.D., from the *Emergency Order of Restriction* issued by the Kentucky Board of Medical Licensure [hereinafter "the Board"] against his license on October 24, 2023. Exhibit 1, Tab B. [Hereafter, the Board's order will be referred to as the "*Emergency Order*," and citations to the order will be to the numbered paragraphs and pages of the order without reference to Exhibit 1, Tab B]. In the *Emergency Order* the Board charged there is probable cause to believe Dr. Hardison violated two of the Board's statutes governing the practice of medicine and that his medical "practice constitutes a danger to the health, welfare and safety of his patients or the general public." *Emergency Order*, Conclusions of Law, Paragraphs 3 and 4, page 9. Based upon those allegations, the Board issued the *Emergency Order* restricting Dr. Hardison's license 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.

In the *Complaint* issued with the *Emergency Order* the Board charged Dr. Hardison with the same misconduct that served as the basis for issuance of the

Emergency Order and charged him with violating the same statutes governing the practice of medicine in Kentucky . Exhibit 1, Tab C.

Dr. Hardison filed a request for an administrative hearing pursuant to KRS 13B.125 to challenge the sufficiency of the *Emergency Order*. See letter from Dr. Hardison's counsel to Board counsel and to the Board's Executive Director that was filed in the record on February 7, 2024. The hearing officer conducted the administrative hearing over the course of four days in February and March 2024, and concluded the hearing with closing arguments on March 13, 2024. At the hearing Hon. Nicole A. King represented the Kentucky Board of Medical Licensure, and Hon. Ed Monarch and Hon. Katy Harvey represented Dr. Hardison, who also appeared at 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 separate patients, 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, the same Board consultant, Dr. Mark Jorrisch, reviewed the care and treatment at issue in both cases, arrived at substantially similar conclusions for both physicians, and drafted substantially similar reports for both physicians.

In November and December 2023 the hearing officer conducted the administrative hearing on the *Emergency Order of Restriction* issued against Dr. Vincent and filed the *Final Order* on December 22, 2023. Although finding that there was substantial evidence in the record that Dr. Vincent's prescribing practices violated the Board's statutes and regulations, the hearing officer found, consistent with Dr. Jorrisch's own findings and opinion, that Dr. Vincent's continued practice of medicine did not constitute "an immediate danger" to his patients and the general public if he refrained from prescribing controlled substances and implemented Dr. Jorrisch's recommendations during the pendency of the *Complaint* action. For that reason the hearing officer overturned the Board's emergency order against Dr. Vincent in Case No. 2128E, and the Board has not appealed that decision.

After considering the evidence admitted at the administrative hearing in this action and the arguments of counsel, the hearing officer finds there is 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*. KRS 13B.125(3) and KRS 311.592(1). There is not, however, substantial evidence in the record that his care and treatment of patients constitutes an immediate danger to the health, safety, or welfare of patients or the general public. That determination is based upon Dr. Jorrisch's findings and opinions and Dr. Hardison's agreement not to prescribe certain controlled substances pending resolution of the allegations in the *Complaint*. The hearing officer's determination is also based upon the assumption that pending the administrative hearing on the *Complaint*, Dr. Hardison will abide by his agreement to

correct the deficiencies in his medical practice and implement all the recommendations found in Dr. Jorrisch's report. Otherwise, Dr. Hardison's continued practice of medicine will constitute an immediate danger to patients and the general public. In support of his decision, the hearing officer submits the following Findings of Fact, Conclusions of Law, and Final Order:

FINDINGS OF FACT

1. On October 24, 2023, the Board issued the *Complaint* and *Emergency Order* that make identical factual allegations against Dr. Hardison in support of his alleged violations of 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. 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 . . . ."

3. 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."

4. Since the Board has regulations governing the prescribing of controlled substances generally, and buprenorphine in particular, the alleged statutory violations

focus largely on Dr. Hardison's prescribing practices. 201 KAR 9:260 and 201 KAR 9:270 respectively.

