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| **IN THE MATTER OF** | * | **BEFORE THE** |
| **MARK T. MATSUNAGA, M.D.** | * | **MARYLAND STATE** |
| **Respondent** | * | **BOARD OF PHYSICIANS** |
| **License Number: D37907** | * | **Case Number: 2219-0106B** |

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## CONSENT ORDER

On March 2, 2020, Disciplinary Panel B ("Panel B") of the Maryland State Board of Physicians (the "Board") charged Mark T. Matsunaga, M.D. (the "Respondent") with violating the Maryland Medical Practice Act (the "Act"), Md. Code Ann., Health Occ. §§ 14-101 *et seq.* (2014 Repl. Vol. & 2019 Supp.). The Respondent was charged with violating the following:

> **§ 14-404. Denials, reprimands, probations, suspensions, and revocations – Grounds.**
>
> (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:
>
> . . .
>
> (28) Fails to comply with the provisions of § 12-102 of this article[.]

The pertinent provisions of Health Occ. include:

> **§ 12-102. Right to practice pharmacy, pharmaceutical care**
>
> (a) . . .
>
> (3) "Personally preparing and dispensing" means that the licensed dentist, physician, or podiatrist:
>
> (i) Is physically present on the premises where the prescription is filled; and

(ii) Performs a final check of the prescription before it is provided to the patient.

. . .

(c) . . .

(2) This title does not prohibit:

(ii) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

. . .

4. The dentist, physician, or podiatrist:

A. Complies with the dispensing and labeling requirements of this title;

. . .

J. Maintains biennial inventories and complies with any other federal and State record-keeping requirements relating to controlled dangerous substances;

. . .

(m) A dentist, physician, or podiatrist who fails to comply with the provisions of this section governing the dispensing of prescription drugs or devices shall:

(1) Have the dispensing permit revoked; and

(2) Be subject to disciplinary actions by the appropriate licensing board.

The pertinent provisions of the Board's regulations in COMAR provide:

**10.32.23.06 Requirements for Permit Holders.**

A. A permit holder shall comply with all federal and State statutes and regulations regarding prescription drugs, including all requirements for:

(1) Dispensing, including labeling;

(2) Storing and securing inventory;

(3) Allowing access only to authorized individuals;

. . .

(5) Recordkeeping;

B. A permit holder shall:

. . .

(2) Sign or initial documentation in person that the final check was completed[.]

On April 22, 2020, Panel B 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 and Order.

## FINDINGS OF FACT

Panel B finds the following:

### I. Background & Licensing Information

1. At all times relevant to these charges, 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 January 12, 1989, under License Number D37907. His license is active through September 30, 2021.
2. At all times relevant to these charges, the Respondent was board-certified in Anesthesiology and a sub-specialty in Pain Medicine. The Respondent holds

hospital privileges at a hospital ("Hospital")[1] and is the owner of a solo practice (the "Practice") with two locations ("Location 1" and "Location 2") in Howard County, Maryland.

3. The Respondent holds a Board-issued permit, permit number 2177, to dispense prescription drugs including controlled dangerous substances ("CDS") in accordance with Health Occ. § 12-102 and COMAR 10.13.01 *et seq.* Dispensing Prescription Drugs by a Licensee.

4. The Respondent only dispenses medications to his workers compensation patients that are seen at Location 1.

## II. Complaint

5. On or about December 6, 2018, the Board received a copy of an Office of Controlled Substances Administration ("OCSA") Licensee Dispensing of Prescription Drugs Inspection Report (the "Report") and OCSA Memorandum (the "Memo") noting several deficiencies of the Respondent's dispensing practice during their on-site inspection conducted on November 26, 2018 at Location 1.

6. The Report and Memo listed the following dispensing physician violations:

> **1B. Violation:** Biennial inventory was recently completed but needs to be properly completed with Schedule II listed separate from Schedule III-V; this inventory done on 9/14/18 has Schedule II, Schedule III-V and non-controlled drugs all listed together. **Action:** Schedule II must be separate from Schedule III-V; non-controlled drugs do not need to be included in required CDS biennial inventory. (CR 5-306(b))[2]

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[1] In order to maintain confidentiality, the names of patients and facilities will not be used in this document.

[2] CR 5-306(b) Records Required. -
(1) A registrant shall make a complete and accurate record of all stocks of controlled dangerous substances on hand every 2 years during the regular fiscal inventory.
(2) The registrant shall keep the record for 2 years.

**1E. Violation:** There is a sign located over the scale regarding prescription drugs being available for purchase, but the proper wording is not currently being used. **Action:** [Inspector] referred them to COMAR 10.13.[01.]04L[3] for the wording which needs to be present on their sign to be compliant with physician dispensing regulations.

