

**BOARD OF PODIATRIC MEDICAL EXAMINERS
OPEN SESSION MEETING VIA GOOGLE MEET**

AGENDA

March 12, 2026

Location: Google Meet meet.google.com/xze-eaqn-bkw

Join by phone: (US) +1 516-399-4811 PIN: 644 563 632#

A. ORDER OF BUSINESS

- 1. Call to Order- Roll Call**
- 2. COMAR 10.01.14.02.B: Except in instances when a public body expressly invites public testimony, questions, comments, or other forms of public participation, or when public participation is otherwise authorized by law, a member of the public attending an open session may not participate in the session.**
- 3. Approval of meeting minutes from the February 12, 2026 meeting Tab A**

B. BOARD PRESIDENT'S REPORT

C. EXECUTIVE DIRECTOR'S REPORT

D. OLD BUSINESS:

- 1. Review of HB 771 Health Occupations - Human Trafficking Awareness Training Tab B**
 - a. Review of Health Occupation Boards' position statement.
- 2. Discussion on Appointing A New Representative for PDMP**
 - a. Follow up from Board members on appointment of a new representative
- 3. Discussion on Structural Racism and Implicit Bias CME Credits**

E. NEW BUSINESS:

- 1. Review of HB 1047/SB 0915- State Board of Physicians – Delegation of Duties – Alterations** **Tab C**

Purpose: Requiring an individual to be registered with the State Board of Physicians to perform limited X-ray machine operations in the State; establishing certain disciplinary procedures for limited X-ray machine operators; recodifying certain provisions of law related to registered cardiovascular invasive specialists and supervised medical graduates; and authorizing a physician assistant to perform X-ray duties under certain circumstances.

- 2. Review of HB 1542- Public Health – Goods, Services, or Technologies Used in Death Sentences – Prohibition** **Tab D**

Purpose: Prohibiting a person doing business in the State from knowingly manufacturing or selling, distributing, dispensing, or otherwise supplying a drug, medical device, or other good, service, or technology or compounding a drug if the person knows or reasonably should know that certain authorization was prompted, either directly or indirectly, by a person seeking the drug, medical device, or other good, service, or technology with a certain intent related to a death sentence.

- 3. Review of HB 1079- Office of Regulatory Management and State Government Authorizations** **Tab E**

Purpose: Establishing the Office of Regulatory Management; providing for the Director, staffing, and duties of the Office; requiring certain units of State government to submit certain reports to certain persons at certain times regarding regulatory actions and permits, licenses, certifications, and registrations; requiring certain units to develop a strategy to simplify certain application processes; requiring certain units of State government, in consultation with the Department of Information Technology, to implement online processes for the submission and amendment of certain applications and fees; and generally relating to the Office of Regulatory Management and the simplification of processes of the State government.

- 4. Review of HB 1372- Public Health – Office of Health Care Quality Information and Maryland Department of Health Centralization Commission** **Tab F**

Purpose: Requiring the Maryland Health Care Commission, in collaboration with the Office of Health Care Quality within the Maryland Department of Health, to develop a process to receive and publish certain inspection information on a certain website; establishing the Maryland Department of Health Centralization Commission to provide certain advice and recommendations relating to the relationship between the Department and the health occupations boards; requiring the Secretary of Information Technology to ensure that minimum cybersecurity requirements are met by all health occupations boards; and generally relating to the sharing of inspection information and the oversight of health occupations boards in the State.

- 5. Review of HB 1527- Complementary and Alternative Health Care – Practice Authorized 2 (Complementary and Alternative Health Care Practice Act)** **Tab G**

Purpose: Authorizing an individual to practice complementary or alternative health care in the State without obtaining a license, certification, or authorization issued under certain provisions of law; establishing certain requirements and limitations regarding the practice of complementary or alternative health care; providing that certain provisions of this Act do not waive certain claims for relief; and generally relating to complementary and alternative health care practitioners.

6. Review of Johns Hopkins University- Diabetic Limb Preservation, Wound Care, and Kinetics Fellowship

- a. [Accessible link to the presentation](#)

7. Review of Scope of Practice Inquiry

Tab H

8. New License Approval

- a. **Andrew Wilson, D.P.M.- Reinstatement from expired for January issuance**
b. **Sonya Wali, D.P.M.- For January 2026 license issuance**

F. ADJOURNMENT



Board of Nursing

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary



February 25, 2026

The Honorable Heather Bagnall
Chair, Health Committee
240 Taylor House Office Building
Annapolis, Maryland 21401

RE: HB 771 – Health Occupations - Human Trafficking Awareness Training – Letter of Support with Amendments

Dear Chair Bagnall and Committee Members:

The Maryland Board of Nursing, the Maryland Board of Acupuncture, the Maryland Board of Chiropractic Examiners, the Maryland Board of Dental Examiners, the Maryland Board of Massage Therapy Examiners, the Maryland Board of Occupational Therapy Practice, the Maryland Board of Examiners in Optometry, the Maryland Board of Physical Therapy Examiners, the Maryland Board of Podiatric Medical Examiners, and the Maryland Board of Professional Counselors and Therapists (the “Boards”) respectfully submit this letter of support with amendments for HB 771 Health Occupations - Human Trafficking Awareness Training. This bill would require the boards to provide human trafficking awareness training for health occupations professionals and adopt regulations before October 1, 2026.

The Boards support the intent of HB 771 and recognize the importance of human trafficking awareness training for healthcare professionals given their proximity to vulnerable populations. Though there is still much more to be done, in recent years patient safety networks have developed procedures for addressing human trafficking when they encounter it, and nursing education programs, as well as other health occupation professions, often address the topic in their curriculum. Furthermore, we believe continuing education on the most recent developments in addressing human trafficking in the healthcare arena is an important step to eliminating the practice in the State altogether.

The Boards would like to present two amendments for the committee's consideration. The first would authorize boards to adopt regulations, rather than require adoption, thereby providing flexibility to implement the training through existing CE structures where feasible. Additionally, board regulations do not typically list courses and/or specific training for continuing education units (CEUs). The second amendment removes the deadline for completion of regulations by October 1, 2026, which the boards feel would be unnecessary language if amendment #1 is agreed to. The specific amendments are below.

- Pg 2, line 1, strike "shall" and substitute "may"
- Pg 3, strike lines 10-11 in their entirety

For all of these reasons, the Boards submit this letter of support with amendments for HB 771 and urge that the Committee adopt these amendments. For more information, please contact Ms. Mitzi Fishman, Director of Legislative Affairs, at 410-585-2049 or mitzi.fishman@maryland.gov, or Ms. Rhonda Scott, Executive Director, at 410-585-1953 or rhonda.scott2@maryland.gov; or Lillian Reese, Legislative Liaison for the Health Occupations Boards at 443-794-4757 or lillian.reese@maryland.gov.

Sincerely,



Christine Lechliter
Board President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.



HOUSE BILL 1047

J2

6lr2415
CF SB 915

By: **Delegate Hutchinson**

Introduced and read first time: February 9, 2026

Assigned to: Health

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Physicians – Delegation of Duties – Alterations**

3 FOR the purpose of requiring an individual to be registered with the State Board of
4 Physicians to perform limited X-ray machine operations in the State; establishing
5 certain disciplinary procedures for limited X-ray machine operators; recodifying
6 certain provisions of law related to registered cardiovascular invasive specialists and
7 supervised medical graduates; authorizing a physician assistant to perform X-ray
8 duties under certain circumstances; and generally relating to the delegation of duties
9 by physicians and physician assistants.

10 BY repealing and reenacting, with amendments,
11 Article – Health Occupations
12 Section 14–206(e)(2)(viii), 14–306, 14–602, and 15–302.1(c)
13 Annotated Code of Maryland
14 (2021 Replacement Volume and 2025 Supplement)

15 BY repealing and reenacting, without amendments,
16 Article – Health Occupations
17 Section 14–206(e)(2)(ix)
18 Annotated Code of Maryland
19 (2021 Replacement Volume and 2025 Supplement)

20 BY adding to
21 Article – Health Occupations
22 Section 14–206(e)(2)(x), 14–306.1, 14–306.2, 14–306.3, and 14–306.4
23 Annotated Code of Maryland
24 (2021 Replacement Volume and 2025 Supplement)

25 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
26 That the Laws of Maryland read as follows:

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.