5. Unlike the action against Dr. Vincent, there is an additional allegation against Dr. Hardison that he prescribed a sleep medication to his sister, Patient 11, in violation of the Board's ethical standards. *Emergency Order*, Paragraph 12, page 7; Day III, 9:11 a.m. (The administrative hearing on the emergency order issued against Dr. Hardison was conducted over the course of four days, and citations to the recordings of the hearing will be to the sequential day of the hearing followed by the time stamp on the video recording.)

6. Dr. Hardison did not have a patient chart for his sister, but the undisputed testimony was that his sister was not a patient in his addiction practice, did not problems with addiction, and that Dr. Hardison stopped prescribing Lunesta, a generally safe, short-acting sleep medication, after the ethical issue of prescribing to a family member was called to his attention. Day II, 2:53-2:55 p.m; Day III, 9:11 a.m.

7. Although by providing a controlled substance to his sister was unethical under the circumstances, that issue does not appear to be independent basis for finding that Dr. Hardison's prescribing of controlled substances constitutes an immediate danger to his patients or the general public. Day III, 9:14 a.m.

8. The allegations of misconduct focus on Dr. Hardison's prescribing practices at A New Start, a medical practice in Central City, Kentucky, that specializes in the treatment of Opiate Use Disorder ("OUD") and Stimulant Use Disorder ("SUD"). *Emergency Order*, pages 2-7; Exhibit 1, marked pages 311-320, 466-491, and 509-591.

9. The evidence showed that Dr. Hardison generally followed the guidelines and requirements in 201 KAR 9:270 for prescribing buprenorphine for the treatment of OUD, but there is substantial evidence in the record that he has failed to rigorously apply the guidelines and their requirements and failed to properly document in his medical records all of the relevant information about his prescribing practices in sufficient detail to determine that he has complied with the professional standards for administering the medication. 201 KAR 9:270, Sections 4 and 5.

10. Dr. Hardison has been licensed to practice medicine in Kentucky since 1984, and practiced internal medicine for thirty-one years. Exhibit 1, marked page 405; Day I, 10:01 and 10:10 a.m.

11. In 2013 he started working at A New Start and became Board Certified in Addiction Medicine in 2018. Day I, 10:02-10:04 a.m.; Exhibit 1, marked page 406.

12. Dr. Hardison is board certified in addiction medicine, and the parties do not dispute that he is qualified and authorized to prescribe, dispense, or administer buprenorphine. Day I, 9:52 a.m.

13. Dr. Hardison is currently retired but hopes to open a primary care clinic with his ex-wife in Lawrenceburg, Kentucky, at which he will focus on behavioral health and treating patients with suboxone for OUD. Day I, 10:18 a.m.; Day III, 4:10-4:13 p.m.

14. A New Start has a specific organizational chart, several categories of specialists to assist patients, and various policies and procedures for the treatment of patients with an OUD. Exhibit 1, marked pages 372-387 and 466-491.

15. In addition, A New Start is certified by the Commission on Accreditation of Rehabilitation Facilities to provide outpatient treatment for substance use disorders in combination with mental health services for those patients. Exhibit 12.

16. There is no dispute that A New Start is not a "pill mill" but is a legitimate, fully operational opioid treatment facility that is well respected by officials in the local community. Exhibit 13.

17. Dr. Hardison saw on average twenty-eight patients per nine-hour work day at A New Start. Day I, 10:15 a.m.

18. Because there is substantial overlap regarding the allegations against Dr. Vincent and Dr. Hardison and since Dr. Vincent provided relevant testimony regarding the operation of A New Start and opioids' effect on the body, the hearing officer adopts from the *Final Order Overturning Emergency Order of Restriction* for Dr. Vincent, Findings of Fact No. 20-41, and 43-44 from that decision as general but relevant background to the allegations against Dr. Hardison. (The citations to the record for the adopted Findings of Fact from the *Emergency Order* for Dr. Vincent's case will be cited as "Vincent DVD.")

19. 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. Vincent DVD I, 11:32-11:34 a.m.

20. Because a person builds a tolerance to the drug, requiring increasing amounts for the same effect and to prevent going into withdrawal, opioids can cause respiratory suppression that results in death. Vincent DVD I, 11:34-11:36 a.m.

