IN THE MATTER OF

\* BEFORE THE

KENNETH A. CARLE, M.D.

MARYLAND STATE

Respondent

\* BOARD OF PHYSICIANS

License Number: D42164

. . .

Case Number: 2220-0129

\* \* \* \* \* \* \* \* \*

## CONSENT ORDER

On August 1, 2022, Disciplinary Panel A ("Panel A") of the Maryland State Board of Physicians (the "Board") charged **KENNETH A. CARLE, M.D.,** ("the Respondent"), License Number D42164, under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 14-101 *et seq.* (2021 Repl. Vol.). The Respondent is charged under the following provisions of the Act:

# Health Occ. § 14-404. License denial, suspension, or revocation.

- (a) In general. Subject to the hearing provisions of § 14-405 of this subtitle, a disciplinary panel, on the affirmative vote of a majority of the quorum of the disciplinary panel, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:
  - (22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State; [and]
  - (40) Fails to keep adequate medical records as determined by appropriate peer review [.]

On February 9, 2023, Panel A was convened as a Disciplinary Committee for Case Resolution ("DCCR") in this matter. Based on negotiations occurring as a result of this DCCR, the Respondent agreed to enter into this Consent Order, consisting of Findings of Fact, Conclusions of Law, Order, and Consent.

## FINDINGS OF FACT

Disciplinary Panel A finds the following:

## I. BACKGROUND

- 1. At all times relevant to the charges, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent was initially licensed to practice on August 19, 1991, under license number D42164. The Respondent's license is presently active and expires on September 30, 2024.
  - 2. The Respondent is board-certified in anesthesiology and pain medicine.
- 3. The Respondent owns and operates a pain management center in Baltimore County, Maryland, where he practices pain management. The Respondent maintains hospital privileges at a hospital in Baltimore County.
- 4. On or about September 19, 2019, the Board received a referral (the "Referral") from the Office of Controlled Substances Administration ("OCSA") regarding the Respondent. The Referral stated that "OCSA Inspectors have noticed a concerning prescribing pattern from [the Respondent] over the past several years involving high dosage

<sup>&</sup>lt;sup>1</sup> To ensure confidentiality and privacy, the names of individuals, patients and institutions involved in this case are not disclosed in this Consent Order.

opioids/two or more immediate release opioids for one patient and dangerous cocktails of opioids with benzodiazepines and/or amphetamines."

- 5. The Referral further stated that, on or about August 26, 2019, OCSA conducted an inspection of a pharmacy in Baltimore County during which OCSA Inspectors noticed "that the majority of prescriptions written by [the Respondent] had red flags."
- 6. OCSA obtained a dispensing report that showed "all prescriptions of [the Respondent's] that were dispensed from this pharmacy between August 27, 2018 and August 26, 2019." The dispensing report included the following information regarding the Respondent's prescriptions:
  - a. "A total of 47 patients were on the report and 70% (33 patients) were on an opioid dosage greater than 90 MME's[]";<sup>2</sup>
  - b. "One patient was prescribed alprazolam 1mg #60, oxycodone 30mg #60, oxycodone 15 mg #20, oxycodone 15mg #40 in the first part of August and on August 26<sup>th</sup> he was prescribed Zubsolv 5.7/1.4mg #60[]";
  - c. "Several of his patients are getting high doses of opioids in combination with other sedating medications, such as benzodiazepines, or in combination with stimulants[]";
  - d. "There are two patients with the same last name... who are prescribed high strength and quantity opioids and the pharmacist states that they are brothers. One brother gets a daily dosage of 390 MME's and the other gets a daily dosage of 470 MME's[]";
  - e. "There are four patients who are prescribed medications that appear to be outside of his scope of practice. One patient is getting ER and IR amphetamines, and three patients are getting long term benzodiazepines[]";

<sup>&</sup>lt;sup>2</sup> "MME" stands for "morphine milligram equivalents."

f. "Several of [the Respondent's] patients receive their short acting opioid as two prescriptions, one that gets filled with insurance and one that does not. For example, the patient . . . was prescribed 30mg #130 and oxycodone 30mg #50 every month."

#### II. BOARD INVESTIGATION

- 7. Based on the Referral, the Board initiated an investigation.
- 8. On or about February 10, 2020, the Board notified the Respondent about the Referral and requested that he provide a written response to the allegations. The Board enclosed a *subpoena duces tecum* and Certification of Medical Records forms. The *subpoena duces tecum* directed the Respondent to produce the complete medical records for 11 named patients to the Board within 10 business days.
- 9. On or about February 20, 2020, the Board received the Respondent's response to the allegations, medical records for the 11 named patients, and signed Certification of Medical Records forms.