Article – Health Occupations

14–206.

(e) A disciplinary panel may issue a cease and desist order or obtain injunctive relief against an individual for:

(2) Representing to the public, by title, description of services, methods, procedures, or otherwise, that the individual is authorized to practice:

(viii) Genetic counseling in this State, in violation of § 14–5G–24 of this title; [or]

(ix) As a physician assistant in this State, in violation of § 15–402 of this article; or

(X) LIMITED X–RAY MACHINE OPERATION IN THE STATE, IN VIOLATION OF § 14–306.3 OF THIS TITLE; OR

14–306.

(a) [Except as provided in subsections (e) and (f) of this section, to] **TO** the extent [permitted] **AUTHORIZED** by the rules, regulations, and orders of the Board, an individual to whom duties are delegated by a licensed physician or physician assistant may perform those duties without a license as provided in this section.

(b) The individuals to whom duties may be delegated under this section include any individual authorized to practice any other health occupation regulated under this article or § 13–516 of the Education Article.

(c) **(1)** The Board shall adopt rules and regulations to delineate the scope of this section.

(2) Before [it] **THE BOARD** adopts any rule or regulation under this section, the Board shall invite and consider proposals from any individual or health group that could be affected by the rule or regulation.

(d) **(1)** If a duty that is to be delegated under this section is a part of the practice of a health occupation that is regulated under this article by another board, any rule or regulation concerning that duty shall be adopted jointly by the Board of Physicians and the board that regulates the other health occupation.

(2) If the two boards cannot agree on a proposed rule or regulation, the proposal shall be submitted to the Secretary for a final decision.

1 [(e) Except as otherwise provided in this section and in accordance with
2 regulations adopted by the Board, an individual may perform X-ray duties without a
3 license only if the duties:

4 (1) Do not include:

5 (i) Computerized or noncomputerized tomography;

6 (ii) Fluoroscopy;

7 (iii) Invasive radiology;

8 (iv) Mammography;

9 (v) Nuclear medicine;

10 (vi) Radiation therapy; or

11 (vii) Xerography;

12 (2) Are limited to X-ray procedures of the:

13 (i) Chest;

14 (ii) Spine, including the:

15 1. Cervical spine;

16 2. Lumbar spine;

17 3. Sacroiliac joints;

18 4. Sacrum and coccyx; and

19 5. Thoracic spine;

20 (iii) Lower extremities, including:

21 1. Toes;

22 2. The foot;

23 3. The ankle;

24 4. The calcaneus;

25 5. The tibia and fibula;

1 6. The knee and patella; and

2 7. The femur; and

3 (iv) Upper extremities, including:

4 1. Fingers;

5 2. The hand;

6 3. The wrist;

7 4. The forearm;

8 5. The elbow;

9 6. The humerus;

10 7. The shoulder;

11 8. The clavicle;

12 9. Acromioclavicular joints; and

13 10. The scapula; and

14 (3) Are performed:

15 (i) In the physician's office under the supervision of a licensed
16 physician or radiologic technologist who is on-site or able to provide immediately available
17 direction; and

18 (ii) 1. By an individual who has:

19 A. Attested to the completion of at least 6 months of clinical
20 care experience; and

21 B. Completed a limited scope X-ray educational program
22 consisting of at least 115 hours of didactic training delivered by a radiologic technologist
23 certified by the American Registry of Radiologic Technologists providing instruction in
24 radiographic anatomy, procedures, and pathology, digital image acquisition and display,
25 fundamentals, ethics, and laws of health care, human anatomy and physiology, image
26 production and analysis, imaging equipment and radiation production, medical
27 terminology, and patient care;

1 C. Completed at least 480 hours of clinical training and
2 successfully completed a minimum of five competencies in each body part listed in item (2)
3 of this subsection under the direct supervision of a radiologic technologist certified by the
4 American Registry of Radiologic Technologists;

5 D. Achieved a passing score, as determined by the Board, on
6 the American Registry of Radiologic Technologists examination for limited scope of practice
7 in radiography or an alternative examination approved by the Board; and

8 E. Registered with the Board attesting to the completion of
9 the requirements of this item and the completion of at least 24 hours of approved continuing
10 education credits earned during the 2-year period immediately following the date of initial
11 registration and every 2 years thereafter; or

12 2. By a licensed physician assistant who has completed a
13 course that includes anterior-posterior and lateral radiographic studies of extremities on
14 at least 20 separate patients under the direct supervision of the delegating physician or
15 radiologist using a mini C-arm or similar low-level radiation machine to perform
16 nonfluoroscopic X-ray procedures, if the duties:

17 A. Include only the X-ray procedures described in paragraph
18 (2)(iii) of this subsection; and

19 B. Are performed pursuant to a Board-approved delegation
20 agreement that includes a request to perform advanced duties under § 15-302(c)(2) of this
21 article.

22 (f) (1) In accordance with regulations adopted by the Board, a licensed
23 physician may delegate duties to a registered cardiovascular invasive specialist assisting
24 in the physician's performance of fluoroscopy if:

25 (i) The delegated duties are limited to a cardiac catheterization
26 procedure performed in a hospital cardiac catheterization laboratory;

27 (ii) The physician is physically present and personally directs each
28 act performed by the registered cardiovascular invasive specialist;

29 (iii) The registered cardiovascular invasive specialist has completed
30 the training and education and has the experience required by regulations adopted by the
31 Board; and

32 (iv) The hospital in which the cardiac catheterization laboratory is
33 located has verified and documented that the registered cardiovascular invasive specialist
34 has completed the training and education and has the experience required by regulations
35 adopted by the Board.

1 (2) The hospital in which the cardiac catheterization laboratory is located
2 and the physician delegating duties to a registered cardiovascular invasive specialist under
3 this subsection are responsible for ensuring that all requirements of this subsection are
4 met for each procedure.

5 (3) A disciplinary panel may impose a civil penalty of up to \$5,000 for each
6 instance of a hospital's failure to comply with the requirements of this subsection.

7 (g) (1) (i) In this subsection the following words have the meanings
8 indicated.

9 (ii) "Direct supervision" means oversight exercised by a delegating
10 physician who is:

11 1. Personally treating the patient;

12 2. In the same medical office as the patient and the
13 supervised medical graduate; and

14 3. Immediately available to provide assistance and guidance
15 to the supervised medical graduate for the duration of the completion of a delegated duty.

16 (iii) "Supervised medical graduate" means an individual who:

17 1. Has a degree of:

18 A. Doctor of medicine from a medical school that is accredited
19 by an accrediting organization that the Board recognizes in its regulations; or

20 B. Doctor of osteopathy from a school of osteopathy in the
21 United States, its territories or possessions, Puerto Rico, or Canada that has standards for
22 graduation equivalent to those established by the American Osteopathic Association; and

23 2. Has passed parts 1 and 2 of:

24 A. The United States Medical Licensing Examination; or

25 B. The Comprehensive Osteopathic Medical Licensing
26 Examination of the United States.

27 (2) Subject to paragraph (3) of this subsection and in accordance with
28 regulations adopted by the Board, a supervised medical graduate may perform delegated
29 duties under direct supervision.

30 (3) An individual may not practice as a supervised medical graduate for a
31 period of more than 2 years.

1 (4) For the purposes of this subsection, a delegating physician is not
2 required to be in the presence of a patient and a supervised medical graduate during the
3 completion of a delegated duty.

4 (h) In accordance with regulations adopted by the Board, a physician's office that
5 employs an individual authorized to perform X-ray duties without a license under
6 subsection (e) of this section is responsible for ensuring that all requirements of subsection
7 (e) of this section are met for each X-ray examination performed.

8 (i) If an unlicensed individual performs X-ray duties without meeting the
9 requirements of subsection (e) of this section, the Board may impose a civil penalty of up
10 to:

11 (1) \$5,000 for each violation on the physician's office where the violation
12 occurred; and

13 (2) \$1,000 for each violation on the individual who committed the
14 violation.]