21. A New Start treats OUD by substituting buprenorphine for heroin or other opioids. Vincent DVD I, 11:32-11:34 a.m.

22. 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. Vincent DVD I, 11:34 and 11:41 a.m.; Vincent DVD II, 11:35-11:38 a.m.

23. Suboxone is a combination of buprenorphine and naloxone by which naloxone knocks the heroin off the receptors and block its effect, and the combined medication has a decreased likelihood of abuse. Vincent DVD I, 11:38-11:42 a.m.

24. Subutex is known as a mono product that consists only of buprenorphine and while still blocking the receptors, it gives a partial euphoric effect. Vincent DVD I, 11:41 a.m.

25. Thus, the mono product can be abused and is thereby subject to diversion, but the medication is not the drug of choice for persons with an OUD. Vincent DVD I, 11:41 a.m.

26. The standards for the prescribing of buprenorphine has been evolving in an effort to allow increased access to the medication for those with an opioid addiction. Vincent DVD I, 11:42-11:45 a.m.

27. Suboxone has an advantage over methadone because it is generally a safer medication and does not have the side effect of respiratory suppression. Vincent DVD I, 11:56-11:58 a.m.

28. Because methadone can be abused, it too is susceptible to diversion and is highly regulated. Vincent DVD I, 11:59 a.m. - 12:01 p.m.

29. Every new patient at A New Start has a urine drug screen and an evaluation to determine whether the person is in withdrawal, currently taking opioids or methadone, and is naive to buprenorphine. Vincent DVD III, 12:42-12:46 p.m.

30. Thus, the urine drug screen is performed for patient safety and to get baseline levels of medications since some medications can stay in the body for weeks. Vincent DVD III, 12:59 p.m.

31. Patients then undergo an "induction" at which they are given increasing doses of Suboxone as necessary in a controlled setting to establish the appropriate level of medication for treatment of their OUD. Vincent DVD III, 12:42-12:44 p.m.

32. If the patient is naive to suboxone, the induction takes place at A New Start, but if the person is not naive, he can undertake the induction in his own home. Vincent DVD III, 12:42 p.m. and 12:49-12:53 p.m.

33. 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 the medication in his body. Vincent DVD III, 12:54-12:57 p.m.

34. One of the issues in this action is whether Dr. Hardison performed a proper and adequate evaluation of patients prior to allowing them to perform the induction at home or whether the medical records simply fail to contain adequate or complete information. *Emergency Order*, page 4.

35. Persons with a stimulant use disorder differ from those with an opiate use disorder because the former is chasing the high rather than attempting to prevent

withdrawal. Vincent DVD I, 1:33-1:34 p.m.

36. SUD patients experience fatigue, lack of concentration, and difficulty completing tasks and will turn to illicit drugs to obtain symptom relief. Vincent DVD I, 1:38 p.m.

37. Thus, medications are not an effective tool for treating SUD, and therefore, therapy and twelve-step type programs are used for treatment. Vincent DVD I, 1:35 p.m.

38. Dr. Hardison 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. Day I, 9:52 a.m.

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

40. Hence, in his opinion the patients must be placed in a structured program, given low levels of Klonopin in place of the methamphetamine, and allowed time to develop new neural pathways for the production of dopamine in order to facilitate harm reduction to the patient. Id.

41. Persons with Attention Deficit Disorder and Attention Deficit Hyperactivity Disorder have symptoms similar to persons with a SUD. Vincent DVD I, 1:39 p.m.

42. Another issue in this action is whether Dr. Hardison has appropriately prescribed stimulants, benzodiazepines, and gabapentin to patients who have an OUD or SUD. *Emergency Order*, pages 6-7.

43. Affiliated with A New Start is the primary care practice, Care Now, that is located in the same building as A New Start. Vincent DVD I, 10:05-10:06 a.m.

44. Care Now was established for patients of A New Start to have a primary care facility available to treat their other healthcare needs, including mental health issues. Vincent DVD I, 10:05-10:06 a.m.

45. The Board initiated an investigation of Dr. Hardison in response to concerns expressed to the Board by a Social Services Clinician with the Kentucky Department of Corrections who noted an increase in the number of her clients who had been treated at the clinic. Exhibit 1, marked page 314.

