COMMONWEALTH OF KENTUCKY BOARD OF MEDICAL LICENSURE CASE NO. 1355

NOV 2 2 2016 K.B.M.L.

IN RE: THE LICENSE TO PRACTICE OSTEOPATHY IN THE COMMONWEALTH OF KENTUCKY HELD BY CURTIS D. EDENS, D.O., LICENSE NO. 02610, 108 WEST MADISON STREET, LOUISA, KENTUCKY 41230-1327

AGREED ORDER OF SURRENDER

Come now the Kentucky Board of Medical Licensure ("the Board"), acting by and through its Inquiry Panel B, and Curtis D. Edens, D.O. ("the licensee"), and, based upon their mutual desire to fully and finally resolve the licensee's non-compliance without an evidentiary hearing, hereby ENTER INTO the following AGREED ORDER OF SURRENDER:

STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Agreed Order of Surrender:

- At all relevant times, Curtis D. Edens, D.O., was licensed by the Board to practice osteopathy within the Commonwealth of Kentucky.
- 2. The licensee's specialty is obstetrics/gynecology.
- 3. On or about June 7, 2011, the Board received a grievance from the Chief of the Louisa Police Department which raised concerns about the licensee's operation of a pain clinic at his obstetric/gynecological practice.
- 4. In January 2011, the Louisa Police Department received four (4) calls for service at the licensee's practice location. Two calls involved domestic disturbances at the office; a third call involved an intoxicated person coming in and out of the

- office; and a fourth call involved a female driving to the office on a suspended license.
- 5. On or around March 3, 2011, the Louisa Police Department responded to a call regarding a female driving to or from the practice location on a suspended license. Upon arrival, the police noted that the parking area was so crowded that patients had to park in other nearby business and residential areas, creating a traffic hazard. The police also noted that numerous vehicles were from surrounding counties and several were from out of state. A stationary patrol, over the next 24-48 hours, resulted in patients being charged with nineteen (19) violations and some were arrested.
- 6. During a meeting with the Chief of the Louisa Police Department, the City Attorney, the County Attorney and the Commonwealth's attorney, the licensee disclosed that he had a DEA license to prescribe Suboxone to up to 100 patients and that he was the only licensee in the country prescribing Suboxone to pregnant women.
- 7. On or about May 31, 2011, the Louisa Police Department received a 911 hang up call from the licensee's office. When the police called back, the licensee's office reported that two female patients had been fighting. When officers responded to the scene, the licensee's office staff informed them that the women had been separated and had agreed to not bother each other again. Later that same day, a female patient called the police and reported that the licensee dismissed her from the Suboxone program after the fight and that he said that he couldn't afford the police coming around his office.

- 8. On or about June 9, 2011, Chris Johnson, R.Ph., Pharmacist Consultant, Drug Enforcement and Professional Practices Branch at the Cabinet for Health Services, informed the Board that the Louisa Police Department had filed a similar complaint with Drug Enforcement in March 2011; that a KASPER report, dated January 1, 2010 through June 2, 2011, was reviewed in response thereto; and that the case was being referred to the Board for any action deemed necessary. Mr. Johnson identified twenty-two (22) patients of the licensee which merited further investigation. Three of those patients shared the same family name as the licensee.
- 9. In a letter to the Board, dated June 30, 2011, the licensee explained that he primarily operates an obstetrical/gynecological practice with the majority of his Suboxone patients being obstetrically-related; that, based upon representations from his Suboxone representative, he is the only physician in the country prescribing Suboxone to pregnant women; that he monitors his Suboxone patients with observed drug testing weekly along with random drug screens and pill counts; and that he does writes prescriptions for weekly supplies and does not replace reportedly-lost prescriptions.
- 10. Charts for fifteen (15) of the twenty-two (22) patients recommended for further review by Drug Enforcement Board were subpoenaed and obtained from the licensee for a consultant review.
- 11. Upon reviewing the patient charts, the licensee's KASPER report and the grievance, the consultant concluded that the licensee departed from and failed to

conform to the standards of acceptable and prevailing medical practices in the Commonwealth of Kentucky in the following:

- a. Eleven (11) of the fifteen (15) charts pertained to patients who were treated with Suboxone. In each case, there was no documented initial evaluation using the clinical opiate withdrawal scale (C.O.W.S.) nor was there evidence that Suboxone was started under observation within the office.
- b. There was no documentation or other evidence of the use of KASPER, random pill counts or random urine drug screens and it was not clear whether the drug screens were observed.
- c. In two instances, urine drug screens that were positive for THC were neither documented in the progress notes nor discussed with the patients.
- d. Four pregnant patients were treated with Suboxone, although the acceptable and prevailing medical practice is to treat pregnant patients with Subutex because Suboxone may precipitate miscarriage or premature labor.
- e. In the case of one patient who allegedly suffered chronic anxiety and misused Valium throughout her pregnancy, there was no clear evaluation of the patient's anxiety, no evidence of KASPER reports and only one urine drug screen, and no timely referral to a specialist.
- f. The licensee prescribed controlled substances to three (3) of his own family members.

- 12. Other than these departures from acceptable and prevailing medical practices, the consultant noted that "...in most respects the care given by Dr. Edens was good. He followed his Suboxone patients carefully, and ensured that they obtained good counseling and with the exception of THC, dealt promptly with positive urine drug screens. Dr. Edens appears to be a good physician who could use a mentor."
- 13. In a letter to the Board, dated August 31, 2011, the licensee acknowledged that he treats his immediate and extended family and that he prescribes pain medications for his father and Suboxone for his daughter.
- 14. The American Medical Association's Code of Medical Ethics, §8.19, provides that physicians should not treat family members, except in emergency or isolated settings where there is no other qualified physician available and then only until another physician becomes available; that physicians should not serve as a regular or primary care provider for immediate family members, unless it is for care of short-term, minor problems; and that it is not appropriate for physicians to prescribe controlled substances to immediate family members, except in emergencies.
- 15. There were no circumstances in which it was appropriate for the licensee to treat and prescribe controlled substances for his family members, at the time he treated and prescribed controlled substances to them.
- 16. On November 9, 2011, the licensee entered into an Agreed Order with the Board, with the following terms and conditions:
 - a. The licensee shall not prescribe controlled substances to himself or any member of his family:

- He must run KASPER reports, initially and periodically, on all patients to whom he prescribes controlled substances;
- c. He shall maintain a controlled substance log, subject to review;
- d. He shall successfully complete the "Prescribing Controlled Drugs" course within six (6) months of the entry of the Agreed Order;
- e. He shall successfully complete the ProBe program at the Center for Personalized Education for Physicians ("CPEP");
- f. He shall successfully complete the Documentation Seminar at CPEP and successfully complete the follow-up Personalized Implementation Program ("PIP");
- g. He shall reimburse the Board the costs of the investigation in the amount of \$675.00 within six months of the entry of the Agreed Order; and
- h. He shall not violate any provision of KRS 311.595 and/or 311.597.
- 17. The licensee completed the Prescribing Controlled Drugs course on June 6-8, 2012.
- 18. He completed the ProBe program on July 12-14, 2012.
- The licensee completed the Patient Care Documentation Seminar on March 10, 2012.
- 20. He reimbursed the Board's costs in full on November 21, 2011.
- 21. On March 20, 2014, Inquiry Panel B reviewed a report that the licensee failed the PIP program. Accordingly, the Panel sent the licensee a Letter of Admonishment.