15 **14-306.1.**

16 **(A) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, A**
17 **LICENSED PHYSICIAN MAY DELEGATE DUTIES TO A REGISTERED CARDIOVASCULAR**
18 **INVASIVE SPECIALIST ASSISTING IN THE PHYSICIAN'S PERFORMANCE OF**
19 **FLUOROSCOPY IF:**

20 **(1) THE DELEGATED DUTIES ARE LIMITED TO A CARDIAC**
21 **CATHETERIZATION PROCEDURE PERFORMED IN A HOSPITAL CARDIAC**
22 **CATHETERIZATION LABORATORY;**

23 **(2) THE PHYSICIAN IS PHYSICALLY PRESENT AND PERSONALLY**
24 **DIRECTS EACH ACT PERFORMED BY THE REGISTERED CARDIOVASCULAR INVASIVE**
25 **SPECIALIST;**

26 **(3) THE REGISTERED CARDIOVASCULAR INVASIVE SPECIALIST HAS**
27 **COMPLETED THE TRAINING AND EDUCATION AND HAS THE EXPERIENCE REQUIRED**
28 **BY REGULATIONS ADOPTED BY THE BOARD; AND**

29 **(4) THE HOSPITAL IN WHICH THE CARDIAC CATHETERIZATION**
30 **LABORATORY IS LOCATED HAS VERIFIED AND DOCUMENTED THAT THE REGISTERED**
31 **CARDIOVASCULAR INVASIVE SPECIALIST HAS COMPLETED THE TRAINING AND**
32 **EDUCATION AND HAS THE EXPERIENCE REQUIRED BY REGULATIONS ADOPTED BY**
33 **THE BOARD.**

1 1. THE UNITED STATES MEDICAL LICENSING
2 EXAMINATION; OR

3 2. THE COMPREHENSIVE OSTEOPATHIC MEDICAL
4 LICENSING EXAMINATION OF THE UNITED STATES.

5 (B) SUBJECT TO SUBSECTION (C) OF THIS SECTION AND IN ACCORDANCE
6 WITH REGULATIONS ADOPTED BY THE BOARD, A SUPERVISED MEDICAL GRADUATE
7 MAY PERFORM DELEGATED DUTIES UNDER ON-SITE SUPERVISION.

8 (C) AN INDIVIDUAL MAY NOT PRACTICE AS A SUPERVISED MEDICAL
9 GRADUATE FOR A PERIOD OF MORE THAN 2 YEARS.

10 (D) FOR THE PURPOSES OF THIS SECTION, A DELEGATING PHYSICIAN IS
11 NOT REQUIRED TO BE IN THE PRESENCE OF A PATIENT AND A SUPERVISED MEDICAL
12 GRADUATE DURING THE COMPLETION OF A DELEGATED DUTY.

13 **14-306.3.**

14 (A) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, AN
15 INDIVIDUAL MAY PERFORM X-RAY DUTIES AS A LIMITED X-RAY MACHINE
16 OPERATOR REGISTERED WITH THE BOARD UNDER THIS SECTION WITHOUT A
17 LICENSE IF THE X-RAY PROCEDURES:

18 (1) DO NOT INCLUDE:

19 (I) COMPUTERIZED OR NONCOMPUTERIZED TOMOGRAPHY;

20 (II) FLUOROSCOPY;

21 (III) INVASIVE RADIOLOGY;

22 (IV) MAMMOGRAPHY;

23 (V) NUCLEAR MEDICINE;

24 (VI) RADIATION THERAPY; OR

25 (VII) XEROGRAPHY;

26 (2) ARE LIMITED TO X-RAY PROCEDURES OF:

27 (I) THE CHEST;

1 **(II) THE SPINE, INCLUDING:**

- 2 1. **THE CERVICAL SPINE;**
3 2. **THE LUMBAR SPINE;**
4 3. **THE SACROILIAC JOINTS;**
5 4. **THE SACRUM AND COCCYX; AND**
6 5. **THE THORACIC SPINE;**

7 **(III) LOWER EXTREMITIES, INCLUDING:**

- 8 1. **TOES;**
9 2. **THE FOOT;**
10 3. **THE ANKLE;**
11 4. **THE CALCANEUS;**
12 5. **THE TIBIA AND FIBULA;**
13 6. **THE KNEE AND PATELLA; AND**
14 7. **THE FEMUR; AND**

15 **(IV) UPPER EXTREMITIES, INCLUDING:**

- 16 1. **FINGERS;**
17 2. **THE HAND;**
18 3. **THE WRIST;**
19 4. **THE FOREARM;**
20 5. **THE ELBOW;**
21 6. **THE HUMERUS;**

1 7. **THE SHOULDER;**

2 8. **THE CLAVICLE;**

3 9. **ACROMIOCLAVICULAR JOINTS; AND**

4 10. **THE SCAPULA; AND**

5 **(3) ARE PERFORMED UNDER THE SUPERVISION OF A LICENSED**
6 **PHYSICIAN OR RADIOGRAPHER WHO IS ON-SITE OR ABLE TO PROVIDE IMMEDIATELY**
7 **AVAILABLE DIRECTION; AND**

8 **(4) ARE PERFORMED BY AN INDIVIDUAL WHO HAS REGISTERED WITH**
9 **THE BOARD AND ATTESTS:**

10 **(i) TO THE SUCCESSFUL COMPLETION OF AT LEAST 6 MONTHS**
11 **OF CLINICAL CARE EXPERIENCE;**

12 **(ii) TO THE SUCCESSFUL COMPLETION OF:**

13 1. **A LIMITED X-RAY EDUCATIONAL PROGRAM; OR**

14 2. **THE FIRST YEAR OF AN ACCREDITED RADIOLOGIC**
15 **TECHNOLOGIST PROGRAM IN GOOD STANDING WITH THE BOARD;**

16 **(iii) TO THE SUCCESSFUL COMPLETION OF AT LEAST 115 HOURS**
17 **OF DIDACTIC TRAINING DELIVERED BY A RADIOLOGIC TECHNOLOGIST CERTIFIED**
18 **BY THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS PROVIDING**
19 **INSTRUCTION IN RADIOGRAPHIC ANATOMY, PROCEDURES, AND PATHOLOGY,**
20 **DIGITAL IMAGE ACQUISITION AND DISPLAY, FUNDAMENTALS, ETHICS, AND LAWS OF**
21 **HEALTH CARE, HUMAN ANATOMY AND PHYSIOLOGY, IMAGE PRODUCTION AND**
22 **ANALYSIS, IMAGING EQUIPMENT AND RADIATION PRODUCTION, MEDICAL**
23 **TERMINOLOGY, AND PATIENT CARE;**

24 **(iv) TO THE SUCCESSFUL COMPLETION OF AT LEAST 480 HOURS**
25 **OF CLINICAL TRAINING;**

26 **(v) TO THE SUCCESSFUL COMPLETION OF A MINIMUM OF FIVE**
27 **COMPETENCIES IN EACH BODY PART LISTED UNDER SUBSECTION (A)(2) OF THIS**
28 **SECTION UNDER THE DIRECT SUPERVISION OF A RADIOLOGIC TECHNOLOGIST**
29 **CERTIFIED BY THE AMERICAN REGISTRY OF RADIOLOGIC TECHNOLOGISTS; AND**

1 **(VI) TO THE SUCCESSFUL ACHIEVEMENT OF A PASSING SCORE,**
2 **AS DETERMINED BY THE BOARD, ON THE AMERICAN REGISTRY OF RADIOLOGIC**
3 **TECHNOLOGISTS EXAMINATION FOR LIMITED SCOPE OF PRACTICE IN**
4 **RADIOGRAPHY OR AN ALTERNATIVE EXAMINATION APPROVED BY THE BOARD.**

5 **(B) IF THE APPLICANT COMPLETED THE FIRST YEAR OF AN ACCREDITED**
6 **RADIOLOGIC TECHNOLOGIST EDUCATIONAL PROGRAM, THE PROGRAM DIRECTOR**
7 **OF THE EDUCATIONAL PROGRAM SHALL PROVIDE AN ATTESTATION DIRECTLY TO**
8 **THE BOARD STATING THAT THE APPLICANT MEETS OR EXCEEDS THE**
9 **REQUIREMENTS OF SUBSECTION (A)(4)(I), (II)2, (III), (IV), (V), AND (VI) OF THIS**
10 **SECTION.**

