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

COMPLAINT

Comes now the Complainant, Chair of the Kentucky Board of Medical Licensure's Inquiry Panel A, and on behalf of the Panel which met on October 19, 2023, states for its Complaint against the licensee, Barry G. Hardison, M.D., as follows:

1. At all relevant times, Barry G. Hardison, M.D. ("the licensee"), was licensed by the Board to practice medicine within the Commonwealth of Kentucky.
2. The licensee's medical specialty is addiction medicine.
3. On or about April 19, 2022, a Social Service Clinician with the Kentucky Department of Corrections contacted the Kentucky Board of Medical Licensure ("the Board") and expressed concern about the prescribing practices at a clinic named A New Start ("ANS") located in Central City, Kentucky. The grievant stated substantially as follows: the licensee is one of the primary prescribers at ANS; the grievant began to see an increase in clients with whom she counseled who were patients at ANS; clients shared with her about their addiction treatment at ANS and some reported being prescribed four to six different drugs from the clinic; one client stated that he was receiving suboxone as treatment for marijuana use; and although the grievant has subsequently been transferred to the Barren River Region, which includes Bowling Green, she still has some clients request to go to ANS in Central City instead of using the local clinics in Bowling Green.

4. The Board's investigator made a request to the Cabinet for Health and Family Services, Office of Inspector General ("OIG") for a review of the KASPER records for the licensee for the date range of May 3, 2021 through May 3, 2022.

5. On or around September 30, 2022, OIG Investigator, Laura Wells, PharmD., R.Ph., issued a report on the licensee's KASPER records she reviewed and analyzed. She noted several patterns of concern, including:

    - Multiple patients appear to be receiving high doses and/or large quantities of controlled substance(s);
    - A large portion of patients appear to be receiving buprenorphine products in combination with other controlled substances (such as: stimulants, benzodiazepines, gabapentin);
    - Multiple patients appear to be receiving buprenorphine mono-product, which may/may not be prescribed in accordance with 201 KAR 9:270;
    - Based on KASPER data and data from the Kentucky Birth Index File, it appears Dr. Hardison may be prescribing to a family member; and
    - Based on KASPER data and employee names provided on the practice website, it appears that Dr. Hardison may be prescribing buprenorphine products and/or other controlled substances to other providers and staff in the practice, which may/may not be appropriate.

6. The OIG Investigative Report included Medicaid/Billing Considerations for the licensee and Ms. Wells found:

    > [...] There were multiple dates when Dr. Hardison appeared to prescribe to more than 40 – 50 unique patients per day. Within the date range evaluated, he appeared to prescribe to the most unique patients on 11/17/2021, when he appeared to prescribe to approximately 56 unique patients. A referral will be made to the CHFS OIG MPI Branch for any necessary evaluation.

7. The OIG Investigative Report included a Personal Use KASPER report for the licensee and Ms. Wells found:

    > Dr. Hardison appears to receive prescriptions for multiple controlled substances, including prescriptions for a medication indicated for the treatment of opioid use disorder. The combination of controlled substances prescribed to Dr. Hardison appears to be similar to the combinations he

prescribes patients. There was no indication on the KASPER report of Dr. Hardison self-prescribing controlled substances; however, the report revealed Dr. Hardison received his personal controlled substance prescriptions from multiple colleagues in his practice.

8. Ms. Wells identified sixteen (16) patients illustrative of some of the above noted concerns. The patient charts were subpoenaed from the licensee and provided to a Board Consultant for review.

9. In or around November 2022, the Board received correspondence from counsel for the licensee, "supplementing" the medical records that had been requested via subpoena, and stating substantially as follows: The licensee disagrees with the OIG investigative report. However, the licensee did recognize that prescribing for his sister was "not ideal" yet maintained he was "comfortable doing so because he knew her history."

10. A Board Consultant conducted a detailed review of each patient chart selected by the OIG, as well as reviewing the OIG Investigative Report and the licensee's letters and attachments dated November 11, 2022 and November 14, 2022. Of the sixteen (16) patient charts reviewed, the Board Consultant found that the licensee deviated from acceptable and prevailing medical practices in fifteen (15). In sum, the Board Consultant came to the following conclusions,

> Patients were admitted to treatment for the primary diagnosis of OUD. Intake did appear to include the elements of History (HPI, PMH, PPH, ROS), psychosocial history, physical exam, laboratory screens. It was not clear that all of these were obtained prior to first prescription. Proper consents and education were a part of the record. Lacking was a clear indication of past treatment episodes especially as it would necessitate differentiation of new patients, patients transitioning to a new prescriber, transfers, patients who have experienced past treatment with buprenorphine. Past medical records were not obtained or reviewed. Kasper reports did not regularly identify continued treatment without a break to justify initial higher doses of buprenorphine. Simply identifying familiarity with buprenorphine does not justify admission without induction and at higher doses.