- 22. In August 2015, the Board initiated a review of the licensee's patient charts pursuant to the Agreed Order. The Board's consultant issued a report on November 17, 2015 with the following opinions:
 - a. Dr. Edens prescribes Suboxone to pregnant patients;
 - b. Dr. Edens consistently fails to document any physical exams:
 - c. Dr. Edens consistently documents UDS as negative when they clearly are not;
 - d. Dr. Edens consistently fails to provide adequate liver screening for his Suboxone patients. In two cases, he provided Suboxone to patients with Hepatitis C;
 - e.
 - f. Dr. Edens does not meet the minimum standard in record keeping;
 - g. Dr. Edens does not meet the minimum standard in prescribing and monitoring medications containing Buprenorphine.
- 23. A copy of the consultant's report, a letter requesting a response from the licensee by December 11, 2015, and an invoice for reimbursement of the consultant's services were shipped to the licensee on November 24, 2015. On December 28, 2015, the licensee submitted a written response to the Board consultant's report.
- 24. On January 5, 2016, the Board consultant issued a final report in which the majority of his findings did not change.
- 25. On or about February 5, 2016, the licensee entered into an Amended Agreed Order, in lieu of the issuance of a Complaint and an Emergency Order of Restriction, in which he agreed to:
 - a. Within twenty (20) days of the filing of this Amended Agreed Order, the licensee SHALL contact the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241, to schedule a clinical skills assessment for the earliest dates available to both CPEP and the licensee;

- 26. The licensee failed to schedule a clinical skills assessment with CPEP as required by the Amended Agreed Order.
- 27. On or about June 6, 2016, the licensee entered into a Second Amended Agreed Order, in lieu of the issuance of a Complaint and Emergency Order of Restriction, in which he agreed to:
 - a. Within twenty (20) days of the filing of this Second Amended Agreed Order, the licensee SHALL contact the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241, to schedule a clinical skills assessment (in areas related to his medical practice including his prescribing of buprenorphine-mono-product and buprenorphine-combined-with-naloxone and his practice of obstetrics and gynecology) for the earliest dates available to both CPEP and the licensee;

•••

- If the Assessment Report recommends development of an Educational Plan, the licensee SHALL take all necessary steps to arrange for CPEP to immediately develop such a plan, at the licensee's expense;
 - 1. Upon receipt of an Educational Intervention by the licensee, the licensee SHALL immediately comply with and SUCCESSFULLY complete all requirements of that Educational Intervention, at his expense and as directed by CPEP:
 - If deemed necessary and appropriate by CPEP, the licensee SHALL SUCCESSFULLY COMPLETE the Post-Education Assessment, at his expense and as directed by CPEP;
 - The licensee SHALL TAKE ALL NECESSARY STEPS, including the execution of waivers and/or releases, to ensure that CPEP provides timely written reports to the Board outlining his compliance with the Educational Intervention;
- 28. The licensee obtained a clinical skills assessment at CPEP on June 27-28, 2016.

 CPEP's Assessment Findings include:

During this Assessment, Dr. Edens demonstrated knowledge of opioid addiction and MAT (with buprenorphine) that was superficial. His knowledge of the OB/GYN topics discussed was broad, with several gaps, particularly in the area of obstetrics. His clinical judgment and reasoning were variable, with concerns raised in the area of individualization of treatment (MAT and gynecology) and selection of gynecologic procedures. On the Fundamentals of Laprascopic Surgery (FLS) exam, Dr. Edens passed the cognitive section but did not pass the manual skills section. His documentation in actual patient charts was variable, ranging from adequate to poor and inadequate for the Simulated Patient (SP) encounters. Dr. Edens's communication skills were adequate with the need for improvement with SPs. His verbal communication with peers was acceptable; the consultants found his appearance to be overly casual. ...

- 29. CPEP recommended that the licensee participate in a structured, individualized education intervention to address the identified areas of need.
- 30. CPEP provided a copy of the Assessment Report to the licensee along with an Agreement to sign to enroll into the Educational Intervention Plan by September 15, 2016.
- 31. The licensee did not enroll in the Educational Intervention Plan.
- 32. The licensee did not respond to communications from CPEP regarding his enrollment in the Education Plan.
- 33. During an interview with a Board investigator, the licensee stated that he was now living in South Carolina and that he had closed his practice in Kentucky and has no intention of returning. He stated he could not complete the Education Plan due to having no income and not having an active practice.

STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Agreed Order of Surrender:

 The licensee's osteopathic license is subject to regulation and discipline by the Board.

- 2. Based upon the Stipulations of Fact, the licensee has engaged in conduct which violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(13). Accordingly, there are legal grounds for the parties to enter into this Agreed Order of Surrender.
- 3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve the licensee's non-compliance without an evidentiary hearing by entering into an informal resolution such as this Agreed Order of Surrender.

AGREED ORDER OF SURRENDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve the licensee's non-compliance without an evidentiary hearing, the parties hereby ENTER INTO the following AGREED ORDER OF SURRENDER:

- 1. The licensee hereby SURRENDERS his Kentucky medical license, in lieu of revocation, with that surrender to become effective immediately upon the filing of this Agreed Order of Surrender, and continuing until further order of the Panel.
- 2. Immediately upon the filing of this Agreed Order of Surrender, the licensee shall not engage in any act which would constitute the "practice of medicine or osteopathy" 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, until approved to do so by the Panel.
- 3. The licensee SHALL NOT petition and the Panel SHALL NOT consider a petition for reinstatement of his license by the licensee unless:
 - a. A minimum period of two (2) years from the date of filing of this Agreed Order of Surrender has passed;
 - b. The licensee has obtained an updated clinical skills assessment at the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241, at his expense, and has ensured that the

Board has received copy of the Assessment Report as well as an Education Plan (if recommended); and

- c. The licensee has submitted payment in full of a FINE in the amount of five-thousand dollars (\$5,000) to the Board.
- 4. The licensee understands and agrees that, if he should petition for reinstatement of his license, the burden shall be upon him to satisfy the Panel that he is presently of good moral character and qualified both physically and mentally to resume the practice of medicine without undue risk or danger to his patients or the public.
- 5. The licensee understands and agrees that the decision whether or not to permit him to resume the practice of medicine within the Commonwealth of Kentucky lies in the sole discretion of the Panel.
- 6. The licensee understands and agrees that if the Panel should grant his request to resume the practice of medicine within the Commonwealth of Kentucky, he shall be restricted from prescribing or dispensing controlled substances until further order of the Panel and subject to terms and conditions decided by the Panel.
- 7. If the Board should receive information that, after the date of filing of this Agreed Order of Surrender, the licensee has performed an act which would constitute the "practice of medicine or osteopathy" within the Commonwealth of Kentucky, it shall refer the licensee to the Attorney General or appropriate Commonwealth Attorney for prosecution of such acts of practicing medicine without a license.
- 8. The licensee expressly agrees that if he should violate any term or condition of the Agreed Order of Surrender, the licensee's practice will constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and 13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Agreed Order of Surrender, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an ex parte presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agrees that the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125 would be whether the licensee violated a term or condition of this Agreed Order of Surrender.
- 9. The licensee understands and agrees that any violation of the terms of this Agreed Order of Surrender would provide a legal basis for additional disciplinary action, including revocation, pursuant to KRS 311.595(13) and may provide a legal basis for criminal prosecution for practicing medicine without a license.