11 **(C) AN INDIVIDUAL SEEKING REGISTRATION UNDER THIS SECTION SHALL:**

12 **(1) APPLY FOR REGISTRATION ON A FORM SUPPLIED BY THE BOARD;**

13 **(2) PAY THE REGISTRATION FEE ESTABLISHED BY THE BOARD; AND**

14 **(3) COMPLETE ANY OTHER REQUIREMENTS ESTABLISHED BY THE**
15 **BOARD.**

16 **(D) IF AN INDIVIDUAL WAS DENIED A LICENSE BY THE BOARD, THE**
17 **INDIVIDUAL IS NOT ELIGIBLE FOR REGISTRATION UNDER THIS SECTION.**

18 **(E) AN INDIVIDUAL REGISTERED UNDER THIS SECTION SHALL COMPLETE**
19 **AT LEAST 24 HOURS OF APPROVED CONTINUING EDUCATION CREDITS EARNED**
20 **DURING THE 2-YEAR PERIOD IMMEDIATELY PRECEDING THE EXPIRATION OF A**
21 **REGISTRATION.**

22 **(F) (1) THE TERM OF A REGISTRATION MAY NOT EXCEED 3 YEARS.**

23 **(2) A REGISTRATION SHALL EXPIRE ON A DATE ESTABLISHED BY THE**
24 **BOARD.**

25 **(3) TO RENEW A REGISTRATION, THE REGISTRANT MUST:**

26 **(I) APPLY FOR RENEWAL ON A FORM SUPPLIED BY THE BOARD;**

27 **(II) PAY THE RENEWAL FEE ESTABLISHED BY THE BOARD; AND**

28 **(III) COMPLETE ANY OTHER REQUIREMENTS ESTABLISHED BY**
29 **THE BOARD.**

1 (G) AN APPLICANT FOR REGISTRATION SHALL COMPLETE A CRIMINAL
2 HISTORY RECORDS CHECK IN ACCORDANCE WITH § 14-308.1 OF THIS SUBTITLE.

3 (H) (1) THE BOARD SHALL SET REASONABLE FEES FOR THE ISSUANCE
4 AND RENEWAL OF REGISTRATIONS AND OTHER SERVICES PROVIDED.

5 (2) THE FEES CHARGED SHALL BE SET SO AS TO PRODUCE FUNDS TO
6 APPROXIMATE THE COST OF MAINTAINING THE REGISTRATION PROGRAM AND
7 OTHER SERVICES PROVIDED TO REGISTRANTS UNDER THIS SECTION.

8 (I) IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE BOARD, A
9 PHYSICIAN'S OFFICE THAT EMPLOYS AN INDIVIDUAL AUTHORIZED TO PERFORM
10 X-RAY DUTIES WITHOUT A LICENSE UNDER THIS SECTION IS RESPONSIBLE FOR
11 ENSURING THAT ALL REQUIREMENTS OF THIS SECTION ARE MET FOR EACH X-RAY
12 EXAMINATION PERFORMED.

13 (J) IF AN UNREGISTERED INDIVIDUAL PERFORMS X-RAY DUTIES WITHOUT
14 MEETING THE REQUIREMENTS OF THIS SECTION, THE BOARD MAY IMPOSE A CIVIL
15 PENALTY OF UP TO:

16 (1) \$5,000 FOR EACH VIOLATION ON THE PHYSICIAN'S OFFICE WHERE
17 THE VIOLATION OCCURRED; AND

18 (2) \$1,000 FOR EACH VIOLATION ON THE INDIVIDUAL WHO
19 COMMITTED THE VIOLATION.

20 14-306.4.

21 (A) SUBJECT TO THE HEARING PROVISIONS OF § 14-405 OF THIS TITLE, A
22 DISCIPLINARY PANEL, ON THE AFFIRMATIVE VOTE OF A MAJORITY OF THE QUORUM
23 OF THE DISCIPLINARY PANEL, MAY DENY A REGISTRATION TO PRACTICE AS A
24 LIMITED X-RAY MACHINE OPERATOR TO ANY APPLICANT, REPRIMAND ANY LIMITED
25 X-RAY MACHINE OPERATOR REGISTRANT, PLACE ANY REGISTRANT ON PROBATION,
26 OR SUSPEND OR REVOKE A REGISTRATION, IF THE APPLICANT OR REGISTRANT:

27 (1) FRAUDULENTLY OR DECEPTIVELY OBTAINS OR ATTEMPTS TO
28 OBTAIN A REGISTRATION FOR THE APPLICANT, REGISTRANT, OR FOR ANOTHER;

29 (2) FRAUDULENTLY OR DECEPTIVELY USES A REGISTRATION;

30 (3) IS GUILTY OF:

1 (I) IMMORAL CONDUCT IN THE PRACTICE OF LIMITED X-RAY
2 MACHINE OPERATION; OR

3 (II) UNPROFESSIONAL CONDUCT IN THE PRACTICE OF LIMITED
4 X-RAY MACHINE OPERATION;

5 (4) IS:

6 (I) PROFESSIONALLY INCOMPETENT;

7 (II) PHYSICALLY INCOMPETENT; OR

8 (III) MENTALLY INCOMPETENT;

9 (5) ABANDONS A PATIENT;

10 (6) IS HABITUALLY INTOXICATED;

11 (7) IS ADDICTED TO OR HABITUALLY ABUSES ANY NARCOTIC OR
12 CONTROLLED DANGEROUS SUBSTANCE AS DEFINED IN § 5-101 OF THE CRIMINAL
13 LAW ARTICLE;

14 (8) PROVIDES PROFESSIONAL SERVICES WHILE:

15 (I) UNDER THE INFLUENCE OF ALCOHOL; OR

16 (II) USING ANY NARCOTIC OR CONTROLLED DANGEROUS
17 SUBSTANCE AS DEFINED IN § 5-101 OF THE CRIMINAL LAW ARTICLE OR ANY OTHER
18 DRUG THAT IS IN EXCESS OF THERAPEUTIC AMOUNTS OR WITHOUT VALID MEDICAL
19 INDICATION;

20 (9) PROMOTES THE SALE OF SERVICES, DRUGS, DEVICES,
21 APPLIANCES, OR GOODS TO A PATIENT SO AS TO EXPLOIT THE PATIENT FOR
22 FINANCIAL GAIN;

23 (10) WILLFULLY MAKES OR FILES A FALSE REPORT OR RECORD IN THE
24 PRACTICE OF LIMITED X-RAY MACHINE OPERATION;

25 (11) WILLFULLY FAILS TO FILE OR RECORD ANY REPORT AS REQUIRED
26 UNDER LAW, WILLFULLY IMPEDES OR OBSTRUCTS THE FILING OR RECORDING OF A
27 REPORT, OR INDUCES ANOTHER TO FAIL TO FILE OR RECORD A REPORT;

28 (12) BREACHES PATIENT CONFIDENTIALITY;

1 **(13) PAYS OR AGREES TO PAY ANY SUM OR PROVIDE ANY FORM OF**
2 **REMUNERATION OR MATERIAL BENEFIT TO ANY PERSON FOR BRINGING OR**
3 **REFERRING A PATIENT OR ACCEPTS OR AGREES TO ACCEPT ANY SUM OR ANY FORM**
4 **OF REMUNERATION OR MATERIAL BENEFIT FROM AN INDIVIDUAL FOR BRINGING OR**
5 **REFERRING A PATIENT;**

6 **(14) WILLFULLY MAKES A MISREPRESENTATION WHILE PRACTICING**
7 **LIMITED X-RAY MACHINE OPERATION;**

8 **(15) WILLFULLY PRACTICES LIMITED X-RAY MACHINE OPERATION**
9 **WITH AN UNAUTHORIZED INDIVIDUAL OR AIDS AN UNAUTHORIZED INDIVIDUAL IN**
10 **THE PRACTICE OF LIMITED X-RAY MACHINE OPERATION;**

11 **(16) OFFERS, UNDERTAKES, OR AGREES TO CURE OR TREAT DISEASE**
12 **BY A SECRET METHOD, TREATMENT, OR MEDICINE;**

13 **(17) IS DISCIPLINED BY A LICENSING OR DISCIPLINARY AUTHORITY OR**
14 **IS CONVICTED OR DISCIPLINED BY A COURT OF ANY STATE OR COUNTRY OR IS**
15 **DISCIPLINED BY ANY BRANCH OF THE UNIFORMED SERVICES OR THE U.S.**
16 **DEPARTMENT OF VETERANS AFFAIRS FOR AN ACT THAT WOULD BE GROUNDS FOR**
17 **DISCIPLINARY ACTION UNDER THE BOARD'S DISCIPLINARY STATUTES;**