Induction dosing was not seen. Patients were routinely admitted, treated with 16-24 mgs. buprenorphine on first day not meeting Kentucky standards. As well it was not clear that COWS [Clinical Opiate Withdrawal Scales] evaluation occurred for all patients and for some COWS did not show moderate to severe [withdrawal]. Patients would then be at risk for precipitated withdrawal on first dose of buprenorphine. Patients were usually seen at intervals identified in the Kentucky Standards although this was inconsistent.

Dosing of buprenorphine included use of buprenorphine mono product without clear identification of requirements necessitating its use. Doses were typically greater than 16 mgs. without clear rationale. Patients remained in extended treatment without efforts to adjust dose to more acceptable levels.

The medical record (EMR) was in general excessive, repetitive, conflictual and difficult to follow. Particularly in earlier years the EMR repeated much information gathered earlier in treatment but did not seem to change through a patient's course suggesting there was little attempt to update. Medication identification in each visit was incomplete as it did not regularly identify all medications a patient was taking. Problem lists were incomplete with an initial problem list not showing all identified problems and a later problem list (assessment of visit) not clearly matching even the incomplete list. Prescriptions written were not a part of the EMR (typically showed RX for buprenorphine but not for other medications provided by the practitioner).

Comments referring to tobacco use as 'under construction', to physical as 'was non focal' were confusing. Documentation of VS's [vital signs] created some questions as these reflected nursing notes which of their own showed limited variability and the question of not actually being measured at each visit. Comment of 'failed two consecutive tapers' was inconsistent through any chart and if taper had actually occurred documentation was lacking. Information regarding the DS review process and results was excessive and unnecessary. Construction of a visit note varied from practitioner to practitioner and varied from note to note creating confusion.

Of considerable concern was the ability to discern from any patient visit the actual conclusion and plan of action particularly for struggling patients. As stated RX's provided were not clear, changes in prescribed medications (new or eliminated) were not clear, changes in dosing were not clear.

HPI provided by Dr. Hardison was typically present but was often incomplete as it did not reflect important patient information visit to visit (e.g. RX change, other practitioner visits and interventions). ROS [review of symptoms] and physical exams, particularly during the earlier years showed a complete review and assessment which suggests very extended visits. This changed in later years where this information was much more limited suggesting less lengthy visits.

Drug screens ("DS") were obtained routinely, including POC screens and then definitive testing. DS results were often not added to the EMR (POC not reviewed) and frequently did not accurately reflect true results. Diluted specimens were not addressed. DS's buprenorphine or norbuprenorphine absent required more serious intervention then was reflected in the EMR. OS's absent for prescribed medications often seen with BZD RX, zolpidem, gabapentin required a more intensive intervention. DS's showing evidence of two BZD's or of a BZD different from that prescribed required more intensive intervention.

Attention to comorbid medical issues was quite limited. Routine laboratory reviews occurred at least annually. However abnormal findings were not incorporated into treatment plans and basically ignored. Significant was lack of attending to HCV [Hepatitis C] positive. A patient with repeatedly elevated calcium had no intervention. A patient with repeatedly elevated BS's was not directed to management. Anemia was identified but not addressed. It was difficult to discern routine attention to tobacco use. It appears that patients were regularly asked about their PCP visits but there was no attention to motivating patients to routine visits or even to more urgent visits to address these problems.

The same issues occurred with MH [mental health] treatment. It appears that referrals were made and some patients did see a MH APRN (it is suggested this APRN had some association with ANS). I could find no exchange of information from this APRN to Dr. Hardison. At times RX's for psychotropics were initiated by, or adopted by, or stopped by the APRN. Some were initiated by or then adopted by Dr. Hardison. Unfortunately, as I have concerns about the prescribing routines of Dr. Hardison, it appears that this APRN was inappropriate in his/her prescribing. Discussion re. approaches to patients did not occur between Hardison and APRN. Considering the significant MH issues that many of these patients faced, this communication would be necessary and consideration of referrals to other MH resources were to be considered.

[...]

Kasper reports were routinely obtained and it appears they were reviewed. Of concern is that in several cases RX's appeared on the Kasper report from practitioners outside of ANS that would directly impact patient treatment. Although these may have been appropriate it was incumbent on Hardison to identify the RX', address with patients, and discuss with the prescribers. I see no documentation that this process occurred.

Of critical concern were the prescribing habits and routines of Dr. Hardison. For patients with a diagnosis of Substance Use Disorder the use of any potentially addicting substance carries risk. Of course there may be comorbid medical problems that would necessitate the use of such medications but this should be carefully and clearly investigated and then followed closely. If there is then evidence of a patient misusing prescribed

medications, using other medications or substances with the prescribed medication, possible diverting the prescribed medication the continued prescription should be avoided. As well alternative approaches to using mood altering, potentially addicting medications exist and these should be exhausted before prescribing the medication.

[...]