SO AGREED on this 2016.

CURTIS D. EDENS, D.O.

COUNSEL FOR THE LICENSEE (IF APPLICABLE)

FOR THE BOARD:

RUSSELL L TRAVIS M.D.

RUSSELL L. TRAVIS, M.D. CHAIR, INQUIRY PANEL B

SARA FARMER

Assistant General Counsel Kentucky Board of Medical Licensure 310 Whittington Parkway, Suite 1B Louisville, Kentucky 40222 Tel. (502) 429-7150

COMMONWEALTH OF KENTUCKY BOARD OF MEDICAL LICENSURE CASE NO. 1355

JUN 06 2016 K.B.M.L.

IN RE: THE LICENSE TO PRACTICE OSTEOPATHY IN THE COMMONWEALTH OF KENTUCKY HELD BY CURTIS D. EDENS, D.O., LICENSE NO. 02610, 108 WEST MADISON STREET, LOUISA, KENTUCKY 41230-1327

SECOND AMENDED AGREED ORDER

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STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Second Amended Agreed Order:

- 1. At all relevant times, Curtis D. Edens, D.O., was licensed by the Board to practice osteopathy within the Commonwealth of Kentucky.
- 2. The licensee's specialty is obstetrics/gynecology.
- 3. On or about June 7, 2011, the Board received a grievance from the Chief of the Louisa Police Department which raised concerns about the licensee's operation of a pain clinic at his obstetric/gynecological practice.
- 4. In January 2011, the Louisa Police Department received four (4) calls for service at the licensee's practice location. Two calls involved domestic disturbances at the office; a third call involved an intoxicated person coming in and out of the

- office; and a fourth call involved a female driving to the office on a suspended license.
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 Upon arrival, the police noted that the parking area was so crowded that patients had to park in other nearby business and residential areas, creating a traffic hazard. The police also noted that numerous vehicles were from surrounding counties and several were from out of state. A stationary patrol, over the next 24-48 hours, resulted in patients being charged with nineteen (19) violations and some were arrested.
- 6. During a meeting with the Chief of the Louisa Police Department, the City Attorney, the County Attorney and the Commonwealth's attorney, the licensee disclosed that he had a DEA license to prescribe Suboxone to up to 100 patients and that he was the only licensee in the country prescribing Suboxone to pregnant women.
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- 8. On or about June 9, 2011, Chris Johnson, R.Ph., Pharmacist Consultant, Drug Enforcement and Professional Practices Branch at the Cabinet for Health Services, informed the Board that the Louisa Police Department had filed a similar complaint with Drug Enforcement in March 2011; that a KASPER report, dated January 1, 2010 through June 2, 2011, was reviewed in response thereto; and that the case was being referred to the Board for any action deemed necessary. Mr. Johnson identified twenty-two (22) patients of the licensee which merited further investigation. Three of those patients shared the same family name as the licensee.
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- 10. Charts for fifteen (15) of the twenty-two (22) patients recommended for further review by Drug Enforcement Board were subpoenaed and obtained from the licensee for a consultant review.
- 11. Upon reviewing the patient charts, the licensee's KASPER report and the grievance, the consultant concluded that the licensee departed from and failed to

conform to the standards of acceptable and prevailing medical practices in the Commonwealth of Kentucky in the following:

- a. Eleven (11) of the fifteen (15) charts pertained to patients who were treated with Suboxone. In each case, there was no documented initial evaluation using the clinical opiate withdrawal scale (C.O.W.S.) nor was there evidence that Suboxone was started under observation within the office.
- b. There was no documentation or other evidence of the use of KASPER, random pill counts or random urine drug screens and it was not clear whether the drug screens were observed.
- c. In two instances, urine drug screens that were positive for THC were neither documented in the progress notes nor discussed with the patients.
- d. Four pregnant patients were treated with Suboxone, although the acceptable and prevailing medical practice is to treat pregnant patients with Subutex because Suboxone may precipitate miscarriage or premature labor.
- e. In the case of one patient who allegedly suffered chronic anxiety and misused Valium throughout her pregnancy, there was no clear evaluation of the patient's anxiety, no evidence of KASPER reports and only one urine drug screen, and no timely referral to a specialist.
- f. The licensee prescribed controlled substances to three (3) of his own family members.

- 12. Other than these departures from acceptable and prevailing medical practices, the consultant noted that "...in most respects the care given by Dr. Edens was good. He followed his Suboxone patients carefully, and ensured that they obtained good counseling and with the exception of THC, dealt promptly with positive urine drug screens. Dr. Edens appears to be a good physician who could use a mentor."
- 13. In a letter to the Board, dated August 31, 2011, the licensee acknowledged that he treats his immediate and extended family and that he prescribes pain medications for his father and Suboxone for his daughter.
- 14. The American Medical Association's Code of Medical Ethics, §8.19, provides that physicians should not treat family members, except in emergency or isolated settings where there is no other qualified physician available and then only until another physician becomes available; that physicians should not serve as a regular or primary care provider for immediate family members, unless it is for care of short-term, minor problems; and that it is not appropriate for physicians to prescribe controlled substances to immediate family members, except in emergencies.
- 15. There were no circumstances in which it was appropriate for the licensee to treat and prescribe controlled substances for his family members, at the time he treated and prescribed controlled substances to them.
- 16. On November 9, 2011, the licensee entered into an Agreed Order with the Board, with the following terms and conditions:
 - a. The licensee shall not prescribe controlled substances to himself or any member of his family;

- He must run KASPER reports, initially and periodically, on all patients to whom he prescribes controlled substances;
- c. He shall maintain a controlled substance log, subject to review;
- d. He shall successfully complete the "Prescribing Controlled Drugs" course within six (6) months of the entry of the Agreed Order;
- e. He shall successfully complete the ProBe program at the Center for Personalized Education for Physicians ("CPEP");
- f. He shall successfully complete the Documentation Seminar at CPEP and successfully complete the follow-up Personalized Implementation Program ("PIP");
- g. He shall reimburse the Board the costs of the investigation in the amount of \$675.00 within six months of the entry of the Agreed Order; and
- h. He shall not violate any provision of KRS 311.595 and/or 311.597.
- 17. The licensee completed the Prescribing Controlled Drugs course on June 6-8, 2012.
- 18. He completed the ProBe program on July 12-14, 2012.
- The licensee completed the Patient Care Documentation Seminar on March 10,
 2012.
- 20. He reimbursed the Board's costs in full on November 21, 2011.
- 21. On March 20, 2014, Inquiry Panel B reviewed a report that the licensee failed the PIP program. Accordingly, the Panel sent the licensee a Letter of Admonishment.

