IN THE MATTER OF * BEFORE THE

HARRY L. SERNAKER, M.D. * MARYLAND STATE

Respondent * BOARD OF PHYSICIANS

License Number: D43515 * Case Number: 2218-0112B

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CONSENT ORDER

On October 16, 2018, Disciplinary Panel B of the Maryland State Board of Physicians (the "Board") charged **HARRY L. SERNAKER, M.D.** (the "Respondent"), License Number D43515, with violating the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. ("Health Occ.") §§ 14-101 *et seq.* (2014 Repl. Vol. and 2017 Supp.).

Disciplinary Panel B charged the Respondent with violating the following provisions of the Act under Health Occ. § 14-404:

- (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 27, 2019, a hearing was held before Panel B, sitting as a Disciplinary Committee for Case Resolution. As a result of negotiations occurring before Panel B, the Respondent agreed to enter into the following Consent Order, consisting of Procedural Background, Findings of Fact, Conclusions of Law, Order, Consent and Notary.

FINDINGS OF FACT

Panel B makes the following Findings of Fact:

I. Licensing Information

- 1. At all times relevant hereto, the Respondent was and is licensed to practice medicine in the State of Maryland. The Respondent was initially licensed to practice medicine in Maryland on July 8, 1992, under License Number D43515. The Respondent's license is currently active and is scheduled for renewal on September 30, 2019.
- 2. The Respondent is board-certified in anesthesiology with a sub-specialty certification in pain medicine.

II. Prior Disciplinary History

The 1998 Consent Order

3. On or about February 1, 1995, the Board (then called the "Maryland State Board of Physician Quality Assurance")¹ received a report from a health care facility² that it had limited the Respondent's medical staff privileges because of "concerns with

¹ The Maryland State Board of Physician Quality Assurance was reconstituted and renamed the Maryland State Board of Physicians in 2003.

² For confidentiality reasons, the names of health care facilities, complainants or patients will not be identified in this document. The Respondent is aware of the identity of all health care facilities, complainants and patients referenced herein.

unacceptable, unprofessional behavior, several episodes of infections in patients, [and] multiple re-implantation of devices not intended for re-implantation."

- 4. The Board initiated an investigation of this matter and on or about July 23, 1997, issued disciplinary charges against the Respondent, alleging that he violated a provision of the Act.
- 5. The Respondent resolved these charges by entering into a Consent Order with the Board, dated September 2, 1998 (the "1998 Consent Order"), in which the Board found as a matter of law that the Respondent failed 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). The Board suspended the Respondent's medical license for one year, with all but six months of the suspension stayed, effective September 21, 1998. After the six-month active suspension of licensure concluded, the Board placed the Respondent on probation for three years, subject to probationary terms and conditions including practice restrictions, practice supervision, medical remediation, and peer review.
- 6. On or about February 7, 2005, the Board issued an order entitled, *Termination of Probation*, in which it terminated the probation it had imposed under its 1998 Consent Order.

The 2008 Consent Order

7. In or around July 2006, the Board initiated a new review of the Respondent's practice and on or about December 18, 2007, issued disciplinary charges against him, alleging that he violated a provision of the Act.

- 8. The Respondent resolved these charges by entering into a Consent Order with the Board, dated March 27, 2008 (the "2008 Consent Order"), in which the Board found as a matter of law that the Respondent failed to keep adequate medical records as determined by appropriate peer review, in violation of Health Occ. § 14-404(a)(40). The Board reprimanded the Respondent and placed him on probation for a minimum of two years, subject to probationary terms and conditions including successful completion of a one-on-one tutorial in medical recordkeeping.
- 9. On or about November 3, 2011, the Board issued an order entitled, *Order Terminating Probation*, in which it terminated the probation it had imposed under its 2008 Consent Order.

III. Complaints

Complaint # 1

10. The Board initiated a new investigation of the Respondent after reviewing an anonymous complaint, dated November 3, 2017, from an individual ("Complainant # 1") who alleged that the Respondent was treating a patient ("Patient 1," *infra*) with a "dangerously high regimen of opioids at this time" that was "well above CDC guidelines." Complainant # 1 reported that the Respondent's prescribing regimen for Patient 1 included: morphine ER 100 mg (a narcotic analgesic and Schedule II controlled dangerous substance, or "CDS"); morphine ER 60 mg (a narcotic analgesic and Schedule II CDS); diazepam 5 mg (a benzodiazepine and Schedule IV CDS); and butalbital with codeine # 3 (a narcotic analgesic and Schedule III CDS). Complainant # 1 stated that the

Respondent's opioid prescribing regimen was equivalent to over 570 morphine milligram equivalents ("MMEs") per day.