18 **(18) FAILS TO MEET APPROPRIATE STANDARDS FOR THE DELIVERY OF**
19 **QUALITY LIMITED X-RAY MACHINE OPERATION CARE PERFORMED IN ANY**
20 **OUTPATIENT SURGICAL FACILITY, OFFICE, HOSPITAL OR RELATED INSTITUTION, OR**
21 **ANY OTHER LOCATION IN THIS STATE;**

22 **(19) WILLFULLY SUBMITS FALSE STATEMENTS TO COLLECT FEES FOR**
23 **WHICH SERVICES ARE NOT PROVIDED;**

24 **(20) (I) HAS BEEN SUBJECT TO INVESTIGATION OR DISCIPLINARY**
25 **ACTION BY A DISCIPLINARY AUTHORITY OR BY A COURT OF ANY STATE OR COUNTRY**
26 **FOR AN ACT THAT WOULD BE GROUNDS FOR DISCIPLINARY ACTION UNDER THE**
27 **BOARD'S DISCIPLINARY STATUTES; AND**

28 **(II) HAS:**

29 **1. SURRENDERED THE LICENSE, REGISTRATION,**
30 **CERTIFICATION, OR PERMIT ISSUED BY THE STATE OR COUNTRY; OR**

1 **2. ALLOWED THE LICENSE, REGISTRATION,**
2 **CERTIFICATION, OR PERMIT ISSUED BY THE STATE OR COUNTRY TO EXPIRE OR**
3 **LAPSE;**

4 **(21) WILLFULLY FAILS TO REPORT SUSPECTED CHILD ABUSE IN**
5 **VIOLATION OF § 5-704 OF THE FAMILY LAW ARTICLE;**

6 **(22) SELLS, PRESCRIBES, GIVES AWAY, OR ADMINISTERS DRUGS FOR**
7 **ILLEGAL OR ILLEGITIMATE MEDICAL PURPOSES;**

8 **(23) PRACTICES OR ATTEMPTS TO PRACTICE BEYOND THE**
9 **AUTHORIZED SCOPE OF PRACTICE;**

10 **(24) REFUSES, WITHHOLDS FROM, DENIES, OR DISCRIMINATES**
11 **AGAINST AN INDIVIDUAL WITH REGARD TO THE PROVISION OF PROFESSIONAL**
12 **SERVICES FOR WHICH THE LICENSEE IS LICENSED AND QUALIFIED TO RENDER**
13 **BECAUSE THE INDIVIDUAL IS HIV POSITIVE;**

14 **(25) PRACTICES OR ATTEMPTS TO PRACTICE A LIMITED X-RAY**
15 **MACHINE OPERATION PROCEDURE OR USES LIMITED X-RAY MACHINE OPERATION**
16 **EQUIPMENT IF THE APPLICANT OR REGISTRANT HAS NOT RECEIVED AN EDUCATION,**
17 **AN INTERNSHIP, TRAINING, OR EXPERIENCE IN THE PERFORMANCE OF THE**
18 **PROCEDURE OR THE USE OF THE EQUIPMENT;**

19 **(26) FAILS TO COOPERATE WITH A LAWFUL INVESTIGATION**
20 **CONDUCTED BY THE BOARD OR A DISCIPLINARY PANEL;**

21 **(27) FAILS TO PRACTICE UNDER THE SUPERVISION OF A LICENSED**
22 **PHYSICIAN OR LICENSED RADIOGRAPHER OR VIOLATES A SUPERVISORY ORDER OF**
23 **A SUPERVISING PHYSICIAN OR SUPERVISING RADIOGRAPHER; OR**

24 **(28) FAILS TO COMPLETE A CRIMINAL HISTORY RECORDS CHECK**
25 **UNDER § 14-308.1 OF THIS SUBTITLE.**

26 **(B) EXCEPT AS OTHERWISE PROVIDED IN THE ADMINISTRATIVE**
27 **PROCEDURE ACT, BEFORE THE BOARD OR A DISCIPLINARY PANEL TAKES ANY**
28 **ACTION UNDER SUBSECTION (A) OF THIS SECTION, THE BOARD OR A DISCIPLINARY**
29 **PANEL SHALL GIVE THE INDIVIDUAL AGAINST WHOM THE ACTION IS**
30 **CONTEMPLATED AN OPPORTUNITY FOR A HEARING BEFORE THE BOARD OR THE**
31 **DISCIPLINARY PANEL IN ACCORDANCE WITH THE HEARING REQUIREMENTS OF §**
32 **14-405 OF THIS TITLE.**

1 **(C) (1) ON THE FILING OF CERTIFIED DOCKET ENTRIES WITH THE BOARD**
2 **BY THE OFFICE OF THE ATTORNEY GENERAL, A DISCIPLINARY PANEL SHALL ORDER**
3 **THE SUSPENSION OF A REGISTRATION IF THE REGISTRANT IS CONVICTED OF OR**
4 **PLEADS GUILTY OR NOLO CONTENDERE WITH RESPECT TO A CRIME INVOLVING**
5 **MORAL TURPITUDE, WHETHER OR NOT ANY APPEAL OR OTHER PROCEEDING IS**
6 **PENDING TO HAVE THE CONVICTION OR PLEA SET ASIDE.**

7 **(2) AFTER COMPLETION OF THE APPELLATE PROCESS, IF THE**
8 **CONVICTION HAS NOT BEEN REVERSED OR THE PLEA HAS NOT BEEN SET ASIDE WITH**
9 **RESPECT TO A CRIME INVOLVING MORAL TURPITUDE, A DISCIPLINARY PANEL**
10 **SHALL ORDER THE REVOCATION OF A REGISTRATION ON THE CERTIFICATION BY**
11 **THE OFFICE OF THE ATTORNEY GENERAL.**

12 **(D) IF, AFTER A HEARING UNDER § 14-405 OF THIS TITLE, A DISCIPLINARY**
13 **PANEL FINDS THAT THERE ARE GROUNDS UNDER SUBSECTION (A) OF THIS SECTION**
14 **TO SUSPEND OR REVOKE A REGISTRATION, TO REPRIMAND A REGISTRANT, OR TO**
15 **PLACE A REGISTRANT ON PROBATION, THE DISCIPLINARY PANEL MAY IMPOSE A**
16 **FINE SUBJECT TO THE BOARD'S REGULATIONS IN ADDITION TO SUSPENDING OR**
17 **REVOKING THE LICENSE, REPRIMANDING THE REGISTRANT, OR PLACING THE**
18 **REGISTRANT ON PROBATION.**

19 **(E) IN ADDITION TO ANY SANCTION AUTHORIZED UNDER THIS SECTION, A**
20 **DISCIPLINARY PANEL MAY REQUIRE A REGISTRANT TO COMPLY WITH SPECIFIED**
21 **TERMS AND CONDITIONS DETERMINED BY THE DISCIPLINARY PANEL.**

22 14-602.

23 (a) Unless authorized to practice medicine under this title, a person may not
24 represent to the public, by description of services, methods, or procedures, or otherwise,
25 that the person is authorized to practice medicine in this State.

26 (b) Except as otherwise provided in this article, a person may not use the words
27 or terms "Dr.", "doctor", "physician", "D.O.", or "M.D." with the intent to represent that the
28 person practices medicine, unless the person is:

29 (1) Licensed to practice medicine under this title;

30 (2) A physician licensed by and residing in another jurisdiction, while
31 engaging in consultation with a physician licensed in this State;

32 (3) A physician employed in the service of the federal government while
33 practicing within the scope of the employment;

34 (4) A physician who resides in and is licensed to practice medicine by any
35 state adjoining this State and whose practice extends into this State;

1 (5) An individual in a postgraduate medical program that is accredited by
 2 an accrediting organization recognized by the Board in regulations while the individual is
 3 practicing medicine in the program; or

4 (6) A licensee who is on emeritus status under § 14–320.1 of this title,
 5 provided that the licensee does not represent to the public that the licensee is authorized
 6 to practice medicine in the State.