- 22. In August 2015, the Board initiated a review of the licensee's patient charts pursuant to the Agreed Order. The Board's consultant issued a report on November 17, 2015 with the following opinions:
 - a. Dr. Edens prescribes Suboxone to pregnant patients;
 - b. Dr. Edens consistently fails to document any physical exams;
 - c. Dr. Edens consistently documents UDS as negative when they clearly are not;
 - d. Dr. Edens consistently fails to provide adequate liver screening for his Suboxone patients. In two cases, he provided Suboxone to patients with Hepatitis C;
 - e.
 - f. Dr. Edens does not meet the minimum standard in record keeping;
 - g. Dr. Edens does not meet the minimum standard in prescribing and monitoring medications containing Buprenorphine.
- 23. A copy of the consultant's report, a letter requesting a response from the licensee by December 11, 2015, and an invoice for reimbursement of the consultant's services were shipped to the licensee on November 24, 2015. On December 28, 2015, the licensee submitted a written response to the Board consultant's report.
- 24. On January 5, 2016, the Board consultant issued a final report in which the majority of his findings did not change.
- 25. On or about February 5, 2016, the licensee entered into an Amended Agreed Order, in lieu of the issuance of a Complaint and an Emergency Order of Restriction, in which he agreed to:
 - a. Within twenty (20) days of the filing of this Amended Agreed Order, the licensee SHALL contact the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241, to schedule a clinical skills assessment for the earliest dates available to both CPEP and the licensee;

- 26. The licensee failed to schedule a clinical skills assessment with CPEP as required by the Amended Agreed Order.
- 27. On or about May 19, 2016, the Board's Inquiry Panel B reviewed the licensee's non-compliance and the licensee appeared before and was heard by the Panel before it deliberated. The Panel and the licensee agreed to enter into this Second Amended Agreed Order, in lieu of the issuance of a Complaint and Emergency Order of Restriction.

STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Second Amended Agreed Order:

- 1. The licensee's osteopathic license is subject to regulation and discipline by the Board.
- 2. Based upon the Stipulations of Fact, the licensee has engaged in conduct which violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(4), and KRS 311.595(13). Accordingly, there are legal grounds for the parties to enter into this Second Amended Agreed Order.
- 3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve the licensee's non-compliance without an evidentiary hearing by entering into an informal resolution such as this Second Amended Agreed Order.

SECOND AMENDED AGREED ORDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve this noncompliance

without an evidentiary hearing, the parties hereby ENTER INTO the following SECOND AMENDED AGREED ORDER:

- The license to practice osteopathy within the Commonwealth of Kentucky held by Curtis D. Edens, D.O., is RESTRICTED/LIMITED FOR AN INDEFINITE PERIOD OF TIME, effective immediately upon the filing of this Second Amended Agreed Order;
- 2. During the effective period of this Second Amended Agreed Order, the licensee's osteopathic license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS:
 - a. The licensee SHALL NOT prescribe, dispense, or otherwise professionally utilize controlled substances unless and until approved to do so by the Panel;
 - b. Within twenty (20) days of the filing of this Second Amended Agreed Order, the licensee SHALL contact the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241, to schedule a clinical skills assessment (in areas related to his medical practice including his prescribing of buprenorphine-mono-product and buprenorphine-combined-with-naloxone and his practice of obstetrics and gynecology) for the earliest dates available to both CPEP and the licensee;
 - Both parties may provide relevant information to CPEP for consideration as part of the clinical skills assessment. In order to permit the Board to provide such relevant information, the licensee SHALL immediately notify the Board's Legal Department of the assessment dates once the assessment is scheduled;
 - ii. The licensee SHALL travel to CPEP and complete the assessment as scheduled, at his expense;
 - iii. The licensee expressly understands and agrees that CPEP will issue its final Assessment Report, in accordance with its internal policies;
 - iv. The licensee SHALL take all steps necessary, including signing any waiver and/or consent forms required to ensure that CPEP will

- provide a copy of the Assessment Report to the Board's Legal Department promptly after its completion;
- v. If the Assessment Report recommends development of an Educational Plan, the licensee SHALL take all necessary steps to arrange for CPEP to immediately develop such a plan, at the licensee's expense;
 - 1. Upon receipt of an Educational Intervention by the licensee, the licensee SHALL immediately comply with and SUCCESSFULLY complete all requirements of that Educational Intervention, at his expense and as directed by CPEP;
 - 2. If deemed necessary and appropriate by CPEP, the licensee SHALL SUCCESSFULLY COMPLETE the Post-Education Assessment, at his expense and as directed by CPEP;
 - 3. The licensee SHALL TAKE ALL NECESSARY STEPS, including the execution of waivers and/or releases, to ensure that CPEP provides timely written reports to the Board outlining his compliance with the Educational Intervention;
- vi. The licensee expressly understands and agrees that if the CPEP Assessment Report recommends that the licensee retrain in a residency or residency-like setting, the licensee SHALL NOT perform any act which would constitute the "practice of medicine or osteopathy," as that term is defined in 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 unless and until approved to do so by the Panel;
- vii. If the CPEP Assessment Report recommends that the licensee retrain in a residency or residency-like setting, the Panel shall neither modify nor terminate this Second Amended Agreed Order unless and until he completes a residency or residency-like program and obtains a CPEP clinical skills assessment demonstrating that he is competent to engage in the "practice of medicine or osteopathy" without additional education;
- c. Pursuant to KRS 311.565(1)(v) the licensee SHALL submit payment of a FINE in the amount of five-thousand dollars (\$5,000) to the Board within six (6) months from the date of entry of this Second Amended Agreed Order; and

- d. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.
- 3. The licensee expressly understands and agrees that the Panel will not consider a request to resume the professional utilization of controlled substances unless and until he has paid the \$5,000 fine in \(\(\)(2)(c) and has ensured that CPEP has provided copies of its assessment and education plan, if so recommended, to the Panel for review.
- 4. The licensee expressly understands and agrees that if the Panel should grant the licensee's request to resume the prescribing, dispensing or professional utilization of controlled substances in the future, it will do so by a Third Amended Agreed Order, which shall at least require that:
 - a. The licensee SHALL NOT prescribe, dispense or otherwise provide controlled substances to himself or any member of his immediate family, including his spouse, parents, children or grandchildren, siblings, or in-laws;
 - b. The licensee SHALL initially, and periodically thereafter, run KASPER reports on each patient to whom he prescribes controlled substances, including but not limited to Suboxone;
 - i. The licensee SHALL document in each patient chart: the fact that a KASPER report was obtained, the date it was obtained, the KASPER Request Number, any problems or concerns reflected in the KASPER report and how those problems or concerns were addressed with the patient;
 - c. The licensee SHALL maintain a "controlled substances log" for all controlled substances prescribed. The controlled substances log must include date, patient name, patient complaint, medication prescribed, when it was last prescribed and how much on the last visit. Note: All log sheets will be consecutively numbered, <u>legible</u> i.e. printed or typed, and must reflect "call-in" and refill information. Prescriptions should be maintained in the following manner: 1) patient; 2) chart; and 3) log;
 - i. The licensee SHALL permit the Board's agents to inspect, copy and/or obtain the controlled substance log and other relevant

- records, upon request, for review by the Board's agents and/or consultants;
- ii. The licensee SHALL reimburse the Board fully for the costs of each consultant review performed pursuant to this Amended Agreed Order. Once the Board receives the invoice from the consultant(s) for each review, it will provide the licensee with a redacted copy of that invoice, omitting the consultant's identifying information. The licensee SHALL pay the costs noted on the invoice within thirty (30) days of the date on the Board's written notice. The licensee's failure to fully reimburse the Board within that time frame shall constitute a violation of this Amended Agreed Order;
- iii. The licensee understands and agrees that at least one favorable consultant review must be performed, on terms determined by the Panel or its staff, before the Panel will consider a request to terminate this Amended Agreed Order; and
- iv. Any other conditions deemed necessary by the Panel or Panel Chair at that time.
- 5. The licensee expressly agrees that if he should violate any term or condition of this Second Amended Agreed Order, the licensee's practice will constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and 13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Second Amended Agreed Order, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an ex parte presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agree and stipulate that a violation of any term or condition of this Second Amended Agreed Order would render the licensee's practice an immediate danger to the health, welfare and safety of

patients and the general public, pursuant to KRS 311.592 and 13B.125; accordingly, the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125 would be whether the licensee violated a term or condition of this Second Amended Agreed Order.

