IN THE MATTER OF

* BEFORE THE

RUWANI GUNAWARDANE, M.D.

MARYLAND STATE

Respondent

* BOARD OF PHYSICIANS

License Number: D47119

Case Number: 2016-0562A

CONSENT ORDER

PROCEDURAL BACKGROUND

Disciplinary Panel A of the Maryland State Board of Physicians (the "Board"), charged **RUWANI GUNAWARDANE**, **M.D.** (the "Respondent"), License Number D47119 under the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. II ("Health Occ. II") §§ 14-101 *et seq.* (2014 Repl. Vol. & 2016 Supp.). The Respondent was charged under the following provisions of Health Occ. II § 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 is:
 - (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;
 - (40) Fails to keep adequate medical records as determined by appropriate peer review[.]

On or about April 11, 2018, a Disciplinary Committee for Case Resolution (DCCR) was held at the Board's office. Following the DCCR, 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

Disciplinary Panel A makes the following Findings of Fact:

I. BACKGROUND

- 1. At all relevant times, the Respondent was and is a physician licensed to practice medicine in the State of Maryland. She was initially licensed in Maryland on March 23, 1995. Her license is presently active and is scheduled to expire on September 30, 2018.
- 2. The Respondent is board-certified in psychiatry, neurology and vascular neurology.
- 3. The Respondent maintains clinical privileges at Hospital A in Maryland. 1
- 4. The Respondent currently works in a private practice in Fulton, Maryland.
- 5. On or about January 28, 2016, the Board received a complaint from a physician ("Complainant") alleging that the Respondent may have misdiagnosed a patient ("Patient A") with multiple sclerosis and inappropriately prescribed an aggressive medication therapy.
- 6. Thereafter, the Board initiated an investigation.
- 7. On or about March 7, 2016, the Board issued a subpoena to the Complainant for Patient A's medical record.
- 8. On or about March 16, 2016, a member of the Board's staff interviewed the Complainant.
- 9. On or about March 21, 2016, the Board notified the Respondent of its investigation and issued a subpoena to the Respondent for Patient A's medical record, a certification of medical record form and a request for a written response.

¹ In order to maintain confidentiality, names will not be used in this Consent Order. The Respondent may obtain a list of the names referenced in the Consent Order by contacting the Administrative Prosecutor.

- 10. On or about March 21, 2016, the Board issued subpoenas to various pharmacies for drug surveys. Specifically, the Board requested from the pharmacies a list of all prescriptions written by the Respondent from January 1, 2015 through the date of the subpoena.
- 11. On or about April 15, 2016, the Board received the Respondent's written response. The Respondent stated that she believes that her diagnosis of Patient A is appropriate and that she "evaluated and treated Patient A properly with different standard therapies all approved by the FDA [Food and Drug Administration]."
- 12. On or about May 23, 2016, the Board issued a subpoena to the Respondent for nine additional patient medical records chosen from the various pharmacy drug surveys. The Board also requested summaries of care and completed certification of medical record forms for the nine patients.
- 13. On or about August 2, 2016, in furtherance of its investigation, the Board transmitted the 10 patient records (and other relevant documents) received from the Respondent for peer review by two physicians, both board-certified in neurology ("the reviewers"). The results of the peer review are summarized below.
- 14. The reviewers submitted their respective reports on December 16, 2016. The reviewers concurred that the Respondent failed to meet appropriate standards for the delivery of quality medical and surgical care and failed to keep adequate medical records for seven out of 10 patients (identified in the peer review reports as Patients 1, 2, 3, 4, 7, 9 & 10)
- 15. On or about January 10, 2017, the Board sent a copy of both reviewers' reports to the Respondent, providing her an opportunity to submit a supplemental response.

16. On January 30, 2017, the Board received the Respondent's supplemental response, along with additional exhibits and an external peer review report.