#### A. Peer Review

- 10. On or about July 15, 2020, the Board referred the 11 patient records obtained through its investigation to a peer review entity for review. Two peer reviewers, each board-certified in pain medicine and anesthesiology, separately reviewed the patient records.
- 11. On or about November 9, 2020, the Board received the peer reviewers' completed reports.

- 12. The peer reviewers concurred that the Respondent failed to meet appropriate standards for the delivery of quality medical and surgical care for nine out of 10 patients<sup>3</sup> (Patients 1, 2, 3, 5, 6, 7, 8, 9, and 10). The peer reviewers cited the following reasons, among others, for their conclusion that the Respondent did not meet the standards for the delivery of quality medical care:
  - a. Maintained patients on high dose opioids as first line therapy, not consistent with Centers for Disease Control and Prevention ("CDC") guidelines (Patients: 1, 2, 3, 5, 6, 7, 8, 9 and 10);
  - b. Utilized high dose opioid therapy; high-dose, short-acting opioid therapy; and other medications, such as Adderall, without appropriate or sufficient clinical or diagnostic findings (Patients: 1, 2, 3, 7, 9 and 10);
  - c. Failed to utilize follow-up imaging to corroborate the need for continued pain management (Patients: 3, 5, 7, 9 and 10);
  - d. Prescribed high dose opioid therapy in conjunction with benzodiazepines (Patients: 2, 3 and 6);
  - e. Failed to implement consistent compliance monitoring practices (Patients: 2, 3, 5, 6, 7, 8, 9 and 10);
  - f. Failed to consider and/or recommend alternative modalities or adjuvant medications for chronic pain treatment (Patients: 1, 2, 3, 5, 6, 7, 8, 9 and 10);
- 13. The peer reviewers also concurred that the Respondent failed to maintain adequate medical records for seven out of 10 patients (Patients 3, 5, 6, 7, 8, 9, and 10). The

<sup>&</sup>lt;sup>3</sup> Through its investigation, the Board determined that one of the patients included in the *subpoena duces* tecum was not a patient of the Respondent.

peer reviewers cited the following reasons, among others, for their conclusion that the Respondent failed to maintain adequate medical records:

- a. The Respondent maintained patient records with apparent treatment date gaps (Patients: 3, 5, 6, 7, 8, 9 and 10);
- b. Some of the Respondent's clinic notes were vague and/or absent (Patients: 5, 6, 8 and 9);
- c. The Respondent failed to document consistent compliance monitoring practices (Patients: 3, 5, 6, 7, 8, 9 and 10).

# B. The Respondent's Response

14. The Board provided the peer reviewers' reports to the Respondent and gave him an opportunity to review and respond to the reports. On or about December 3, 2020, the Board received the Respondent's written response. In his response, the Respondent stated that the 2016 CDC Guidelines "are erroneously being applied to chronic pain patients, not just opiate naïve patients who were the target of the guidelines." The Respondent further stated:

Of the 2000 patients I treat, approximately 150 are maintained on high dose opiates. That accounts for 7% of my practice. All patients on high doses are "Legacy Patients" meaning their high doses were prescribed before the CDC guidelines came out in 2016. . . . In the future, by following the guidelines for opioid naïve patients, we will not have patients on high doses. Until then, we cannot abandon the [l]egacy patients who are functioning thanks to the high-dose opioids prescribed.

## **CONCLUSIONS OF LAW**

Based on the foregoing Findings of Fact, Panel A concludes as a matter of law that the Respondent is guilty of failing to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care, in violation of Health Occ. § 14-404(a)(22); and failing to keep adequate medical records as determined by appropriate peer review, in violation of Health Occ. § 14-404(a)(40).

## **ORDER**

It is thus by a majority of a quorum of Disciplinary Panel A of the Board hereby:

ORDERED that the Respondent is REPRIMANDED; and it is further

ORDERED that the Respondent's license to practice medicine is SUSPENDED for a minimum of TEN DAYS and until the terms and conditions of the suspension have been met; and it is further

**ORDERED** that during the suspension, the Respondent shall comply with the following terms and conditions of the suspension:

- a. The suspension goes into effect THIRTY CALENDAR DAYS after the effective date of this Consent Order to facilitate the transition of patients to other providers as needed;
- b. Prior to termination of the suspension, the Respondent shall provide the disciplinary panel with the name, pertinent professional background information of the supervisor whom the Respondent is offering for approval, and written notice to the disciplinary panel from the supervisor confirming his or her acceptance of the supervisory role of the Respondent and that there is no personal or professional relationship with the supervisor;
- c. During the suspension period, the Respondent shall not:
  - (1) practice medicine;
  - (2) take any actions after the effective date of this Order to hold himself or herself out to the public as a current provider of medical services;