Complaint # 2

11. While investigating the above complaint, the Board, on or about March 2, 2018, received a second complaint from an individual ("Complainant # 2") who also questioned the Respondent's prescribing practices. Complainant # 2 raised concerns about the Respondent's judgment in prescribing significant quantities of opioid medications (*e.g.*, oxycodone 30 mg every six hours) to her family member ("Patient 11," *infra*), who had a substance abuse disorder.

III. Investigative Findings

12. As part of its investigation, the Board obtained eleven patient records involving individuals to whom the Respondent provided high-dose opioid treatment. The Respondent provided chronic pain treatment for these patients from in or around 2012 to in or around 2017. In these cases, the Respondent, often for a period of years, prescribed alone or in combination, immediate and extended release narcotic analgesics and other medications. In each case presented the MME exceeded 100, and the average MME exceeded 500. In some of the cases, the Respondent prescribed this opioid regimen in conjunction with benzodiazepines and other medications with high abuse potential. The Board also obtained written responses to the complaints and summaries of care from the Respondent and interviewed him under oath. The Board submitted the eleven patient records and related materials to two physicians who are board-certified in anesthesiology with sub-specialty certifications in pain medicine for a practice review.

- 13. The reviewers independently concluded that in all eleven cases (Patients 1-11), the Respondent failed to meet appropriate standards for the delivery of quality medical care, and that in nine of the eleven cases (Patients 1-8, 10), failed to keep adequate medical records.
- 14. The Respondent failed to meet appropriate standards for the delivery of quality medical care, in violation of Health Occ. § 14-404(a)(22) of the Act, with respect to Patients 1 through 11, and failed to keep adequate medical records, in violation of Health Occ. § 14-404(a)(40) of the Act, with respect to Patients 1 through 8, and Patient 10. The Respondent:
 - (a) inappropriately prescribed immediate release and extended release opioid medications in dosages that far exceeded 90 MMEs (Patients 1-11);
 - (b) failed to establish or document a clear rationale for maintaining patients on high-dose opioid regimens. The Respondent employed an office note form that does not provide for, document or convey adequately the Respondent's thought processes or rationale for maintaining patients on extended high-dose opioid regimens (Patients 1-11);
 - (c) failed to establish or document a clear rationale or thought processes when renewing or modifying opioid prescriptions (Patients 1-11);
 - (d) failed to order compliance measures, such as urine toxicology screening, at appropriate intervals, or employed such measures at insufficient intervals, particularly in view of the high-dose opioid regimens prescribed (Patients 1-10);

- (e) failed to order toxicology screening for certain prescribed opioids (e.g., fentanyl) (Patient 2);
- (f) failed to address inconsistent or unexpected toxicology screening results based on opioid medications prescribed (Patients 2, 3, 4, 9);
- (g) failed to obtain diagnostic studies (e.g., radiographic imaging, nerve conduction tests), or failed to obtain current or updated studies (Patients 6, 7, 8, 10);
- (h) continued to prescribe high-dose opioids to patients whose diagnostic studies did not support such prescribing (Patients 5, 7, 11);
- (i) failed to refer patients for surgical consultation or alternative therapies such as physical therapy, injection therapy, or cognitive behavioral therapy (Patients 1, 4, 6, 7, 8, 9, 11);
- (j) failed to refer patients for psychotherapy treatment for whom screening tool suggested psychopathology (Patients 2, 4);
- (k) prescribed excessive dosages of immediate release opioid medications (e.g., oxycodone 30 mg) for breakthrough pain (Patients 2, 6, 8);
- (l) prescribed excessive dosages of immediate release opioid medications to be taken around the clock (e.g., oxycodone 30 mg, five times daily) (Patient 10);
- (m) failed to address or document a patient's violation of an opioid agreement (Patient 5);

- (n) continued to prescribe high-dose opioid medications to a patient after the patient's disease process (malignancy) was documented to be in complete remission according to a consultant (Patient 3);
- (o) failed to address or document a patient's termination from another pain management practice (Patient 3);
- (p) failed to act on a consultant's recommendation that a patient's opioid regimen be tapered (Patient 3); and
- (q) failed to act on a consultant's recommendation that a patient's benzodiazepine prescription be discontinued (Patient 1).

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, Panel A finds as a matter of law that the Respondent violated Health Occ. § 14-404(a): (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.