6. The licensee understands and agrees that any violation of the terms of this Second Amended Agreed Order would provide a legal basis for additional disciplinary action, including revocation, pursuant to KRS 311.595(13) and may provide a legal basis for criminal prosecution for practicing osteopathy without a license.

SO AGREED on this OZ day of June, 2016.

FOR THE LICENSEE:

CURTIS D. EDENS, D.O

COUNSEL FOR THE LICENSEE

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OF APPLICABLE)

FOR THE BOARD:

RANDEL C. GIBSON, D.O. CHAIR, INQUIRY PANEL B

SARA FARMER

Assistant General Counsel

Kentucky Board of Medical Licensure 310 Whittington Parkway, Suite 1B

Louisville, Kentucky 40222

Tel. (502) 429-7150

FEB 05 2016 K.B.M.L.

COMMONWEALTH OF KENTUCKY BOARD OF MEDICAL LICENSURE CASE NO. 1355

IN RE: THE LICENSE TO PRACTICE OSTEOPATHY IN THE COMMONWEALTH OF KENTUCKY HELD BY CURTIS D. EDENS, D.O., LICENSE NO. 02610, 108 WEST MADISON STREET, LOUISA, KENTUCKY 41230-1327

AMENDED AGREED ORDER

Come now the Kentucky Board of Medical Licensure ("the Board"), acting by and through its Inquiry Panel B, and Curtis D. Edens, D.O. ("the licensee"), and, based upon their mutual desire to fully and finally resolve the licensee's non-compliance without an evidentiary hearing, hereby ENTER INTO the following AMENDED AGREED ORDER:

STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Amended Agreed Order:

- At all relevant times, Curtis D. Edens, D.O., was licensed by the Board to practice osteopathy within the Commonwealth of Kentucky.
- 2. The licensee's specialty is obstetrics/gynecology.
- 3. On or about June 7, 2011, the Board received a grievance from the Chief of the Louisa Police Department which raised concerns about the licensee's operation of a pain clinic at his obstetric/gynecological practice.
- 4. In January 2011, the Louisa Police Department received four (4) calls for service at the licensee's practice location. Two calls involved domestic disturbances at the office; a third call involved an intoxicated person coming in and out of the

- office; and a fourth call involved a female driving to the office on a suspended license.
- 5. On or around March 3, 2011, the Louisa Police Department responded to a call regarding a female driving to or from the practice location on a suspended license. Upon arrival, the police noted that the parking area was so crowded that patients had to park in other nearby business and residential areas, creating a traffic hazard. The police also noted that numerous vehicles were from surrounding counties and several were from out of state. A stationary patrol, over the next 24-48 hours, resulted in patients being charged with nineteen (19) violations and some were arrested.
- 6. During a meeting with the Chief of the Louisa Police Department, the City Attorney, the County Attorney and the Commonwealth's attorney, the licensee disclosed that he had a DEA license to prescribe Suboxone to up to 100 patients and that he was the only licensee in the country prescribing Suboxone to pregnant women.
- 7. On or about May 31, 2011, the Louisa Police Department received a 911 hang up call from the licensee's office. When the police called back, the licensee's office reported that two female patients had been fighting. When officers responded to the scene, the licensee's office staff informed them that the women had been separated and had agreed to not bother each other again. Later that same day, a female patient called the police and reported that the licensee dismissed her from the Suboxone program after the fight and that he said that he couldn't afford the police coming around his office.

- 8. On or about June 9, 2011, Chris Johnson, R.Ph., Pharmacist Consultant, Drug Enforcement and Professional Practices Branch at the Cabinet for Health Services, informed the Board that the Louisa Police Department had filed a similar complaint with Drug Enforcement in March 2011; that a KASPER report, dated January 1, 2010 through June 2, 2011, was reviewed in response thereto; and that the case was being referred to the Board for any action deemed necessary. Mr. Johnson identified twenty-two (22) patients of the licensee which merited further investigation. Three of those patients shared the same family name as the licensee.
- 9. In a letter to the Board, dated June 30, 2011, the licensee explained that he primarily operates an obstetrical/gynecological practice with the majority of his Suboxone patients being obstetrically-related; that, based upon representations from his Suboxone representative, he is the only physician in the country prescribing Suboxone to pregnant women; that he monitors his Suboxone patients with observed drug testing weekly along with random drug screens and pill counts; and that he does writes prescriptions for weekly supplies and does not replace reportedly-lost prescriptions.
- 10. Charts for fifteen (15) of the twenty-two (22) patients recommended for further review by Drug Enforcement Board were subpoenaed and obtained from the licensee for a consultant review.
- 11. Upon reviewing the patient charts, the licensee's KASPER report and the grievance, the consultant concluded that the licensee departed from and failed to

conform to the standards of acceptable and prevailing medical practices in the Commonwealth of Kentucky in the following:

- a. Eleven (11) of the fifteen (15) charts pertained to patients who were treated with Suboxone. In each case, there was no documented initial evaluation using the clinical opiate withdrawal scale (C.O.W.S.) nor was there evidence that Suboxone was started under observation within the office.
- b. There was no documentation or other evidence of the use of KASPER, random pill counts or random urine drug screens and it was not clear whether the drug screens were observed.
- c. In two instances, urine drug screens that were positive for THC were neither documented in the progress notes nor discussed with the patients.
- d. Four pregnant patients were treated with Suboxone, although the acceptable and prevailing medical practice is to treat pregnant patients with Subutex because Suboxone may precipitate miscarriage or premature labor.
- e. In the case of one patient who allegedly suffered chronic anxiety and misused Valium throughout her pregnancy, there was no clear evaluation of the patient's anxiety, no evidence of KASPER reports and only one urine drug screen, and no timely referral to a specialist.
- f. The licensee prescribed controlled substances to three (3) of his own family members.