- (3) authorize, allow or condone the use of the Respondent's name or provider number by any health care practice or any other licensee or health care provider;
- (4) function as a peer reviewer for the Board or for any hospital or other medical care facility in the state;
- (5) prescribe or dispense medications;
- (6) supervise physician assistants; or
- (6) perform any other act that requires an active medical license; and it is further

ORDERED that after the minimum period of suspension imposed by the Consent Order has passed and the Respondent has fully and satisfactorily complied with all terms and conditions for the suspension, the Respondent may submit a written petition for termination of suspension. After determination that the Respondent has complied with the relevant terms of the Suspension, the disciplinary panel may administratively terminate the Respondent's suspension through an order of the disciplinary panel. Upon termination, the Respondent is placed on **PROBATION** for a minimum period of **TWO YEARS**. During the probationary period the Respondent shall comply with the following probationary terms and conditions:

- (1) The Respondent shall be subject to supervision for **TWO YEARS** (eight quarterly reports)<sup>4</sup> by a disciplinary panel-approved supervisor who is board-certified in pain medicine as follows:
  - (a) within 40 CALENDAR DAYS of the effective date of this Consent Order, the Respondent shall provide the disciplinary panel with the name, pertinent professional background information of the supervisor whom the Respondent is offering for approval, and written notice to the disciplinary panel from the supervisor confirming his or her acceptance of the supervisory role of the Respondent and that there is no personal or professional relationship with the supervisor;

<sup>&</sup>lt;sup>4</sup> If the Respondent is not practicing medicine, the supervision shall begin when the Respondent resumes the practice of medicine, and the disciplinary panel has approved the proposed supervisor. The Respondent shall submit the name of a proposed supervisor within 30 days of resuming the practice of medicine and shall be subject to supervision by a disciplinary panel approved supervisor upon the return to the practice of medicine.

- (b) the Respondent's proposed supervisor, to the best of the Respondent's knowledge, should not be an individual who is currently under investigation, and has not been disciplined by the Board within the past five years;
- (c) if the Respondent fails to provide a proposed supervisor's name, the Respondent's suspension will not be terminated;
- (d) the disciplinary panel, in its discretion, may accept the proposed supervisor or request that the Respondent submit a name and professional background, and written notice of confirmation from a different supervisor;
- (e) the supervision begins after the disciplinary panel approves the proposed supervisor;
- (f) the disciplinary panel will provide the supervisor with a copy of this Consent Order and any other documents the disciplinary panel deems relevant;
- (g) the Respondent shall grant the supervisor access to patient records selected by the supervisor from a list of all patients, which shall, to the extent practicable, focus on the type of treatment at issue in the Respondent's charges;
- (h) if the supervisor for any reason ceases to provide supervision, the Respondent shall immediately notify the Board and shall not practice medicine beyond the 30<sup>th</sup> day after the supervisor has ceased to provide supervision and until the Respondent has submitted the name and professional background, and written notice of confirmation, from a proposed replacement supervisor to the disciplinary panel;
- (i) it shall be the Respondent's responsibility to ensure that the supervisor:
  - (1) reviews the records of 10 patients each month, such patient records to be chosen by the supervisor and not the Respondent;
  - (2) meets in-person with the Respondent at least once each month and discuss in-person with the Respondent the care the Respondent has provided for these specific patients;
  - (3) be available to the Respondent for consultations on any patient;
  - (4) maintains the confidentiality of all medical records and patient information;
  - (5) provides the Board with quarterly reports which detail the quality of the Respondent's practice, any deficiencies, concerns, or needed improvements, as well as any measures that have been taken to improve patient care; and
  - (6) immediately reports to the Board any indication that the Respondent may pose a substantial risk to patients;
- (j) the Respondent shall follow any recommendations of the supervisor;
- (k) if the disciplinary panel, upon consideration of the supervisory reports and the Respondent's response, if any, has a reasonable basis to believe that the Respondent is not meeting the standard of quality care or failing to keep adequate medical records in his or her practice, the disciplinary panel may find a violation of probation after a hearing;
- (2) Within TWO MONTHS from the beginning of the probationary period, the Respondent is required to take and successfully complete two courses, a course in

CDS prescribing and a course in medical recordkeeping. The Respondent may complete these courses any time after the Consent Order is signed, even prior to the commencement of probation. The following terms apply:

- (a) It is the Respondent's responsibility to locate, enroll in and obtain the disciplinary panel's approval of the courses before the courses are begun;
- (b) The Respondent must provide documentation to the disciplinary panel that he has successfully completed the courses;
- (c) The courses may not be used to fulfill the continuing medical education credits required for license renewal;
- (d) The Respondent is responsible for the cost of the courses; and it is further