Medications such as antiemetics (promethazine), antihistamines (hydroxyzine), and gabapentin are known to often be misused by patients with OUD. Use of these medications by Dr. Hardison in some patients did not show clear rationale and carried inherent dangers. In particular gabapentin, a controlled substance, is widely misused, dangerous with its sedative properties, and notably misused in patients with OUD. Its prescription by Dr. Hardison in his patients necessitated clear rationale for an FDA approved purpose to be acceptable.

As a final conclusion I see Dr. Hardison's practice 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.

11. In reviewing the published articles submitted by the licensee under cover of letter dated November 11, 2022, the Board Consultant substantially stated,

> To conclude these studies looked for the most part at use of Methylphenidate, sustained release formulations, were limited studies, have not been replicated, and do not come close to showing any conclusive evidence for treating stimulant use disorders with stimulants. To the contrary of the conclusions of Dr. Hardison and [his counsel] "incorporation of ADHD medications into the treatment program for patients suffering from an addiction to stimulants such as cocaine and methamphetamine has proved successful" and that "the accepted treatment of patients experiencing a meth addiction includes prescribing of medications used for ADHD treatment" carries little support and is inaccurate. Treatment of Stimulant Use Disorder continues to be a purely behavioral approach albeit difficult and with limited success.
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> [...]
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> This practice is definitely not an accepted approach by leaders in the addiction field nor in this community. His use as well showed little to no success for his patients mostly evidenced by misuse of the medication and continued illicit stimulant use.

12. The Board Consultant also briefly addressed the issue regarding the licensee prescribing to his sister. He opined that regardless of adequate record keeping, the practice of prescribing for self or family members is considered unethical and to be avoided.

13. The Board Consultant's report, including review worksheets, is adopted and incorporated herewith in its entirety by reference.

14. On or about May 24, 2023, the licensee, through counsel, responded to the Board Consultant's report by letter. He provided more literature as well as reviews by Patrick Murphy, M.D., Starner Jones, M.D. and Jeffrey Segal, J.D., M.D., which he retained who support his practice of medicine. The licensee also provided certification that he completed the Vanderbilt University course, Prescribing Controlled Drugs.

15. The Board Consultant reviewed and considered the licensee's response of May 24, 2023 and stated that the information provided did not change his findings about the licensee's practices, specifically those related to elements of diagnosis, treatment, and documentation.

16. On or about August 11, 2023, the licensee further supplemented his May 24, 2023 response and included several more attachments.

17. The Board Consultant also reviewed and considered the licensee's August 11, 2023 supplementation and again found that the information provided did not change his findings.

18. On October 19, 2023, the licensee appeared before Panel A, with counsel, and stated substantially as follows: he quit working at ANS in December 2022 and he

is currently not practicing but plans to open a clinic with his ex-wife, a Nurse Practitioner.

19. Simultaneous with this Complaint and in accordance with KRS 311.592, the Chair of the Board's Inquiry Panel A authorized the issuance of an emergency order of restriction pursuant to which licensee will become prohibited from prescribing, dispensing or otherwise professional utilizing controlled substances in the Commonwealth of Kentucky pending resolution of this Complaint.

20. By his conduct, the licensee has violated KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(12). Accordingly, legal grounds exist for disciplinary action against his license to practice medicine in the Commonwealth of Kentucky.

21. The licensee is directed to respond to the allegations delineated in the Complaint within thirty (30) days of service thereof and is further given notice that:

    (a) His failure to respond may be taken as an admission of the charges; and

    (b) He may appear alone or with counsel, may cross-examine all prosecution witnesses and offer evidence in his defense.

22. NOTICE IS HEREBY GIVEN that a hearing on this Complaint is scheduled for **June 3 - 7, 2024**, at 9:00 a.m., Eastern Standard Time, at the Kentucky Board of Medical Licensure, Hurstbourne Office Park, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Said hearing shall be held pursuant to the Rules and Regulations of the Kentucky Board of Medical Licensure and pursuant to KRS Chapter 13B. This hearing shall proceed as scheduled and the hearing date shall only be modified by leave of the Hearing Officer upon a showing of good cause.

WHEREFORE, Complainant prays that appropriate disciplinary action be taken against the license to practice medicine in the Commonwealth of Kentucky held by Barry G. Hardison, M.D.

This 24th day of October, 2023.

W. Saleem.

WAQAR A. SALEEM, M.D.
CHAIR, INQUIRY PANEL A

CERTIFICATE OF SERVICE

I certify that the original of this Complaint 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 to Thomas J. Hellmann, Esq., 810 Hickman Hill Road, Frankfort, Kentucky 40601; and copies were mailed via certified mail return-receipt requested to the licensee, Barry G. Hardison, M.D., License No. 23875, 222 Phillip Stone Way, Central City, Kentucky 42330 and via email to barry.hardison@aol.com; and to counsel for the licensee, Lisa English Hinkle, Esq., McBrayer, PLLC, 201 East Main Street, Suite 900, Lexington, Kentucky 40507, and via email to lhinkle@mcbrayerfirm.com on this 24th day of October, 2023.

Nicole A. King

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