**1G7. Violation:** They are not currently ensuring that the expiration date on their label, when dispensing, is the lesser of one year from [the] date of dispensing or month and year of expiration if less than one year (according to stock bottle). They do not know what the system is creating for an expiration date, but one year from the date is not currently what is being generated according to [medical assistant]. **Action:** [Inspector] informed them they must ensure their expiration date is in compliance with HO 12-505,[4] as the lesser of one year from dispensing date or month and year when drug expires (from stock bottle).

**1I2. Violation:** The final check made by the dispensing doctor is not being documented for each prescription. [Medical assistant] stated the doctor checks the prescription but only signs a sheet at the end of the day that includes all prescriptions dispensed. [Medical assistant] stated he signs the prescription so that is the documentation. [Inspector] explained that is his signature for prescribing, not dispensing. **Action:** [Inspector] explained [the Respondent] must document his check of each dispensed prescription and recommended [the Respondent] sign or initial the small label [the staff] are placing on the back of the printed prescription. [The staff] currently have the

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[3] COMAR 10.13.01.04 Dispensing Requirements

L. A licensee shall display prominently a sign which informs the patient that prescription drugs can be purchased from the permit holder if the patient determines that a pharmacy is not conveniently available to the patient. (2014).

[4] Health Occ. 12-505 Labeling Requirements for prescription medicines.

. . .

(d) Medication dispensed by an authorized prescriber

. . .

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

. . .

(iii) An expiration date of the drug or device which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drug or device expires; or
3. A shorter period as determined by the authorized prescriber[.]

patient sign this label, so [Inspector] recommended the doctor sign before or after the patient.

**2D Violation:** They are in violation as this question refers to records of purchase and disposition of CDS being maintained in accordance with State and Federal regulations. Records of purchase of Schedule II are currently with purchase records of Schedule III-V and non-controlled drugs. Additionally, they are currently improperly disposing of expired drugs by taking them to a police station and further, improperly requesting and receiving unused patient medications and taking them to a police station as well. **Action:** [Inspector] explained they must keep all Schedule II records separate from all other records (including purchase, disposition, and prescriptions).

Other violations not listed as part of the formatted outline on dispensing inspection report:

1) Requesting patient bring in unused medications; accepting those medications; placing in Ziploc bag and taking to a police station. All of the above actions are violations as the doctor is prohibited from taking any dispensed patient medications. **Action:** [Inspector] informed the doctor he must immediately stop this procedure.

2) Expired stock drugs are being taken to a police station. **Action:** [Inspector] informed Dr. Matsunaga of the proper disposal by returning to the supplier from where they were ordered or returned to a reverse distributor.

7. The Inspectors found that the Respondent kept both CDS (i.e. carisoprodol[5]) and non-CDS (i.e. cyclobenzaprine,[6] promethazine[7]) drugs in unlocked kitchen-type cabinets in an area where the medical assistants work, which is located off of the

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[5] **carisoprodol** – (Brand name - Soma) – Currently a Schedule IV CDS used as a muscle relaxer that blocks pain sensations between the nerves and the brain.

[6] **cyclobenzaprine** – (Brand name – Flexeril, Fexmid, Amrix) – A non-scheduled drug used as a muscle relaxant. It is known as a drug that is commonly diverted.

[7] **promethazine** – (Brand name – Phenergan) A non-scheduled drug used to treat allergy symptoms such as itching, runny nose, sneezing, itchy or watery eyes, hives, and itchy skin rashes. It also prevents motion sickness and treats nausea and vomiting or pain after surgery. It is also used as a sedative or sleep aid. It is highly diverted and commonly used as an adjunct to opioids to enhance the euphoric effects.

central area. The area was not enclosed, nor did it have a door. The Respondent also kept drugs including methadone[8] and oxycodone[9] in a small safe below the cabinets.

8. During the inspection, the Inspector became concerned when the Respondent explained that he often has his patients bring their filled prescription bottles with them to their appointments. The Respondent added: "If I change a patient's prescription, the drug or the strength, I have the patient bring the unused portion to me." The Respondent further stated that he collects the unused pills, enters the information on a log, and pours the pills into a Ziploc bag that is stored in the safe. When the area in the safe becomes filled with Ziploc bags full of pills, the Respondent then takes the Ziploc bags of loose, returned pills and disposes of them at a local police station's "take back program" drop box.

9. When informed that this practice was not allowed, the Respondent became argumentative and stated, "They are my meds . . . I prescribed them so they are mine."

10. The Inspector explained that once filled, the medication belongs solely to the patient and only the patient can turn in their unused medication to a "take back program." The Inspector referenced the DEA Disposal Act – General Public Fact Sheet[10] which states in part:

> Only ultimate users may dispose of pharmaceutical controlled substances. An ultimate user, which includes a household member of the person or pet who was prescribed the medication, may transfer

[8] **Methadone** is a narcotic (opiate base) analgesic used to treat narcotic addiction (such as heroin or morphine) and certain types of pain. It is a Schedule II CDS.

[9] **Oxycodone** (Brand name – OxyContin) Is a narcotic analgesic used to treat patients who have moderate to severe pain. It is a schedule II CDS.