46. In response and 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 contained the concerns found by the Inspector General's Office. Exhibit 1, marked pages 310-320.

47. The Board obtain copies of medical records for the fifteen patients other than Dr. Hardison's sister from A New Start and provided them to Dr. Jorrisch, who reviewed the records and found deviations from the standards of acceptable and prevailing medical practices in the care and treatment of those patients. Exhibit 1, marked pages 310-311 and 509-591.

48. Dr. Jorrisch has been a consultant with the Board since 2005, and at the administrative hearing he was qualified as an expert in medicine generally and in Addiction Medicine specifically. Day III, 9:06 a.m.; Exhibit 15.

49. Dr. Jorrisch and Dr. Hardison treat similar patient populations. Day III, 11:30 a.m.

50. For each of the fifteen patients whose care he reviewed other than Dr. Hardison's sister, Dr. Jorrisch prepared an "Expert Review Worksheet" that is provided by the Board to its consultants in order to generally address whether the diagnosis, treatment, and records for the patient met minimum standards, and Dr. Jorrisch attached an extensive narrative for each patient explaining the basis for his opinions related to the three categories. Exhibit 1, marked pages 509-591.

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

52. All of the fifteen patients had been treated by Dr. Hardison for OUD and/or SUD and had various other medical and health conditions. Exhibit 1, marked pages 509-591.

53. 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. Exhibit 1, marked pages 509-515.

54. The hearing officer notes that the findings and conclusions contained in Dr. Jorrisch's multi-page cover letter to his report is substantially identical both in format and content to the report he prepared for Dr. Vincent's medical practice.

55. Hence, Dr. Jorrisch's concerns related to the care and treatment provided by Dr. Hardison for his patients are the same as those expressed for those provided by Dr. Vincent, which were addressed in the hearing officer's Final Order for the emergency order issued in that case.

56. The hearing officer isn't suggesting, however, that Dr. Jorrisch failed to perform a rigorous and detailed review of each physician's care and treatment of their patients. His Expert Review Worksheet for each patient shows the exact opposite. Dr. Jorrisch's findings, conclusions, and opinions show deficiencies in the medical practice's "team approach" to the care and treatment of patients with OUD and SUD as reflected in the medical records for both Dr. Vincent and Dr. Hardison. Exhibit 1, marked page 510.

57. Dr. Jorrisch found that Dr. Hardison's medical care for the patients at issue in this action fell below minimum standards for the diagnosis of nine patients and for treatment and records of fourteen patients. Exhibit 1, marked pages 509-591.

58. Dr. Jorrisch's "overall opinion" for fourteen patients was that Dr. Hardison's care and treatment was "clearly below minimum standards." Id.

59. Dr. Jorrisch found that Dr. Hardison met the minimum standards for the diagnosis, treatment, and records for only one patient, and the "overall opinion" for that patient's care was "borderline." Exhibit 1, marked pages 588-591.

60. Although Dr. Jorrisch found several deficiencies in Dr. Hardison's addiction medicine practice, he never suggested in his report or in his testimony that the 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.

61. In his cover letter under the category of "Prescribing," Dr. Jorrisch found the medications Dr. Hardison prescribed were "excessive under accepted and prevailing medical practice standards." Exhibit 1, marked page 509.

62. Dr. Jorrisch also found under that category, as well as under the categories in his cover letter of "Substandard Care" and "Medical Necessity," that Dr. Hardison "engaged in conduct which departs from or fails to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky" and that his medical practice "constitute[s] a danger to the health, welfare, and safety of the physician's patients and the general public." Id, marked pages 509-510.

63. Dr. Jorrisch's concerns extended to Dr. Hardison's treating with stimulants patients diagnosed with Attention Deficit Hyperactivity Disorder, treating with benzodiazepines patients's diagnosed with a substance use disorder, and prescribing promethazine, hydroxyzine, gabapentin to patients with an OUD since those medications are often misused by such patients. Id., marked page 514-515.

64. In spite of Dr. Hardison's assertions to the contrary and studies cited by him that allegedly supported the use of stimulants for treatment of an SUD, 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.