7 (c) An unlicensed individual who acts under § 14–302 [or], § 14–306, **§ 14–306.1,**
 8 **§ 14–306.2, OR § 14–306.3** of this title may use the word “physician” together with another
 9 word to describe the occupation of the individual as in phrases such as “physician’s
 10 assistant” or “physician’s aide”.

11 15–302.1.

12 (c) (1) Subject to paragraph (2) of this subsection and subsection (d) of this
 13 section and except as provided in subsection (e) of this section, a physician assistant may
 14 perform advanced duties in a practice setting that is not an exempt facility only after the
 15 physician assistant obtains Board approval of the advanced duty under the collaboration
 16 agreement.

17 (2) [(i) Subject to subparagraph (ii) of this paragraph, a] A physician
 18 assistant may perform X–ray duties [authorized under § 14–306(e) of this article] in the
 19 medical office of a patient care team physician [only after the] **IF:**

20 **(I) THE PHYSICIAN ASSISTANT HAS COMPLETED A COURSE**
 21 **THAT INCLUDES RADIOGRAPHIC STUDIES OF THE EXTREMITIES OF AT LEAST 20**
 22 **SEPARATE PATIENTS;**

23 **(II) THE X–RAYS ARE LIMITED TO THE EXTREMITIES;**

24 **(III) THE X–RAYS ARE PERFORMED UNDER THE DIRECT**
 25 **SUPERVISION OF A COLLABORATING PHYSICIAN OR RADIOLOGIST;**

26 **(IV) THE X–RAYS ARE PERFORMED USING A MINI C–ARM OR A**
 27 **SIMILAR LOW–LEVEL RADIATION MACHINE TO PERFORM NONFLUOROSCOPIC X–RAY**
 28 **PROCEDURES; AND**

29 **(V) THE** physician assistant obtains Board approval of the X–ray
 30 **duty AS AN ADVANCED DUTY** under the collaboration agreement.

31 [(ii) A collaboration agreement may authorize the delegation of X–ray
 32 duties limited to nonfluoroscopic X–ray procedures of the extremities, anterior–posterior
 33 and lateral, not including the head.]

1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
2 October 1, 2026.



HOUSE BILL 1542

J1, J2

6lr3479

By: **Delegate Rosenberg**

Introduced and read first time: February 13, 2026

Assigned to: Judiciary and Health

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Goods, Services, or Technologies Used in Death Sentences –**
3 **Prohibition**

4 FOR the purpose of prohibiting a person doing business in the State from knowingly
5 manufacturing or selling, distributing, dispensing, or otherwise supplying a drug,
6 medical device, or other good, service, or technology or compounding a drug if the
7 person knows or reasonably should know that certain authorization was prompted,
8 either directly or indirectly, by a person seeking the drug, medical device, or other
9 good, service, or technology with the intent that the drug, medical device, or other
10 good, service, or technology will be used to carry out a death sentence; requiring a
11 health occupations board to deny or revoke a license or certificate to an applicant,
12 licensee, or certificate holder if the holder violates or has violated a certain provision;
13 and generally relating to goods, services, or technologies used in death sentences.

14 BY adding to
15 Article – Health – General
16 Section 21–1114
17 Annotated Code of Maryland
18 (2023 Replacement Volume and 2025 Supplement)

19 BY adding to
20 Article – Health Occupations
21 Section 1–231
22 Annotated Code of Maryland
23 (2021 Replacement Volume and 2025 Supplement)

24 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
25 That the Laws of Maryland read as follows:

26 **Article – Health – General**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 21-1114.

2 (A) A PERSON DOING BUSINESS IN THE STATE MAY NOT KNOWINGLY
3 MANUFACTURE OR SELL, DISTRIBUTE, DISPENSE, OR OTHERWISE SUPPLY A DRUG,
4 MEDICAL DEVICE, OR OTHER GOOD, SERVICE, OR TECHNOLOGY OR COMPOUND A
5 DRUG IF THE PERSON KNOWS OR REASONABLY SHOULD KNOW THAT THE ORDER,
6 PRESCRIPTION, OR OTHER AUTHORIZATION FOR THE MANUFACTURE,
7 COMPOUNDING, OR SUPPLYING OF THE DRUG, MEDICAL DEVICE, OR OTHER GOOD,
8 SERVICE, OR TECHNOLOGY WAS PROMPTED, EITHER DIRECTLY OR INDIRECTLY, BY
9 A PERSON SEEKING THE DRUG, MEDICAL DEVICE, OR OTHER GOOD, SERVICE, OR
10 TECHNOLOGY WITH THE INTENT THAT THE DRUG, MEDICAL DEVICE, OR OTHER
11 GOOD, SERVICE, OR TECHNOLOGY WILL BE USED TO CARRY OUT A DEATH SENTENCE.

12 (B) A PERSON WHO VIOLATES THIS SECTION IS SUBJECT TO A CIVIL
13 PENALTY OF \$10,000.

14 Article - Health Occupations

15 1-231.

16 IF AN APPLICANT, LICENSEE, OR CERTIFICATE HOLDER UNDER THIS ARTICLE
17 VIOLATES OR HAS VIOLATED § 21-1114 OF THE HEALTH - GENERAL ARTICLE, A
18 HEALTH OCCUPATIONS BOARD SHALL:

19 (1) DENY A LICENSE OR CERTIFICATE TO THE APPLICANT; OR

20 (2) REVOKE THE LICENSE OR CERTIFICATE.

21 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
22 October 1, 2026.



Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

Maryland Health Occupations Boards
4201 Patterson Avenue
Baltimore, MD 21215

Maryland Board of Nursing
4140 Patterson Avenue
Baltimore, Maryland 21215

March 11, 2026

The Honorable Melissa Wells
Chair, Government, Labor, and Elections Committee
145 Lowe House Office Building
Annapolis, Maryland 21401

RE: HB 1079- Office of Regulatory Management and State Government Authorizations - Letter of Concern

Dear Chair Wells and Committee Members:

The following Maryland health occupations boards (the “Boards”) respectfully submit this Letter of Concern for HB 1079: the Board of Physical Therapy Examiners, the Board of Morticians and Funeral Directors, the Board of Nursing, the Board of Examiners in Optometry, and the Board of Podiatric Medical Examiners.

The Boards recognize and support the importance of sound policies, oversight, accountability, and efforts to streamline licensure processes. However, the Boards currently license qualified health occupation practitioners within **ten (10) business days** after receipt and verification of all required documentation. As such, the Boards have already implemented efficient licensure processing practices consistent with the stated goals of the legislation.

The Boards maintain transparency through their publicly accessible website, which includes:

- The Practice Acts (statutes and regulations);
- Detailed licensing application instructions and applicant responsibilities;
- Direct links to applications;
- Monthly Public Open Session approved minutes.

In addition, the Boards maintain a comprehensive Standard Operating Procedures (SOP) Manual, which is reviewed and updated annually to ensure operational efficiency and effectiveness. These

procedures are benchmarked against performance data and aligned with annually reviewed staff job descriptions (MS-22).

Government Efficiency and Performance Reporting

Oversight and performance monitoring mechanisms are already in place. The Governor's Transparent Government Act of 2024 established the Government Efficiency Commission. In response, the Health Occupations Boards submitted detailed operational data for inclusion in the Commission's catalog, including:

- License titles and descriptions
- Number of licenses issued annually
- Fee structures
- Expedited processing practices
- Special fund revenue structures
- Application timelines
- IT systems utilized
- Criminal background check requirements
- Statutory and regulatory authority
- Recommendations for improved efficiency

Given the depth, scope, and recency of this information, it would be prudent to build upon the Commission's collected and analyzed data rather than create duplicative reporting or oversight structures.

Additionally, the Department of Health's (MDH) Managing for Results (MFR) process annually collects and reports measurable goals, objectives, and performance data, including initial licensure timelines, renewal processing, and complaint investigation metrics. This data allows for year-over-year performance comparisons. The Boards are currently working with the MDH Budget Management Office to modernize MFR language and update data collection methodologies.

Further, the MDH Units of Measurement form is completed annually and directly informs fiscal year budget estimates and workload projections.