[10] Currently located at: https://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public_06222018.pdf

pharmaceutical controlled substances to authorized collectors or law enforcement via a collection receptacle, mail-back package, or take-back event.

11. The Respondent persisted and described a common example from his practice - patient has 120 pills prescribed and dispensed but does not consume all of the pills and/or their prescription changes prior to completion, resulting in approximately 110 unconsumed pills. The Respondent claimed by personally taking back the unused medication, he was preventing the unused drugs from "ending up on the street."

12. To address this example, the Inspector recommended the Respondent prescribe a small quantity when starting a patient on a new CDS or opioid until he knows the dose and drug will work well. That way, if it does not work for the patient, there won't be much left over.

13. The Inspector also directed the Respondent to the Board's website under the heading "FAQ for Drug Dispensing" as the prohibition of taking back drugs is discussed there as well.[11]

14. The Inspector also asked the Respondent about his handling of expired drugs, specifically if they used a reverse distributer. The Respondent stated that he

[11] Currently located at: https://www.mbp.state.md.us/forms/drug_dispense_faqs.pdf

34. If a patient wants to return a medication previously dispensed, do I have to take it back? No. It is a violation of law to take back CDS. And taking back any other dispensed medication is also prohibited except in the very limited circumstances set out in the pharmacy regulations at COMAR 10.34.10.07. That regulation does not require you to take back any drugs in any instance. You may advise patients that there are repositories around the state, including many police stations and pharmacies that accept excess drugs.

35. If a patient wants to return just the unused portion of a drug that I previously dispensed, do I have to take it back? No. You should not take back any unused portions of any medications. You may advise patients of repositories available for this purpose.

followed the same procedure for expired stock drugs that he used for his patient's returned medications – he collected the drugs and disposed of them personally at the local police "take back program." The Inspector explained that expired and unwanted stock drugs could only be sent back to the original supplier, if they were willing, or to a reverse distributer.[12]

## III. Board Investigation

15. The Board initiated an investigation into the OCSA's Report and Memo.

16. During its investigation, the Board subpoenaed ten (10) patient medical records chosen from the "returned patient medication" log provided by OCSA.

17. In a review of the medical records provided, the Respondent documented all medication changes, however, neither he nor his staff recorded when they accepted medication back from the patient.

18. On May 21, 2019, the Respondent and his attorney attended an in-person investigative interview at the Board's offices. The Respondent stated in part:

    a. "It wasn't until this investigation that we found out that the rules of physicians not being able to take back prescriptions from patients existed."

    b. "I was not aware at the time of the requirement to send [expired meds] back to the distributer programs, which I think is a new thing as well."

    c. "I never contacted [State or Federal agencies to ensure this practice was allowed], but that's what I was learning in all the pain society meetings and my training of take-back and destroy."

    d. "We have taken back some cancer patient meds that were prescribed by hospice or something like that because – for convenience of the

[12] 21 CFR 1300.01(b) - Reverse distributors are defined as "a person who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal."

family because they didn't want to go to the drop box and we were trying to help them out."

e. "I look at [the returned medication log] once in awhile just to verify that what we're bringing is being recorded because my whole responsibility, I think, is to make sure that we're doing accurate recordings of the medicines that we're confiscating to take back to the [local police] drop boxes."

19. During the interview, the Respondent acknowledged that as a holder of a Board-issued drug dispensing permit, he should be aware of all State and Federal regulations that govern the practice.

## CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, Disciplinary Panel B of the Board concludes as a matter of law that that the Respondent failed to comply with the provisions of § 12-102 of the Health Occupations Article, in violation of Health Occ. § 14-404(a)(28). Panel B dismisses the charges issued under Health Occ. § 14-404(a)(3)(ii) and Health Occ. § 14-404(a)(43).

## ORDER

Based upon the Findings of Fact and Conclusions of Law, it is, on the affirmative vote of a majority of the quorum of Disciplinary Panel B, **HEREBY:**

**ORDERED** that Respondent Mark T. Matsunaga, M.D. is **REPRIMANDED**; 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. The Executive Director signs the Consent Order on behalf of the disciplinary panel which has imposed the sanction in 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).

05/15/2020
Date

***Signature on File***

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

**CONSENT**

I, Mark T. Matsunaga, 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.

5/5/20
Date

***Signature on File***

Mark T. Matsunaga, M.D.

## NOTARY

**STATE OF:** MD

**CITY/COUNTY OF:** Howard

**I HEREBY CERTIFY** that on this 5 day of May, 2020, before me, a Notary Public of the State and City/County aforesaid, appeared Mark T. Matsunaga, M.D. and made oath in due form of law that the foregoing Consent Order was his voluntary act and deed.

**AS WITNESS**, my hand and Notary Seal.

Notary Public

My commission expires: 6/12/23

JUSTIN LUNA
NOTARY PUBLIC
MY COMMISSION EXPIRES JUNE 12, 2023
HOWARD COUNTY, MD