65. Dr. Jorrisch identified several other specific practices that fell below the applicable standards, including the failure to obtain a complete history, the patient's

past medical records, or past treatment history for OUD; failure to follow the appropriate protocol to initiate treatment for an OUD; failure to set forth for all patient visits "the actual conclusion and plan of action, particularly for struggling patients;" failure to provide a complete history of present illness; failure to identify alcohol use by patients; failure to address drug screens that were inconsistent with the prescribed medications; failure to adequately address mental health concerns; and failure to address non-opiate related medical issues revealed through examination or testing. Id, marked pages 512-515.

66. 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.

67. Dr. Jorrisch summarized his findings and conclusions 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.

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

69. In addition, Dr. Hardison provided opinions from two addiction medicine specialists, Dr. Roger Starner Jones and Dr. James Patrick Murphy, who found Dr. Hardison's practice of medicine to fall within the applicable standards. Exhibit 1, marked pages 607-623 and 734-782.

70. Dr. Jorrisch provided two written responses to the information provided by Dr. Hardison, and Dr. Jorrisch reported in both that his opinions had not changed as a result of that additional information. Exhibit 1, marked pages 1146-1151.

71. By agreement of the parties, testimony at the administrative hearing focused on four patients whose care and treatment he reviewed, Patients 4, 5, 6, and 10, as a representative sample of the types of deficiencies and concerns found by Dr. Jorrisch for fifteen patients treated for OUD and SUD.

72. The parties also provided testimony on Dr. Hardison's sister, Patient 11, who, as stated previously, not treated for a substance use disorder.

73. At the administrative hearing Dr. Hardison acknowledged many of the deficiencies found by Dr. Jorrisch in the record keeping for his patients. See e.g., Day 1, 4:04-4:06 p.m.

74. Dr. Hardison noted that the record keeping system and practices have improved substantially from 2017 and 2018. Day II, 9:40-9:42 a.m.

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

76. Dr. Hardison asserted that he has provided excellent care to his patients and has never had a patient overdose in his ten years of treating addiction. Day II, 2:35-2:36 p.m.

77. In addition, many patients such as Patient 5 were doing well in their recovery for OUD, although she was struggling with her recovery from SUD. Day I, 3:37 p.m.

78. Dr. Hardison reported that half of the sixteen patients whose care was reviewed by Dr. Jorrisch are sober and have jobs. Day II, 3:16 and 3:19 p.m.

79. Even though Dr. Hardison asserted that his patient care met the applicable standards and provided evidence to support his position, that evidence did not overcome or call into question the fact there is substantial evidence in support of Dr. Jorrisch's findings and opinions.

80. Dr. Jorrisch asserted 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. Day III, 9:57-9:58 a.m.

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

82. Dr. Jorrisch presented in his testimony an overview of some of the deficiencies found in his report regarding Dr. Hardison's medical practice and management of the patients' OUD and SUD.

83. He found that Dr. Hardison had inadequate documentation regarding the patient's past use of buprenorphine to justify the induction process utilized for the

patient, including the initial dose and escalation of the dosage. Day III, 9:15-9:20 a.m.

84. Dr. Hardison failed to adequately address diluted urine drug screens. Day III, 9:24 a.m.

85. 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. Day III, 9:28-9:30 a.m.

86. Dr. Jorrisch found that Dr. Hardison prescribed stimulants to ADHD patients without a proper diagnosis and often did so based upon their own assertion as suffering from that condition, which Dr. Jorrisch asserted, "just doesn't cut it" for making a diagnosis. Day III, 9:31 a.m.

87. While acknowledging that stimulants are the best available treatment for ADHD, those medications carry a higher level of concern for a patient with a substance use disorder. Day III, 9:31 a.m.

88. Dr. Hardison, however, frequently prescribed stimulant medications without a proper, secure diagnosis, which Dr. Jorrisch characterized as "dangerous" for a patient with a SUD. Day III, 9:32 a.m.

89. Dr. Jorrisch also had concerns with Dr. Hardison's benzodiazepine prescriptions for patients with a diagnosis of a SUD or hypnotic use disorder, and although such medications may be appropriate in some circumstances, Dr. Hardison did not have a clear diagnosis, did not start with safer medications, did not refer such patients to a psychiatrist as required by the standard of care. Day III, 9:33-9:34 a.m.