ORDER

It is thus by Disciplinary Panel A of the Board, hereby:

ORDERED that the Respondent is **REPRIMANDED**; and it is further

ORDERED that the Respondent is placed on probation for a minimum period of **three (3) years.** During probation, the Respondent shall comply with the following terms and conditions of probation:

- 1. Within one (1) year of the effective date of this Consent Order, the Respondent is required to take and successfully complete **two** panel-approved courses: one in medical recordkeeping and a separate course in prescribing of Controlled Dangerous Substances. The following terms apply to both courses:
 - (a) it is the Respondent's responsibility to locate, enroll in and obtain the disciplinary panel's approval of the course before the course is begun;
 - (b) the disciplinary panel will not accept a course taken over the internet;
 - (c) the Respondent must provide documentation to the disciplinary panel that the Respondent has successfully completed the course;
 - (d) the course may not be used to fulfill the continuing medical education credits required for license renewal;
 - (e) the Respondent is responsible for the cost of the course.
- 2. The Respondent shall be subject to supervision during the three-year probationary period by a disciplinary panel-approved supervisor who is board-certified in pain medicine or in anesthesiology with a subspecialty certification in pain medicine, as follows:
 - (a) within **THIRTY** (30) calendar days of the effective date of this Consent Order, the Respondent shall provide the disciplinary panel with the name, pertinent professional

³ If the Respondent's license expires while the Respondent is on probation, the probationary period and any probationary conditions will be tolled.

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;

- (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 within 30 days from the effective date of this Consent Order, the Respondent's license shall be automatically suspended from the 31st day until the Respondent provides the name and background of a supervisor;
- (d) the disciplinary panel, in its discretion, may accept the proposed supervisor or request that the Respondent submit a name and professional background of a different supervisor, and written notice of confirmation;
- (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, 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 30th day after the supervisor has ceased to provide supervision and until the disciplinary panel has received a submission from the Respondent with the name and professional background of a proposed replacement supervisor, and written notice of confirmation, as set forth in Condition 2(a), *infra*;

- (i) it shall be the Respondent's responsibility to ensure that the supervisor:
 - (i) reviews the records of ten (10) patients each month, such patient records to be chosen by the supervisor and not the Respondent;
 - (ii) meets in-person with the Respondent at least once each month and discusses in-person with the Respondent the care the Respondent has provided for these specific patients;
 - (iii) be available to the Respondent for consultations on any patient;
 - (iv) maintains the confidentiality of all medical records and patient information;
 - (v) 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
 - (vi) immediately reports to the Board any indication that the Respondent may pose a substantial risk to patients.
- 3. 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 subpoena will request the Respondent's CDS prescriptions from the beginning of each quarter.
- 4. During probation the Respondent is prohibited from certifying patients for the medical use of cannabis.

- 5. The Respondent shall comply with the Maryland Medical Practice Act, Md. Code Ann., Health Occ. §§ 14-101—14-702, and all federal and state laws and regulations governing the practice of medicine in Maryland.
 - 6. The Respondent shall not apply for early termination of probation.

AND IT IS FURTHER ORDERED that a violation of probation constitutes a violation of the Consent Order; and it is further

ORDERED that if the Respondent allegedly fails to comply with any term or condition imposed by this Consent Order, the Respondent shall be given notice and an opportunity for a hearing. If 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 there is no genuine dispute as to a material fact, the 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 Consent Order, the disciplinary panel may reprimand the Respondent, place the Respondent on probation with appropriate terms and conditions, or suspend 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 after the Respondent has complied with all terms and conditions of probation and the minimum period of three (3) years of probation imposed by the Consent Order has passed, the Respondent may submit a written petition for termination of probation. After consideration of the petition, the Respondent's probation may be terminated through an order of the disciplinary panel. The Respondent may be required to appear before the disciplinary panel to discuss his petition for termination. The disciplinary panel may grant the petition to terminate the probation, through an order of the disciplinary panel if the Respondent has complied with all probationary terms and conditions and there are no pending complaints relating to the charges; and it is further

ORDERED that the Respondent is responsible for all costs incurred in fulfilling the terms and conditions of this Consent Order; 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 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* Md. Code Ann., Health Occ. §§ 1-607, 14-411.1(b)(2) and Gen. Prov. § 4-333(b)(6).

03/14/2019 Date

Christine A. Farrelly

Executive Director

Maryland State Board of Physicians

CONSENT

I, Harry L. Sernaker, 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 these rights 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 their 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 understands the language and meaning of its terms.

Signature on File

3	11/19	
Date		

Harry L. Sernaker, M.D. Respondent

Read and approved:

M. Patalie M. Gherry Counsel for Dr. Sernaker

NOTARY

STATE OF MARY LAND CITY/COUNTY OF BAltimore

I HEREBY CERTIFY that on this _______ day of _______ 2019, before me, a Notary Public of the foregoing State and City/County, personally appeared Harry L. Sernaker, M.D., and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed.

AS WITNESSETH my hand and notarial seal.

My Commission expires: $\frac{|\lambda|}{2|\lambda|}$