COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 1925

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY PAUL E. McLAUGHLIN, M.D., LICENSE NO. 24118, 250 FOXGLOVE DRIVE, SUITE 6, MT. STERLING, KENTUCKY 40353

AGREED ORDER

Come now the Kentucky Board of Medical Licensure (hereafter "the Board"), acting by and through its Inquiry Panel A, and Paul E. McLaughlin, M.D. ("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, Paul E. McLaughlin, M.D., was licensed by the Board to practice medicine within the Commonwealth of Kentucky.
2. The licensee's medical specialty is Family Medicine.
3. On or about January 9, 2019, the Commissioner of the Kentucky Department of Public Health ("KDPH") reported to the Board its investigation regarding an outbreak of vaccination reactions associated with a Montgomery County business, "Location Vaccination," which operates under and through the licensee. The KDPH stated that the outbreak was likely due to the preparation, storage and/or handling practices. The KDPH expressed concern that the primary operators, handlers and vaccinators were unlicensed medical providers, including the licensee's wife; and that when patients reported reactions, they were assessed and

prescribed antibiotics by the licensee's wife, under the licensee's name and without a physical assessment or medically appropriate cultures or susceptibility testing. According to the KDPH, the inappropriate prescribing of antibiotics could lead to serious outcomes, particularly in light of the steroid prescriptions given to several patients, and that disseminated mycobacterium infection could be fatal in the case if individuals with immune disorders. It was unclear to the KDPH whether the licensee was aware of the prescriptions being called in by his wife, but they were being submitted under his name and license.

4. On June 20, 2019, the licensee appeared before the Inquiry Panel and stated that he is not involved in the Location Vaccination business, it being operated separately and solely by his wife; that he and his wife first became aware of the outbreak during Thanksgiving week of 2018; and that it was appropriate to prescribe short term antibiotics in order to allow patients time to see their providers after the holiday. However, many of the antibiotic prescriptions under the licensee's name and license predated Thanksgiving week and the national Centers for Disease Control and Prevention ("CDC") records reflect that it was first contacted about the outbreak on November 5, 2018, the caller stating

> ... I'm reporting this from a doctor's office. We are a doctor's office in Mount Sterling, Kentucky. We had 16 patients with these abscess nodules a month after receiving the flu shot; like 3-4 weeks afterwards they're getting these big abscess nodule and they're not, um, antibiotics are not affected by it. We cultured it and it comes back negative for bacterial growth. We don't understand what the heck is going on.

5. On November 5, 2018, although the CDC instructed that the reactions be reported to the Kentucky Immunization Program in VAERS, a report was not submitted.

6. On November 13, 2018, the CDC was contacted again, the caller stating

> … I called last week about reporting a bunch of adverse events with our flu vaccine that they were getting cystic nodules. Everyone seems to be getting them. We don't understand why. And the doctor was asking if there is any way that we can like call CDC and see if they can test like our needles and syringes that we are using to see if there is something on those.

7. On November 13, 2018, although the CDC instructed that syringes may be tested at local, county and state health departments and provided information about submitting batches to the CDC, using Form 50.34, no specimens were submitted.

8. On December 4, 2018, the Clark County Health Department ("CCHD") treated three patients who reported that they received their vaccinations from Location Vaccination at the same time and location in Montgomery County. The CCHD reported the reactions to the Montgomery County Health Department ("MCHD").

9. On December 4, 2018, MCHD contacted Location Vaccination, which then confirmed the outbreak and that it had not reported into VAERS.

10. On or about December 18, 2018, the licensee was interviewed by the KDPH and it reported that the licensee confirmed to KDPH that he was aware of the reactions; stated that the CDC had been contacted but "wasn't really interested"; disclosed that he had received a vaccination in October 2018 and also suffered a reaction which resolved after treatment with antibiotics; and confirmed that he had received the regional and state alerts sent to providers and understood that he should counsel patients to seek care from their primary care providers.

11. On or about December 20, 2018, KDPH sent a letter to each company where employees received vaccinations through Location Vaccination and began receiving calls from patients who reported to the KDPH that they were being

contacted for treatment by the licensee's wife directly to have antibiotics and steroid prescriptions called-in, without any physical assessment or testing, and offering to pay for medical treatment.

12. On June 20, 2019, the licensee appeared before the Inquiry Panel, which opined that the licensee's blanket delegation of his professional and medical responsibilities to an unqualified and unlicensed person without sufficient oversight, and his failure to evaluate, treat and report the patients with adverse vaccinations reactions appropriately, constitutes a failure to conform to prevailing medical practices in the Commonwealth of Kentucky and contributed to a public health crisis.

13. The licensee denies that he delegated his professional or medical responsibilities or that he inappropriately responded to the vaccination reactions when he became aware of 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 medical 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(11). 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 investigation without an evidentiary hearing, the parties hereby ENTER INTO the following **AGREED ORDER:**

1. The license to practice medicine held by Paul E. McLaughlin, M.D., is hereby PLACED ON PROBATION FOR A PERIOD OF FIVE (5) YEARS, with that period of probation to become effective immediately upon the filing of this Agreed Order.

2. During the effective period of this Agreed Order, the licensee's medical license SHALL BE SUBJECT TO THE FOLLOWING TERMS AND CONDITIONS:

    a. Within twenty (20) days of the filing of this Agreed Order, the licensee SHALL make all necessary arrangements to enroll in the *ProBE* Program offered through the Center for Personalized Education for Professionals (CPEP), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232, at the earliest time available;

        i. The licensee SHALL complete and "unconditionally pass" the *ProBE* Program at the time and date(s) scheduled, at his expense and as directed by CPEP's staff;
        ii. The licensee SHALL provide the Board's staff with written verification that he has completed and "unconditionally passed" CPEP's *ProBE* Program, promptly after completing the program;
        iii. 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, reports or essays from the *ProBE* Program to the Board's Legal Department promptly after their completion;

b. Within sixty (60) days of the filing of this Agreed Order, the licensee SHALL complete at least five (5) hours of continuing medical education, certified in Category I, on a subject related to the administration of vaccines and follow up in the event of adverse vaccination reactions;

c. Within sixty (60) days of the filing of this Agreed Order, the licensee SHALL develop a written policy regarding the storage and administration of vaccines and protocols for follow up in the event of adverse vaccination reactions;

d. Within five (5) years of the filing of this Agreed Order, the licensee SHALL submit payment of a FINE in the amount of five-thousand dollars ($5,000) pursuant to KRS 311.565(1)(v);

e. Within five (5) years of the filing of this Agreed Order, the licensee SHALL REIMBURSE the Board the amount of one-thousand seven hundred and ninety-three dollars and seventy-five cents ($1,793.75) pursuant to KRS 311.565(1)(v); and

f. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.

3. The licensee expressly understands and 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 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).

SO AGREED on this 9TH day of JULY, 2019.

FOR THE LICENSEE:

PAUL E. McLAUGHLIN, M.D.

TRACY S. PREWITT, ESQ.
COUNSEL FOR THE LICENSEE

FOR THE BOARD:

DALE E. TONEY, M.D.
CHAIR, INQUIRY PANEL A

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