Another concern is the Bill's desire for an "increased transparency of the State regulatory process." (pg. 3, lines 3-4) The Boards are unsure what that would entail since the regulations already go through a stringent review process by MDH, the Governor's Office, the AELR Committee, the licensees and public stakeholders through the regulations 30-day public comment period published in the *Maryland Register*. Regulations are also discussed and voted on in Board open meetings. There is also an existing comprehensive process every 8 years as a result of the Regulatory Review and Evaluation Act. HB 1079 would add unnecessary steps into the regulations process with needless, onerous reporting.

Given these existing accountability frameworks and recent statewide efficiency reviews, the Boards respectfully submit that the objectives of HB 1079 are already being addressed through established mechanisms.

For these reasons, the Boards respectfully urge the Committee to issue an unfavorable report on HB 1079.

Should you require any further information or clarification on this matter, please contact Laurie Kendall-Ellis, Executive Director for the Board of Physical Therapy Examiners at (443) 610-8047 or at laurie.kendall-ellis@maryland.gov or Lillian Reese, Legislative Liaison, at (443) 794-4757 or lillian.reese@maryland.gov.

Respectfully,

Handwritten signature of Laurie Kendall-Ellis in black ink.

Laurie Kendall-Ellis, PT, CAE
Executive Director

The opinion of the Boards expressed in this letter of concern do not necessarily reflect that of the Department of Health or the Administration.

HOUSE BILL 1079

P3, P1

6lr1952

By: **Delegates Hutchinson, Adams, Anderson, Arentz, Baker, Beauchamp, Buckel, Chisholm, Ciliberti, Ghrist, Griffith, Hartman, Hinebaugh, Hornberger, Jacobs, Kipke, R. Long, Mangione, McComas, Metzgar, Miller, T. Morgan, Pippy, Reilly, Rose, Schmidt, Stonko, Tomlinson, Valentine, and Wivell**

Introduced and read first time: February 10, 2026

Assigned to: Government, Labor, and Elections

A BILL ENTITLED

1 AN ACT concerning

2 **Office of Regulatory Management and State Government Authorizations**

3 FOR the purpose of establishing the Office of Regulatory Management; providing for the
4 Director, staffing, and duties of the Office; requiring certain units of State
5 government to submit certain reports to certain persons at certain times regarding
6 regulatory actions and permits, licenses, certifications, and registrations; requiring
7 certain units to develop a strategy to simplify certain application processes;
8 requiring certain units of State government, in consultation with the Department of
9 Information Technology, to implement online processes for the submission and
10 amendment of certain applications and fees; and generally relating to the Office of
11 Regulatory Management and the simplification of processes of the State government.

12 BY adding to

13 Article – State Government

14 Section 9–4201 through 9–4206 to be under the new subtitle “Subtitle 42. Office of
15 Regulatory Management”

16 Annotated Code of Maryland

17 (2021 Replacement Volume and 2025 Supplement)

18 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
19 That the Laws of Maryland read as follows:

20 **Article – State Government**

21 **SUBTITLE 42. OFFICE OF REGULATORY MANAGEMENT.**

22 **9–4201.**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
2 INDICATED.

3 (B) "OFFICE" MEANS THE OFFICE OF REGULATORY MANAGEMENT.

4 (C) "REGULATION" HAS THE MEANING STATED IN § 10-101 OF THIS
5 ARTICLE.
6 9-4202.

7 THE REQUIREMENTS OF THIS SUBTITLE ARE IN ADDITION TO THE
8 REQUIREMENTS OF TITLE 10, SUBTITLE 1 OF THIS ARTICLE.

9 9-4203.

10 (A) THERE IS AN OFFICE OF REGULATORY MANAGEMENT.

11 (B) (1) THE HEAD OF THE OFFICE IS THE DIRECTOR.

12 (2) THE DIRECTOR:

13 (i) SHALL BE APPOINTED BY THE GOVERNOR WITH THE ADVICE
14 AND CONSENT OF THE SENATE; AND

15 (ii) IS ENTITLED TO THE SALARY PROVIDED IN THE STATE
16 BUDGET.

17 (C) THE OFFICE SHALL HAVE THE STAFF PROVIDED FOR IN THE STATE
18 BUDGET.

19 9-4204.

20 ON OR BEFORE DECEMBER 31, 2026, THE OFFICE SHALL DEVELOP POLICIES
21 AND PROCEDURES FOR:

22 (1) THE OVERSIGHT AND IMPLEMENTATION OF A 25% REDUCTION IN
23 REGULATORY REQUIREMENTS;

24 (2) THE OVERSIGHT AND IMPLEMENTATION OF THE STREAMLINING
25 OF THE REGULATORY AND PERMITTING APPROVAL PROCESS OF ALL UNITS OF
26 STATE GOVERNMENT TO ACHIEVE A SUBSTANTIAL REDUCTION IN THE TIME

1 REQUIRED FOR APPROVAL OR REJECTION OF PERMITS, LICENSES,
2 CERTIFICATIONS, AND REGISTRATIONS; AND

3 (3) THE INCREASED TRANSPARENCY OF THE STATE REGULATORY
4 PROCESS.

5 9-4205.

6 ON OR BEFORE JULY 1, 2027, AND EACH JULY 1 THEREAFTER, EACH UNIT OF
7 STATE GOVERNMENT SHALL SUBMIT A REPORT TO THE OFFICE AND, IN
8 ACCORDANCE WITH § 2-1257 OF THIS ARTICLE, THE JOINT COMMITTEE ON
9 ADMINISTRATIVE, EXECUTIVE, AND LEGISLATIVE REVIEW LISTING ALL
10 REGULATIONS THAT THE UNIT ANTICIPATES AMENDING, ADOPTING, OR REPEALING
11 DURING THE NEXT FISCAL YEAR.

12 9-4206.

13 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
14 INDICATED.

15 (2) "AUTHORIZATION" MEANS A PERMIT, LICENSE, CERTIFICATION,
16 REGISTRATION, OR ANY OTHER INSTRUMENT THAT A PERSON IS REQUIRED TO
17 OBTAIN FROM A UNIT BEFORE ENGAGING IN A PARTICULAR ACTIVITY.

18 (3) "AVERAGE PROCESSING DURATION" MEANS THE AMOUNT OF
19 TIME IN THE PREVIOUS FISCAL YEAR THAT A UNIT TAKES TO FULLY PROCESS ANY
20 GIVEN APPLICATION FOR AN AUTHORIZATION.

21 (4) "LOW-VOLUME AUTHORIZATION" MEANS AN AUTHORIZATION
22 FOR WHICH A UNIT RECEIVES AN AVERAGE OF FEWER THAN FIVE APPLICATIONS PER
23 YEAR.

24 (B) THIS SECTION APPLIES ONLY TO UNITS IN THE EXECUTIVE BRANCH OF
25 STATE GOVERNMENT.

26 (C) ON OR BEFORE DECEMBER 1, 2026, EACH UNIT SHALL SUBMIT A
27 REPORT TO THE OFFICE CONTAINING:

28 (1) FOR EACH AUTHORIZATION, INFORMATION ON:

29 (I) THE TOTAL NUMBER OF APPLICATIONS PROCESSED
30 ANNUALLY;

1 (II) THE AVERAGE PROCESSING TIME;

2 (III) ANY FEES OR CHARGES ASSOCIATED WITH THE
3 AUTHORIZATION;

4 (IV) ANY INVOLVEMENT OF ANOTHER FEDERAL, STATE, OR
5 LOCAL GOVERNMENT ENTITY IN THE AUTHORIZATION PROCESS, INCLUDING THE
6 AVERAGE PROCESSING DURATION BY EACH ENTITY;

7 (V) THE PROVISION OF LAW THAT MANDATES OR AUTHORIZES
8 THE AUTHORIZATION;

9 (VI) INFORMATION ON WHETHER THE APPLICATION, FEE
10 PAYMENT, AND OTHER RELEVANT DETAILS MAY BE COMPLETED ONLINE;

11 (VII) WHETHER THE AUTHORIZATION HAS A TARGET
12 PROCESSING TIME OF 15 DAYS OR LESS;

13 (VIII) WHETHER THE AUTHORIZATION INVOLVES MORE THAN ONE
14 PROCEDURAL STEP; AND

15 (IX) IF THE AUTHORIZATION IS A LOW-VOLUME
16 AUTHORIZATION, A RECOMMENDATION ON WHETHER THE AUTHORIZATION SHOULD
17 BE ELIMINATED;