III. PATIENT-SPECIFIC FINDINGS

- 17. Specifically, the reviewers found that the Respondent failed to meet the standard of quality care and failed to maintain adequate medical documentation for reasons including but not limited to the following. The Respondent:
 - a. Prescribed an expensive and controversial medication, IVIG, at a high dosage to treat multiple sclerosis when the medication is not a generally accepted therapy.
 In addition to IVIG², the Respondent also prescribed Acthar³ without any clinical indication for the necessity of both medications Patient 1;
 - b. Failed to order laboratory testing to ensure therapeutic levels of anti-epileptic medications Patients 1 and 4;
 - c. Prescribed Onfi⁴ without documenting that the reason for prescribing the medication was breakthrough seizures -- Patients 1 and 9;
 - d. Restarted or continued to prescribe a medication despite documenting that the patient experienced an adverse reaction to the medication. For instance, Patient 1 previously reported bloating and edema with Acthar. However, the Respondent restarted the medication despite Patient 1's prior adverse reaction. Similarly, the Respondent documented that she contacted the pharmaceutical company on

² IVIG (Intravenous Immunoglobulin) contains antibodies from blood donors and is administered via an IV (intravenous) infusion thought to strengthen various parts of the immune system.

³ Acthar is a purified preparation of adrenocorticotropic hormone (ACTH) in a gel that is designed to provide extended release of the ACTH following injection and acts as a short-term treatment for acute exacerbations of MS.

⁴ Onfi (generic: clobazam) is FDA-approved for the treatment of seizures in patients with Lennox-Gastault Syndrome. The patients reviewed do not have a diagnosis of Lennox-Gastault Syndrome.

- behalf of Patient 2, who complained of side effects from Gilenya.⁵ However, the Respondent continued to prescribe Gilenya to Patient 2. Patients 1 and 2;
- e. Continued to prescribe opioids to patients despite inconsistent urinalysis results or results that were positive for illicit drugs. In addition, the Respondent often failed to document inconsistent urinalysis results in the medical record -- Patients 4 and 9;
- f. Failed to clearly document that the exceptional combination of opioids and benzodiazepines was acceptable because the patients were being closely monitored Patient 1;
- g. Prescribed testing, medication and/or medical devices without adequate documentation of the necessity for such care. The Respondent prescribed B12 injections for Patients 1, 2, 3, and 7 without documenting B12 insufficiency. The Respondent recommended an evaluation for a vagus nerve stimulator⁶ for Patients 4 and 10 without adequately documenting evidence of intractable seizures and/or patient refusals to undergo the additional testing required for surgery. The Respondent prescribed various medications, some of which were clinically inappropriate, to Patients 1, 3, 7, 9, and 10.
- h. The Respondent ordered tests without documenting their necessity. For example, the Respondent ordered a 72-hour EEG⁷ test (Patient 2), without documentation of seizure activity and without first obtaining a routine EEG or less

⁵ Gilenya is an immunosuppressive drug used to treat flare-ups of Multiple Sclerosis.

⁶ A vagus nerve stimulator or VNS is a medical treatment that involves delivering electrical impulses to the vagus nerve. It is used as an adjunctive treatment for certain types of intractable epilepsy and treatment-resistant depression.

⁷ An electroencephalogram (EEG) is a test that detects electrical activity in the brain.

- invasive testing (Patient 10). The Respondent ordered a carotid ultrasound for Patient 7, without specifically documenting which symptoms necessitated a carotid ultrasound Patients 2, 7, and 10;
- i. Failed to document adequate descriptions of patient complaints. For instance, the Respondent failed to document any details of breakthrough seizures when reported by patients Patients 1 and 4;
- j. Failed to correctly document current medications in the medical record Patients
 2, 4, 9, and 10;
- k. Documented multiple inconsistencies in the medical records. For instance, for Patient 7, the Respondent requested hospital admission due to pneumonia, but the Respondent documented a normal respiratory examination. Also, the Respondent documented that Patient 7 "misses work" due to headaches but Patient 7 was not employed Patients 7, 9, and 10;
- Failed to document a discussion of laboratory results with patients Patients 2, 3,
 4, and 10;
- m. Used cutting and pasting of documentation as well as templates resulting in inaccurate information in the medical records Patients 1, 2, 9, and 10.

CONCLUSIONS OF LAW

The Respondent's conduct, as outlined in pertinent part in ¶ 17 above, constitutes: failure to meet appropriate standards for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State, in violation of Health Occ. II § 14-404(a)(22) and failure to keep

adequate medical records as determined by appropriate peer review, in violation of Health Occ. II § 14-404(a)(40).