90. Dr. Jorrisch had further concerns regarding Dr. Hardison's prescriptions for gabapentin. Day III, 9:35-9:36 a.m.

91. Gabapentin is often misused by individuals with OUD, and although the medication is approved for specific uses, it is not approved for the treatment of pain, anxiety, and other mental health issues. Day III, 9:35-9:36 a.m.

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

93. Dr. Jorrisch noted that currently there is not good support for the use of medications for the treatment of SUD, and the danger to the patient already suffering from a SUD is always highlighted in the studies that advocate for the use of those medications. Day III, 9:40 a.m.

94. Dr. Jorrisch testified consistently with the information provided in his report for his specific concerns with the care provided to Patients 4, 5, 6, and 10. Exhibit 1, marked pages 533, 538, 543, and 563.

95. Hence, considering Dr. Jorrisch's reports and testimony in light of the information and testimony provided by Dr. Hardison, there is credible and substantial evidence in the record that Dr. Hardison violated KRS 311.595, as illustrated by KRS 311.597(4).

96. Since Dr. Jorrisch's report and the evidence presented at the administrative hearing focused on whether Dr. Hardison violated the standards of acceptable and prevailing medical practice in Kentucky, rather than on violations of the specific provisions of 201 KAR 9:260 or 201 KAR 9:270, the hearing officer will not address specific violations of those regulations in this order. Day III, 11:39-11:40 a.m.

97. In the cover letter to his report for each of the categories of "Prescribing," Substandard Care," and "Medical Necessity," Dr. Jorrisch asserted that Dr. Hardison's medical "practice constitutes a danger to the health, welfare, and safety of the physician's patients and general public." Exhibit 1, marked pages 509-510.

98. In response to the question in the Expert Review Worksheet for each patient, however, that asks the reviewing physician whether any violations of the standards of acceptable practice constitutes an "imminent" danger requiring the Board to restrict or suspend the physician's license or whether the violations "may be addressed by the Board in an orderly process" through remedial education, training, and monitoring, Dr. Jorrisch left that section blank. See e.g., Exhibit 1, marked pages 534-535.

99. At the administrative hearing Dr. Jorrisch stated that Dr. Hardison's medical practice was not an "imminent danger" to his patients or the general public. Day III, 11:43-11:44 a.m.; KRS 13B.125, KRS 311.592(1).

100. If he had identified an immediate danger in Dr. Hardison's medical practice through the review of his records, Dr. Jorrisch would have reported that danger to the Board, but he did not find such a danger. Day III, 2:00 p.m.

101. Instead, Dr. Jorrisch stated that his concerns could be addressed in an "orderly" process as referenced in the worksheets, but he also testified that he would not be surprised to hear that any the patients at issue in this action had died. Day III, 11:43 a.m. and 1:59-2:00 p.m.

102. The orderly process for addressing Dr. Jorrisch's concerns and to avoid being a danger to patients is for Dr. Hardison to implement in his medical practice the changes set forth in the Dr. Jorrisch's report and worksheets for the patients at issue in this action. Day III, 2:09 p.m.; Exhibit 1, marked pages 512-515, and the individual patient worksheets, marked pages 516-590.

103. For Patient 4 the changes include, among other listed requirements, clear and complete documentation in his notes, alternative medications for anxiety disorder, not prescribing benzodiazepines, not prescribing stimulants for SUD, and paying attention to the patients other medical conditions and issues not directly related to the person's OUD or SUD. Exhibit 1, marked page 534; Day III, 2:10-2:12 p.m.

104. If Dr. Hardison opens his own medical practice he must implement Dr. Jorrisch's recommendations in order not to be a danger to his patients or the public. Day 3, 2:12 p.m.

105. In addition, for any employees of the clinic that Dr. Hardison will oversee as the licensed professional for the facility, he must make the final decision on the prescribing of controlled substances and "squelch" any mis-prescribing. Day III, 2:12 p.m.