ORDERED that, after the Respondent has complied with all terms and conditions of probation, the Respondent may submit a written petition for termination of probation. The Respondent's probation may be administratively terminated through an order of the disciplinary panel if the Respondent has complied with all probationary terms and conditions including receiving four satisfactory supervisory reports and there are no pending complaints relating to the charges, but will not be terminated unless the Board has received four satisfactory supervisory reports; and it is further

**ORDERED** that the Respondent is responsible for all costs incurred in fulfilling the terms and conditions of this Final Decision and Order; and it is further

ORDERED that, if the Respondent allegedly fails to comply with any term or condition imposed by this Final Decision and Order including if the reports of the supervisor do not demonstrate that the Respondent meets appropriate standards of care or adequate medical recordkeeping, the Respondent shall be given notice and an opportunity for a hearing. If the disciplinary panel determines there is a genuine dispute as to a material fact, the hearing shall be before an Administrative Law Judge of the Office of Administrative Hearings followed by an exceptions process before a disciplinary panel; and if the disciplinary panel determines there is no genuine dispute as to a material fact, Respondent shall be given a show cause hearing before a disciplinary panel; and it is further

ORDERED that, after the appropriate hearing, if the disciplinary panel determines that the Respondent has failed to comply with any term or condition imposed by this Final Decision and Order, the disciplinary panel may reprimand the Respondent, place the Respondent on probation with appropriate terms and conditions, or suspend with appropriate terms and conditions, or revoke the Respondent's license to practice medicine in Maryland. The disciplinary panel may, in addition to one or more of the sanctions set forth above, impose a civil monetary fine on the Respondent; and it is further

ORDERED that the disciplinary panel may issue administrative subpoenas to the Maryland Prescription Drug Monitoring Program on a quarterly basis for the Respondent's Controlled Dangerous Substances ("CDS") prescriptions. The administrative subpoenas will request the Respondent's CDS prescriptions from the beginning of each quarter; and it is further

ORDERED that within ONE YEAR, the Respondent shall pay a \$7,500 fine to be paid by certified check or money order payable to The Maryland Board of Physicians, P.O. Box 37217, Baltimore, Maryland 21297. The Board will not renew or reinstate the Respondent's license if the Respondent fails to timely pay the fine to the Board; and it is further

ORDERED that the effective date of the Consent Order is the date the Consent Order is signed by the Executive Director of the Board or her designee. The Executive Director or her designee signs the Consent Order on behalf of the disciplinary panel which has imposed the terms and conditions of this Consent Order; and it is further

**ORDERED** that this Consent Order is a public document. See Health Occ. §§ 1-607, 14-411.1(b)(2) and Gen. Prov. § 4-333(b)(6).

5/5/2033 Date Signature on File

Ellen Douglas Smith
Deputy Director
Maryland State Board of Physicians

#### CONSENT

I, Kenneth A. Carle, M.D., acknowledge that I have consulted with counsel before signing this document.

By this Consent, I agree to be bound by this Consent Order and all its terms and conditions and understand that the disciplinary panel will not entertain any request for amendments or modifications to any condition.

I assert that I am aware of my right to a formal evidentiary hearing, pursuant to Md. Code Ann., Health Occ. § 14-405 and Md. Code Ann., State Gov't §§ 10-201 et seq. concerning the pending charges. I waive this right and have elected to sign this Consent Order instead.

I acknowledge the validity and enforceability of this Consent Order as if entered after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my behalf, and to all other substantive and procedural protections as provided by law. I waive those procedural and substantive protections. I acknowledge the legal authority and the jurisdiction of the disciplinary panel to initiate these proceedings and to issue and enforce this Consent Order.

I voluntarily enter into and agree to comply with the terms and conditions set forth in the Consent Order as a resolution of the charges. I waive any right to contest the Findings of Fact and Conclusions of Law and Order set out in the Consent Order. I waive all rights to appeal this Consent Order.

I sign this Consent Order, without reservation, and fully understand the language and meaning of its terms.

Signature on File

5-3-2023

Date

Kenneth A. Carle, M.D.

# **NOTARY**

STATE OF Mary	land		
CITY/COUNTY OF	Baltimore		
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I HEREBY CERTIFY th	nat on this $3^{20}$	$\_$ day of $\_\_$ $\bigcirc$ $\bigcirc$	
$202^{\circ}$ , before me, a Notary Publ	ic of the State and	County aforesaid,	personally appeared
Kenneth A. Carle, M.D., and gave	e oath in due form	of law that the fore	going Consent Order
was his voluntary act and deed.			
AS WITNESS, my hand and N	otary Seal.	angulas	Mays
ORE COUNTIN	No	otary Public	U
My Commission Expires:	18/2024		