<u>ORDER</u>

IT IS thus, by Panel A of the Board, hereby:

ORDERED that the Respondent is REPRIMANDED; and it is further

ORDERED that the Respondent is placed on PROBATION⁸ for a minimum period of ONE YEAR, subject to the following terms and conditions:

- (1) During the probationary period, the Respondent shall be subject to chart and/or peer review at the Panel's discretion;
- (2) Within six (6) months, the Respondent shall successfully complete a course, approved by the Board in advance, in medical documentation. The course shall be in-person (i.e. not an online course). The course shall not count towards the Respondent's continuing medical education (CME) credits necessary for continued medical licensure;
- (3) The Respondent shall continue to use a scribe to assist with her medical documentation; and
- (4) The Respondent shall comply with the Maryland Medical Practice Act, Md. Code Ann., Health Occ. §§ 14-101 et seq., and all laws and regulations governing the practice of medicine in Maryland; and it is further

ORDERED that the Respondent shall not apply for the early termination of probation; and it is further

ORDERED that after a minimum of one (1) year, the Respondent may submit a written petition to Disciplinary Panel A requesting termination of probation. After consideration of the petition, the probation may be terminated through an order of the

⁸ If the Respondent's license expires while the Respondent is on probation, the probationary period and any probationary conditions will be tolled.

Board or Panel A. The Board or Panel A will grant the petition to terminate the probation if the Respondent has complied with all of the probationary terms and conditions and there are no pending complaints related to the charges; and it is further

ORDERED that if the Respondent allegedly fails to comply with any term or condition of 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. If there is no genuine dispute as to a material fact, the Respondent shall be given a show cause hearing before the Board or a disciplinary panel; and it is further

ORDERED that if, after the appropriate hearing, the Board or a disciplinary panel determines that the Respondent has failed to comply with any term or condition of this Consent Order, the Board or a 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 as a physician in Maryland. The Board or a disciplinary panel a disciplinary panel may, in addition to one or more of the sanctions set forth above, impose a civil monetary fine upon the Respondent; 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, unless stated otherwise in the order, any time period prescribed in this order begins when the Consent Order goes into effect. The Consent Order goes into effect upon the signature of the Board's Executive Director, who signs on behalf of Panel A; and it is further

ORDERED that this Consent Order is a public document pursuant to Md. Code Ann., Gen. Prov. §§ 4-101 et seq. (2014 Vol. & 2017 Supp.).

April 23,2018

Christine A. Farrelly, Executive Director Maryland State Board of Physicians

CONSENT

I, Ruwani Gunawardane, M.D., acknowledge that I have had the opportunity to consult with counsel at this and all stages of this matter. I understand that this Consent Order will resolve the Charges issued against me in the above referenced case. By this Consent and for the sole purpose of resolving the issues raised by Disciplinary Panel A of the Board, I agree and accept to be bound by the foregoing Consent Order and its conditions. I acknowledge that the Findings of Fact and the Conclusions of Law contained in this Consent Order will be treated as proven as if entered into 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 own behalf, and to all other substantive and procedural protections provided by the law. I agree to forego my opportunity to challenge these Findings of Fact and Conclusions of Law. I acknowledge the legal authority and jurisdiction of the Disciplinary Panel A to initiate these proceedings and to issue and enforce this Consent Order. I affirm that I waive my right to any appeal in this matter. I affirm that I have asked and received satisfactory answers to all my questions regarding the language, meaning, and terms of this Consent Order. I sign this Consent Order, voluntarily and without reservation, and I fully understand and comprehend the language, meaning, and terms of this Consent Order.

4 (19) 2018 Date

Signature on File

Ruwani Gunawardane, M.D. *The Respondent*

NOTARY

OTATE OF ____

CATÝ/COUNTY OF

AS WITNESSETH my hand and notary seal.

SUCHARU RISHI ARORA
Notary Public
Montgomery County
Maryland
My Commission Expires Aug 6, 2019

Notary Public

My commission expires: $Ay 6^{TL}$, 2019