- 12. Other than these departures from acceptable and prevailing medical practices, the consultant noted that "...in most respects the care given by Dr. Edens was good. He followed his Suboxone patients carefully, and ensured that they obtained good counseling and with the exception of THC, dealt promptly with positive urine drug screens. Dr. Edens appears to be a good physician who could use a mentor."
- 13. In a letter to the Board, dated August 31, 2011, the licensee acknowledged that he treats his immediate and extended family and that he prescribes pain medications for his father and Suboxone for his daughter.
- 14. The American Medical Association's Code of Medical Ethics, §8.19, provides that physicians should not treat family members, except in emergency or isolated settings where there is no other qualified physician available and then only until another physician becomes available; that physicians should not serve as a regular or primary care provider for immediate family members, unless it is for care of short-term, minor problems; and that it is not appropriate for physicians to prescribe controlled substances to immediate family members, except in emergencies.
- 15. There were no circumstances in which it was appropriate for the licensee to treat and prescribe controlled substances for his family members, at the time he treated and prescribed controlled substance to them.
- 16. On November 9, 2011, the licensee entered into an Agreed Order with the Board, with the following terms and conditions:
 - a. The licensee shall not prescribe controlled substances to himself or any member of his family;

- He must run KASPER reports, initially and periodically, on all patients to whom he prescribes controlled substances;
- c. He shall maintain a controlled substance log, subject to review;
- d. He shall successfully complete the "Prescribing Controlled Drugs" course within six (6) months of the entry of the Agreed Order;
- e. He shall successfully complete the ProBe program at the Center for Personalized Education for Physicians ("CPEP");
- f. He shall successfully complete the Documentation Seminar at CPEP and successfully complete the follow-up Personalized Implementation Program ("PIP");
- g. He shall reimburse the Board the costs of the investigation in the amount of \$675.00 within six months of the entry of the Agreed Order; and
- h. He shall not violate any provision of KRS 311.595 and/or 311.597.
- 17. The licensee completed the Prescribing Controlled Drugs course on June 6-8, 2012.
- 18. He completed the ProBe program on July 12-14, 2012.
- 19. The licensee completed the Patient Care Documentation Seminar on March 10, 2012.
- 20. He reimbursed the Board's costs in full on November 21, 2011.
- 21. On March 20, 2014, Inquiry Panel B reviewed a report that the licensee failed the PIP program. Accordingly, the Panel sent the licensee a Letter of Admonishment.

- 22. In August 2015, the Board initiated a review of the licensee's patient charts pursuant to the Agreed Order. The Board's consultant issued a report on November 17, 2015 with the following opinions:
 - a. Dr. Edens prescribes Suboxone to pregnant patients;
 - b. Dr. Edens consistently fails to document any physical exams;
 - c. Dr. Edens consistently documents UDS as negative when they clearly are not;
 - d. Dr. Edens consistently fails to provide adequate liver screening for his Suboxone patients. In two cases, he provided Suboxone to patients with Hepatitis C;
 - e.
 - f. Dr. Edens does not meet the minimum standard in record keeping;
 - g. Dr. Edens does not meet the minimum standard in prescribing and monitoring medications containing Buprenorphine.
- 23. A copy of the consultant's report, a letter requesting a response from the licensee by December 11, 2015, and an invoice for reimbursement of the consultant's services were shipped to the licensee on November 24, 2015. On December 28, 2015, the licensee submitted a written response to the Board consultant's report.
- 24. On January 5, 2016, the Board consultant issued a final report in which the majority of his findings did not change.
- 25. The licensee chose to enter into this Amended Agreed Order in lieu of the filing of a Complaint and an Emergency Order of Restriction.

STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Amended Agreed Order:

1. The licensee's osteopathic license is subject to regulation and discipline by the Board.

- Based upon the Stipulations of Fact, the licensee has engaged in conduct which
 violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(4), and
 KRS 311.595(13). Accordingly, there are legal grounds for the parties to enter
 into this Amended Agreed Order.
- 3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve the licensee's non-compliance without an evidentiary hearing by entering into an informal resolution such as this Amended Agreed Order.

AMENDED AGREED ORDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve this noncompliance without an evidentiary hearing, the parties hereby ENTER INTO the following AMENDED AGREED ORDER:

- The license to practice osteopathy within the Commonwealth of Kentucky held by Curtis D. Edens, D.O., is RESTRICTED/LIMITED FOR AN INDEFINITE PERIOD OF TIME, effective immediately upon the filing of this Amended Agreed Order;
- During the effective period of this Amended Agreed Order, the licensee's osteopathic license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS:
 - a. Within twenty (20) days of the filing of this Amended Agreed Order, the licensee SHALL contact the Center for Personalized Education for Physicians ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241, to schedule a clinical skills assessment for the earliest dates available to both CPEP and the licensee;

- Both parties may provide relevant information to CPEP for consideration as part of the clinical skills assessment. In order to permit the Board to provide such relevant information, the licensee SHALL immediately notify the Board's Legal Department of the assessment dates once the assessment is scheduled;
- ii. The licensee SHALL travel to CPEP and complete the assessment as scheduled, at his expense;
- iii. The licensee expressly understands and agrees that CPEP will issue its final Assessment Report, in accordance with its internal policies;
- iv. The licensee SHALL take all steps necessary, including signing any waiver and/or consent forms required to ensure that CPEP will provide a copy of the Assessment Report to the Board's Legal Department promptly after its completion;
- v. If the Assessment Report recommends development of an Educational Plan, the licensee SHALL take all necessary steps to arrange for CPEP to immediately develop such a plan, at the licensee's expense;
 - 1. Upon receipt of an Educational Intervention by the licensee, the licensee SHALL immediately comply with and SUCCESSFULLY complete all requirements of that Educational Intervention, at his expense and as directed by CPEP:
 - 2. If deemed necessary and appropriate by CPEP, the licensee SHALL SUCCESSFULLY COMPLETE the Post-Education Assessment, at his expense and as directed by CPEP;
 - 3. The licensee SHALL TAKE ALL NECESSARY STEPS, including the execution of waivers and/or releases, to ensure that CPEP provides timely written reports to the Board outlining his compliance with the Educational Intervention;
- vi. The licensee expressly understands and agrees that if the CPEP Assessment Report recommends that the licensee retrain in a residency or residency-like setting, the licensee SHALL NOT perform any act which would constitute the "practice of medicine or osteopathy," as that term is defined in 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 - unless and until approved to do so by the Panel;

- vii. If the CPEP Assessment Report recommends that the licensee retrain in a residency or residency-like setting, the Panel shall neither modify nor terminate this Amended Agreed Order unless and until he completes a residency or residency-like program and obtains a CPEP clinical skills assessment demonstrating that he is competent to engage in the "practice of medicine or osteopathy" without additional education;
- b. Pursuant to KRS 311.565(1)(v) the licensee SHALL submit payment of a FINE in the amount of five-thousand dollars (\$5,000) to the Board within six (6) months from the date of entry of this Amended Agreed Order;
- c. The licensee SHALL NOT prescribe, dispense or otherwise provide controlled substances to himself or any member of his immediate family, including his spouse, parents, children or grandchildren, siblings, or inlaws;
- d. The licensee SHALL initially, and periodically thereafter, run KASPER reports on each patient to whom he prescribes controlled substances, including but not limited to Suboxone;
 - i. The licensee SHALL document in each patient chart: the fact that a KASPER report was obtained, the date it was obtained, the KASPER Request Number, any problems or concerns reflected in the KASPER report and how those problems or concerns were addressed with the patient;
- e. The licensee SHALL maintain a "controlled substances log" for all controlled substances prescribed. The controlled substances log must include date, patient name, patient complaint, medication prescribed, when it was last prescribed and how much on the last visit. Note: All log sheets will be consecutively numbered, <u>legible</u> i.e. printed or typed, and must reflect "call-in" and refill information. Prescriptions should be maintained in the following manner: 1) patient; 2) chart; and 3) log;
 - i. The licensee SHALL permit the Board's agents to inspect, copy and/or obtain the controlled substance log and other relevant records, upon request, for review by the Board's agents and/or consultants;
 - ii. The licensee SHALL reimburse the Board fully for the costs of each consultant review performed pursuant to this Amended Agreed Order. Once the Board receives the invoice from the

consultant(s) for each review, it will provide the licensee with a redacted copy of that invoice, omitting the consultant's identifying information. The licensee SHALL pay the costs noted on the invoice within thirty (30) days of the date on the Board's written notice. The licensee's failure to fully reimburse the Board within that time frame shall constitute a violation of this Amended Agreed Order;

- iii. The licensee understands and agrees that at least one consultant review must be performed, on terms determined by the Panel or its staff, before the Panel will consider a request to terminate this Amended Agreed Order; and
- f. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.
- 2. The licensee expressly agrees that if he should violate any term or condition of this Amended Agreed Order, the licensee's practice will constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and 13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Amended Agreed Order, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an ex parte presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agree and stipulate that a violation of any term or condition of this Amended Agreed Order would render the licensee's practice an immediate danger to the health, welfare and safety of patients and the general public, pursuant to KRS 311.592 and 13B.125; accordingly, the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125

would be whether the licensee violated a term or condition of this Amended Agreed Order.