106. Thus, assuming Dr. Jorrisch's recommendations are implemented by Dr. Hardison pending the administrative hearing on the *Complaint*, Dr. Jorrisch asserted Dr. Hardison's practice will not be an immediate danger to his patients or the general public. Day III, 2:09-2:12 p.m.

107. In essence, Dr. Jorrisch's recommendations represent a more rigorous and complete application of the standards and regulations for record-keeping and for the prescribing of controlled substances and do not reflect a lack of knowledge on the standards for prescribing controlled substances or an unwillingness or inability by Dr. Hardison to follow the applicable standards.

108. Pending the resolution of the allegations in the *Complaint*, Dr. Hardison agreed at the administrative hearing that neither he nor any other prescribers in his practice will prescribe benzodiazepines, gabapentin, and stimulant medications, including Adderall and Ritalin. Day III, 3:59-4:00 and 4:03 p.m.

109. The only exception will be mental health nurse practitioners who can prescribe stimulants for ADHD to patients, but instead, Dr. Hardison agreed those practitioners will not prescribe to any patients with a stimulant use disorder. Day III, 4:08 and 4:12 p.m.

110. Furthermore, Dr. Hardison agreed to incorporate Dr. Jorrisch's recommendations for improvements in his documentation and record keeping in his medical practice, including appropriate histories and physicals and the specific requirements of the Board's administrative regulations. Day III, 4:01 p.m.

111. He also agreed in accordance with Dr. Jorrisch's recommendation to refer patients to a higher level of care when appropriate and will document that fact irrespective of whether the patients follow through with the recommendation. Day III, 4:02 p.m.

112. After the Board restricted his license, Dr. Hardison attended the Vanderbilt University Medical Center's professional development course on August 16-18, 2023 titled *Proper Prescribing of Controlled Substances*, and presumably the course materials are consistent with Dr. Jorrisch's recommendations. Exhibit 18; Day II, 2:30 p.m.

113. Dr. Hardison shall incorporate into his practice the guidance and information obtained through the Vanderbilt professional development course and each of the recommendations set forth in Dr. Jorrisch's cover letter and his worksheets for the individual patients at issue in this action in order to verify that he is following the standards of acceptable and prevailing medical practice in Kentucky.

CONCLUSIONS OF LAW

1. The Board issued the *Emergency Order* pursuant to KRS 311.592(1), which authorizes the Board to issue an emergency order "suspending, limiting, or restricting" a physician's license when there is "probable cause to believe that . . . a physician's practice constitutes a danger to the health, welfare, and safety of his patients or the general public . . . ."

2. Pursuant to that same statute, the administrative hearing on the emergency order was conducted in accordance with the provisions of KRS 13B.125.

3. Under KRS 13B.125(3), "the emergency order shall be affirmed if there is substantial evidence of a violation of law which constitutes an immediate danger to the public health, safety, or welfare."

4. For purposes of the emergency hearing, "the findings of fact in the emergency order shall constitute a rebuttable presumption of substantial evidence of a violation of law that constitutes immediate danger to the health, welfare, or safety of patients or the general public." KRS 311.592(2).

5. Thus, applying the provisions of KRS 13B.125 and KRS 311.592 in conjunction with KRS 13B.090(7), the Board had the burden to prove there is substantial evidence of a violation of law and that the violation constitutes an immediate danger.

6. "Substantial evidence" is defined as "evidence of substance and relevant consequence, having the fitness to induce conviction in the minds of reasonable men." *Kentucky State Racing Commission v. Fuller*, 481 S.W.2d 298, 308 (Ky. 1972), *quoting O'Nan v. Ecklar Moore Express, Inc.*, 339 S.W.2d 466 (Ky. 1960).

7. Furthermore, "[t]he test of substantiality of evidence is whether when taken alone or in the light of all the evidence it has sufficient probative value to induce conviction in the minds of reasonable men." *Fuller*, 481 S.W.2d at 308.

8. Stated another way, substantial evidence is "evidence that a reasonable mind would accept as adequate to support a conclusion." *Black's Law Dictionary*, 7th ed., p. 580. In addition, "if there is substantial evidence in the record to support an agency's findings, the findings will be upheld, even though there may be conflicting evidence in the record." *Kentucky Commission on Human Rights v. Fraser*, 625 S.W.2d 852, 856 (Ky. 1981).