3. The licensee understands and agrees that any violation of the terms of this Amended Agreed Order would provide a legal basis for additional disciplinary action, including revocation, pursuant to KRS 311.595(13) and may provide a legal basis for criminal prosecution for practicing osteopathy without a license.

SO AGREED on this a day of Feb., 2016.

FOR THE LICENSEE:

CURTIS D. EDENS, D.O.

COUNSEL FOR THE LICENSEE (IF APPLICABLE)

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FOR THE BOARD:

RANDEL C. GIBSON, D.O. CHAIR, INQUIRY PANEL B

SARA FARMER

Assistant General Counsel Kentucky Board of Medical Licensure 310 Whittington Parkway, Suite 1B Louisville, Kentucky 40222

Tel. (502) 429-7150

COMMONWEALTH OF KENTUCKY BOARD OF MEDICAL LICENSURE CASE NO. 1355

IN RE: THE LICENSE TO PRACTICE OSTEOPATHY IN THE COMMONWEALTH OF KENTUCKY HELD BY CURTIS D. EDENS, D.O., LICENSE NO. 02610, P.O. BOX 567, LOUISA, KENTUCKY 41230-0567

AGREED ORDER

Come now the Kentucky Board of Medical Licensure ("the Board"), acting by and through its Inquiry Panel B, and Curtis D. Edens, D.O. ("the licensee"), and, based upon their mutual desire to fully and finally resolve this pending grievance without an evidentiary hearing, hereby ENTER INTO the following **AGREED ORDER**:

STIPULATIONS OF FACT

The parties stipulate the following facts, which serve as the factual bases for this Agreed Order:

- 1. At all relevant times, Curtis D. Edens, D.O., was licensed by the Board to practice osteopathy within the Commonwealth of Kentucky.
- 2. The licensee's specialty is obstetrics/gynecology.
- 3. On or about June 7, 2011, the Board received a grievance from the Chief of the Louisa Police Department which raised concerns about the licensee's operation of a pain clinic at his obstetric/gynecological practice.
- 4. In January 2011, the Louisa Police Department received four (4) calls for service at the licensee's practice location. Two calls involved domestic disturbances at the office; a third call involved an intoxicated person coming in and out of the office; and a fourth call involved a female driving to the office on a suspended license.

- 5. On or around March 3, 2011, the Louisa Police Department responded to a call regarding a female driving to or from the practice location on a suspended license. Upon arrival, the police noted that the parking area was so crowded that patients had to park in other nearby business and residential areas, creating a traffic hazard. The police also noted that numerous vehicles were from surrounding counties and several were from out of state. A stationary patrol, over the next 24-48 hours, resulted in patients being charged with nineteen (19) violations and some were arrested.
- 6. During a meeting with the Chief of the Louisa Police Department, the City Attorney, the County Attorney and the Commonwealth's attorney, the licensee disclosed that he had a DEA license to prescribe Suboxone to up to 100 patients and that he was the only licensee in the country prescribing Suboxone to pregnant women.
- 7. On or about May 31, 2011, the Louisa Police Department received a 911 hang up call from the licensee's office. When the police called back, the licensee's office reported that two female patients had been fighting. When officers responded to the scene, the licensee's office staff informed them that the women had been separated and had agreed to not bother each other again. Later that same day, a female patient called the police and reported that the licensee dismissed her from the Suboxone program after the fight and that he said that he couldn't afford the police coming around his office.
- 8. On or about June 9, 2011, Chris Johnson, R.Ph., Pharmacist Consultant, Drug Enforcement and Professional Practices Branch at the Cabinet for Health

Services, informed the Board that the Louisa Police Department had filed a similar complaint with Drug Enforcement in March 2011; that a KASPER report, dated January 1, 2010 through June 2, 2011, was reviewed in response thereto; and that the case was being referred to the Board for any action deemed necessary. Mr. Johnson identified twenty-two (22) patients of the licensee which merited further investigation. Three of those patients shared the same family name as the licensee.

- 9. In a letter to the Board, dated June 30, 2011, the licensee explained that he primarily operates an obstetrical/gynecological practice with the majority of his Suboxone patients being obstetrically-related; that, based upon representations from his Suboxone representative, he is the only physician in the country prescribing Suboxone to pregnant women; that he monitors his Suboxone patients with observed drug testing weekly along with random drug screens and pill counts; and that he does writes prescriptions for weekly supplies and does not replace reportedly-lost prescriptions.
- 10. Charts for fifteen (15) of the twenty-two (22) patients recommended for further review by Drug Enforcement Board were subpoenaed and obtained from the licensee for a consultant review.
- 11. Upon reviewing the patient charts, the licensee's KASPER report and the grievance, the consultant concluded that the licensee departed from and failed to conform to the standards of acceptable and prevailing medical practices in the Commonwealth of Kentucky in the following:

- a. Eleven (11) of the fifteen (15) charts pertained to patients who were treated with Suboxone. In each case, there was no documented initial evaluation using the clinical opiate withdrawal scale (C.O.W.S.) nor was there evidence that Suboxone was started under observation within the office.
- b. There was no documentation or other evidence of the use of KASPER, random pill counts or random urine drug screens and it was not clear whether the drug screens were observed.
- c. In two instances, urine drug screens that were positive for THC were neither documented in the progress notes nor discussed with the patients.
- d. Four pregnant patients were treated with Suboxone, although the acceptable and prevailing medical practice is to treat pregnant patients with Subutex because Suboxone may precipitate miscarriage or premature labor.
- e. In the case of one patient who allegedly suffered chronic anxiety and misused Valium throughout her pregnancy, there was no clear evaluation of the patient's anxiety, no evidence of KASPER reports and only one urine drug screen, and no timely referral to a specialist.
- f. The licensee prescribed controlled substances to three (3) of his own family members.
- 12. Other than these departures from acceptable and prevailing medical practices, the consultant noted that "...in most respects the care given by Dr. Edens was good.

 He followed his Suboxone patients carefully, and ensured that they obtained good

- counseling and with the exception of THC, dealt promptly with positive urine drug screens. Dr. Edens appears to be a good physician who could use a mentor."
- 13. In a letter to the Board, dated August 31, 2011, the licensee acknowledged that he treats his immediate and extended family and that he prescribes pain medications for his father and Suboxone for his daughter.
- 14. The American Medical Association's Code of Medical Ethics, §8.19, provides that physicians should not treat family members, except in emergency or isolated settings where there is no other qualified physician available and then only until another physician becomes available; that physicians should not serve as a regular or primary care provider for immediate family members, unless it is for care of short-term, minor problems; and that it is not appropriate for physicians to prescribe controlled substances to immediate family members, except in emergencies.
- 15. There were no circumstances in which it was appropriate for the licensee to treat and prescribe controlled substances for his family members, at the time he treated and prescribed controlled substance to them.

STIPULATED CONCLUSIONS OF LAW

The parties stipulate the following Conclusions of Law, which serve as the legal bases for this Agreed Order:

- 1. The licensee's osteopathic license is subject to regulation and discipline by the Board.
- 2. Based upon the Stipulations of Fact, the licensee has engaged in conduct which violates the provisions of KRS 311.595(9), as illustrated by KRS 311.597(4).

Accordingly, there are legal grounds for the parties to enter into this Agreed Order.

3. Pursuant to KRS 311.591(6) and 201 KAR 9:082, the parties may fully and finally resolve this pending grievance without an evidentiary hearing by entering into an informal resolution such as this Agreed Order.

AGREED ORDER

Based upon the foregoing Stipulations of Fact and Stipulated Conclusions of Law, and, based upon their mutual desire to fully and finally resolve this pending grievance without an evidentiary hearing, the parties hereby ENTER INTO the following AGREED ORDER:

- The license to practice osteopathy within the Commonwealth of Kentucky held by Curtis D. Edens, D.O., SHALL BE SUBJECT to this Agreed Order for a period of five (5) years from the date of filing of the Agreed Order.
- 2. During the effective period of this Agreed Order, the licensee's osteopathic license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS:
 - a. The licensee SHALL NOT prescribe, dispense or otherwise provide controlled substances to himself or any member of his immediate family, including his spouse, parents, children or grandchildren, siblings, or inlaws;
 - b. The licensee SHALL initially, and periodically thereafter, run KASPER reports on each patient to whom he prescribes controlled substances, including but not limited to Suboxone;

- i. The licensee SHALL NOT maintain the KASPER reports in each patient's chart;
- ii. The licensee SHALL document in each patient chart: the fact that a KASPER report was obtained, the date it was obtained, the KASPER Request Number, any problems or concerns reflected in the KASPER report and how those problems or concerns were addressed with the patient;
- c. The licensee SHALL maintain a "controlled substances log" for all controlled substances prescribed. The controlled substances log must include date, patient name, patient complaint, medication prescribed, when it was last prescribed and how much on the last visit. Note: All log sheets will be consecutively numbered, <u>legible</u> i.e. printed or typed, and must reflect "call-in" and refill information. Prescriptions should be maintained in the following manner: 1) patient; 2) chart; and 3) log;
 - The licensee SHALL permit the Board's agents to inspect, copy and/or obtain the controlled substance log and other relevant records, upon request, for review by the Board's agents and/or consultants;
 - ii. The licensee SHALL reimburse the Board fully for the costs of each consultant review performed pursuant to this Agreed Order.

 Once the Board receives the invoice from the consultant(s) for each review, it will provide the licensee with a redacted copy of that invoice, omitting the consultant's identifying information.

The licensee SHALL pay the costs noted on the invoice within thirty (30) days of the date on the Board's written notice. The licensee's failure to fully reimburse the Board within that time frame shall constitute a violation of this Agreed Order;

- iii. The licensee understands and agrees that at least one consultant review must be performed, on terms determined by the Panel or its staff, before the Panel will consider a request to terminate this Agreed Order;
- d. Within six (6) months of the filing of this Agreed Order, the licensee SHALL successfully complete the "Prescribing Controlled Drugs" course at The Center for Professional Health at Vanderbilt University Health Center, Nashville, TN, (615) 936-0678 or the University of South Florida, 3515 E. Fletcher Avenue, Tampa, Florida 33613, Tel. (813) 396-9217, at his expense;
- e. Within twenty (20) days of the filing of this Agreed Order, the licensee SHALL make all necessary arrangements to enroll in the ProBe Program at the Center for Personalized Education for Physicians (CPEP), 7351 Lowry Boulevard, Suite 100, Denver, Colorado 80230 303/577-3232, at the earliest time. The licensee shall complete the ProBe Program at the time and date(s) scheduled, at his expense;
- f. Within twenty (20) days of the filing of this Agreed Order, the licensee SHALL make all necessary arrangements to enroll in the Documentation Seminar at the Center for Personalized Education for Physicians (CPEP),

- 7351 Lowry Boulevard, Suite 100, Denver, Colorado 80230 303/577-3232, at the earliest time. The licensee shall complete the Documentation Seminar at the time and date(s) scheduled, at his expense;
- g. Following completion of the Documentation Seminar, the licensee SHALL take all necessary steps to enroll in the CPEP Personalized Implementation Program. The licensee shall complete the Personalized Implementation Program, at his expense, as directed by CPEP's staff;
 - i. The licensee SHALL provide the Board's staff with written verification that he has enrolled in the CPEP Personalized Implementation Program following the Documentation Seminar;
- h. The licensee SHALL take all steps necessary, including signing any waiver and/or consent forms required to ensure that CPEP will provide a copy of any evaluations from the ProBe Program, Documentation Seminar and Personalized Implementation Program to the Board's Legal Department promptly after their completion;
- i. The licensee SHALL provide the Board's staff with written verification that he has successfully completed the "Prescribing Controlled Drugs" course, the CPEP ProBe Program, Documentation Seminar, and the Personalized Implementation Programpromptly upon completion of each;
- j. The licensee SHALL pay the costs of the investigation in the amount of \$675.00 within six (6) months of the date of entry of this Agreed Order;
 and

- k. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.
- 3. The licensee expressly agrees that if he should violate any term or condition of this Agreed Order, the licensee's practice will constitute an immediate danger to the public health, safety, or welfare, as provided in KRS 311.592 and 13B.125. The parties further agree that if the Board should receive information that he has violated any term or condition of this Agreed Order, the Panel Chair is authorized by law to enter an Emergency Order of Suspension or Restriction immediately upon a finding of probable cause that a violation has occurred, after an ex parte presentation of the relevant facts by the Board's General Counsel or Assistant General Counsel. If the Panel Chair should issue such an Emergency Order, the parties agree and stipulate that a violation of any term or condition of this Agreed Order would render the licensee's practice an immediate danger to the health, welfare and safety of patients and the general public, pursuant to KRS 311.592 and 13B.125; accordingly, the only relevant question for any emergency hearing conducted pursuant to KRS 13B.125 would be whether the licensee violated a term or condition of this Agreed Order.
- 4. The licensee understands and agrees that any violation of the terms of this Agreed Order would provide a legal basis for additional disciplinary action, including revocation, pursuant to KRS 311.595(13) and may provide a legal basis for criminal prosecution for practicing osteopathy without a license.

SO AGREED on this 2 day of November, 2011.

FOR THE LICENSEE:

CURTIS D. EDENS, D.O.

COUNSEL FOR THE LICENSEE (IF APPLICABLE)

FOR THE BOARD:

RANDEL C. GIBSON, D.O. CHAIR, INQUIRY PANEL B

LEANNE K. DIAKOV Assistant General Counsel Kentucky Board of Medical Licensure 310 Whittington Parkway, Suite 1B

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