9. The Board has met its burden to prove there is substantial evidence in the record that Dr. Hardison is in violation of KRS 311.595(9), as illustrated by KRS 311.597(4).

10. Dr. Jorrisch presented numerous examples in Exhibit 1, marked pages 509-590, and through his testimony at the administrative hearing, to support the conclusion that Dr. Hardison's medical practice violates the standard of acceptable and prevailing medical practice in Kentucky.

11. Based upon that evidence, there is substantial evidence in the record that Dr. Hardison did not properly initiate induction dosing at the time of treatment, failed to have clear and complete prescribing notes, failed to properly diagnose ADHD, improperly prescribed stimulants, benzodiazepines, and gabapentin to patients with substance use disorders and stimulant use disorders, failed to have adequate consultation and coordination with psychiatrists, and failed to properly utilize referrals for mental health treatment and for higher levels of care for patients.

12. Although Dr. Hardison and his expert witnesses disagreed with Dr. Jorrisch's findings, conclusions, and professional opinions, none of that evidence called into question the substantial nature of the evidence in support of Dr. Jorrisch's opinions.

13. Therefore, there is substantial evidence in the record to support a violation of KRS 311.595(9), as illustrated by KRS 311.597(4), due to Dr. Hardison's "departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky."

14. Although there is substantial evidence of the violation of KRS 311.595(9), as illustrated by KRS 311.597(4), there is not substantial evidence in the record that Dr. Hardison's practice of medicine "constitutes an immediate danger to the public health, safety, or welfare" as required by KRS 13B.125(3) to affirm the emergency order.

15. That determination is based upon the testimony of Dr. Jorrisch and upon the representation by Dr. Hardison that he will not prescribe stimulants, benzodiazepines, or gabapentin during the pendency of the *Complaint* action.

16. If Dr. Hardison prescribes stimulants, benzodiazepines, and gabapentin or if he fails to incorporate Dr. Jorrisch's recommendations into his practice of medicine during the pendency of the *Complaint* action, that will represent an immediate danger to Dr. Hardison's patients and to the public health, safety, and welfare as set forth in KRS 13B.125(3) and KRS 311.592(1).

17. Although under KRS 311.592(2) the emergency order shall constitute a rebuttable presumption of an immediate danger, the testimony of Dr. Jorrisch overcame that presumption since as the Board's consultant and expert witness, he did not find an immediate danger, and the Board did not make any additional findings in the *Emergency Order* that would suggest they relied upon anything other than Dr. Jorrisch's own opinion in arriving at that determination.

FINAL ORDER

Based upon the foregoing, the hearing officer overturns the Board's *Emergency Order of Restriction* issued against the license of Barry G. Hardison, M.D., on October 24, 2023. There is substantial evidence in the record to support the Board's

determination that Dr. Hardison engaged in conduct in violation of KRS 311.595(9), as illustrated by KRS 311.597(4), but there is not substantial evidence in the record that his continued practice of medicine constitutes an immediate danger to his patients or the public health, safety, or welfare if he refrains from prescribing stimulants, benzodiazepines, and gabapentin and implements the recommendations of Dr. Mark Jorrisch as set forth in his report.

NOTICE OF APPEAL RIGHTS

Pursuant to KRS 13B.125(4), this Final Order may be appealed pursuant to KRS 13B.140(1). That subsection of the statute 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 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 a summons also be served upon filing an appeal in circuit court.

SO ORDERED this 20th day of March 2024.

THOMAS J. HELLMANN
HEARING OFFICER
810 HICKMAN HILL RD
FRANKFORT KY 40601
(502) 330-7338
thellmann@mac.com

CERTIFICATE OF SERVICE

I hereby certify that the original of this FINAL ORDER was mailed this 20th day of March, 2024, by first-class mail, postage prepaid, to:

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

for filing; and pursuant to the parties' agreement to waive service of the Final Order by certified mail, a true copy was sent by email and by first-class mail, postage prepaid, on March _____, 2024, to:

NICOLE KING
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