18 (2) A CERTIFICATION THAT THE UNIT HAS, FOR EACH
19 AUTHORIZATION:

20 (I) ASSIGNED STAFF TO BE RESPONSIBLE FOR THE
21 AUTHORIZATION;

22 (II) DEVELOPED A PROCESS FOR EACH AUTHORIZATION;

23 (III) IMPLEMENTED A SYSTEM TO TRACK THE DURATION TIME
24 FOR THE PROCESSING OF AN APPLICATION; AND

25 (IV) ESTABLISHED A STANDARDIZED INTERNAL PROCESS FOR
26 APPLICATION REVIEW; AND

27 (3) A STRATEGY TO SIMPLIFY EXISTING AUTHORIZATIONS,
28 INCLUDING:

1 **(I) REDUCING THE NUMBER OF PROCEDURAL STAGES IN THE**
2 **AUTHORIZATION PROCESS;**

3 **(II) CONVERTING INDIVIDUAL AUTHORIZATIONS TO GENERAL**
4 **AUTHORIZATIONS WHERE PERMISSIBLE BY REGULATORY, STATUTORY, OR**
5 **ADMINISTRATIVE AUTHORITY; AND**

6 **(III) REDUCING THE OVERALL NUMBER OF AUTHORIZATIONS.**

7 **(D) ON OR BEFORE APRIL 1, 2027, AND QUARTERLY THEREAFTER, EACH**
8 **UNIT SHALL SUBMIT AN UPDATE TO THE REPORT DESCRIBING ANY PROGRESS THE**
9 **UNIT HAS MADE IN IMPLEMENTING THE STRATEGY OUTLINED IN THE REPORT.**

10 **(E) EACH UNIT, IN COORDINATION WITH THE DEPARTMENT OF**
11 **INFORMATION TECHNOLOGY, SHALL DEVELOP AND IMPLEMENT PROCESSES FOR:**

12 **(1) SUBMITTING APPLICATIONS FOR AUTHORIZATIONS ONLINE;**

13 **(2) PROCESSING PAYMENTS ELECTRONICALLY; AND**

14 **(3) AMENDING PENDING APPLICATIONS.**

15 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July
16 1, 2026.



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary
Maryland Health Occupations Boards
The Commission on Kidney Disease
4201 Patterson Avenue, Third Floor
Baltimore, Maryland 21215

Maryland Board of Dental Examiners
Spring Grove Hospital Center, Rush Bldg.
55 Wade Avenue/Tulip Drive
Catonsville, Maryland 21228

2026 SESSION POSITION PAPER

BILL NO: HB 1372
COMMITTEE: Health
POSITION: Opposition

TITLE: Public Health – Office of Health Care Quality Information and Maryland Department of Health Centralization Commission

BILL ANALYSIS: The bill requires the Maryland Health Care Commission and the Office of Health Care Quality within the Maryland Department of Health to establish the Maryland Department of Health Centralization Commission to make recommendations on the oversight relationship between the Department and the health occupations boards. The bill further requires the Secretary of Information Technology to ensure that all health occupations boards adhere to State cybersecurity standards and to develop a process to identify, share for inspection, and publish certain information on a website.

POSITION AND RATIONALE: The following Maryland health occupations boards (the “Boards”) and the Maryland Commission on Kidney Disease respectfully oppose HB 1372: The Board of Acupuncture, the Board of Examiners for Audiologists, Hearing Aid Dispensers, Speech Language Pathologists, and Music Therapists, the Board of Chiropractic Examiners, the Board of Dental Examiners, the Board of Dietetic Practice, the Board of Environmental Health Specialists, the Board of Long-Term Care Administrators, the Board of Massage Therapy Examiners, the Board of Morticians and Funeral Directors, the Board of Examiners in Optometry, the Maryland Board of Podiatric Medical Examiners, the Board of Professional Counselors and Therapists, Board of Examiners of Psychologists, and the Board of Social Work Examiners.

While well intended, the bill proposes structural changes that do not recognize the Boards’ demonstrated resilience and continued public protection during extraordinary disruptions including the COVID-19 pandemic; a December 4, 2021 Department-wide cyber incident; the substantial corrective actions and operational improvements implemented since the most recent audit period; or the findings and recommendation of the 2022 legislatively created Workforce Commission that specifically examined the relationship between the Department and the Boards.

Commitment to Accountability and Transparency

The Boards fully support operational accountability, efficiency, and transparency in government operations. This commitment is demonstrated by:

- Consistent submission of Managing for Results (MFR) data with full knowledge that the information is publicly reported;
- Submission of data secondary to the 2024 Maryland Government Transparency Act (2024), including the update of information on our websites about application submission processing timelines;
- Active participation in the Commission to Study the Health Care Workforce Crisis, including the State Efficiencies and Cooperation Advisory Workgroup;
- Ongoing collaboration with the Department to modernize performance standards and improve efficiency; and
- Timely responses to transparency-related requirements, including Public Information Act requests, IQ system inquiries, reasonable accommodation reports, and other Departmental oversight mechanisms.

The Bill Relies on Outdated Audit Findings

HB 1372 is premised on findings from the Office of Legislative Audits (OLA) report covering the period **September 25, 2019, through July 31, 2023**, and the subsequent presentation at a hearing for the Joint Audit and Review Committee. The audit covered an operational period marked by a significant cyber-attack on the Department, the COVID-19 pandemic, and elevated vacancy rates across the Department and the Boards.

It is important to note:

- Not all Boards had deficiencies or repeat findings.
- Multiple Boards were cited for only two or three findings, many of which have since been resolved.
- Findings related to criminal background checks were cited against Boards that lacked statutory authority to conduct such checks at the time. In response, those Boards introduced corrective legislation during the 2026 Session (SB 806/HB 1420)
- The audit report alludes to all Boards being deficient in completing timely investigations, although accompanying data demonstrated that not all Boards were cited for this issue.
- The audit report noted that high vacancy rates “may have contributed” to certain findings
- In 2024, the Boards submitted a Request For Proposals (“RFP”) to begin the process of acquiring a new management information system, and the former Secretary put on hold its progress in favor of the Department’s current development process with the Board of Nursing.
- The Boards initiated discussions with the Department’s Budget Office to examine the relevance and modernization of existing MFRs metrics to bring them current with today’s performance expectations.
- The vast majority of the Boards have online application and payment submission.
- HB 1372 is designated as an emergency bill, giving the impression that all the Boards are operationally at risk of not having the capacity or resources to perform, and thus require intervention to maintain continuity of operations.

Since the audit’s conclusion in 2023, corrective actions have been implemented, staffing levels have improved, and operational enhancements continue. Creating a new centralization commission

represents a disproportionate response, given that oversight mechanisms are already in place and functioning.

The 2022 Workforce Commission Already Studied This Issue

In 2022, the General Assembly enacted SB 440 (Chapter 708), establishing the Commission to Study the Health Care Workforce Crisis (the “Commission”). The Commission’s **State Efficiencies and Cooperation Advisory Workgroup** examined the relationship between the Secretary of the Department (the “Secretary”) and the Boards. The Commission’s December 2023 Final Report concluded:

- The Boards serve a **vital public protection role** in regulating Maryland’s healthcare workforce.
- The Boards possess statutory fiscal independence while remaining answerable to the Secretary.
- The Department expressed commitment to collaborative administrative support to ensure operational success; and
- Continued exploration of cooperative efficiencies was encouraged.

Notably, the Commission did **not** recommend centralizing authority, restructuring Board governance, or expanding Department control over Board operations.

Oversight Mechanisms Already Exist: Secretary and Legislative Oversight

The Boards are already units of the Maryland Department of Health and are subject to the authority of the Secretary pursuant to Md. Code Ann., Health Occ. (“HO”) § 1-203. Oversight tools include: confirmation of executive directors, pursuant to HO § 1-217; approval of regulations; monitoring the timeliness of complaint resolution, pursuant to HO § 1-608; Departmental budget, fiscal & procurement processes; oversight by the Department’s Office of Internal Controls, Audit Compliance & Information Security; Sunset evaluations; review by the Office of Legislative Audits; and annual Department of Legislative Services (DLS) budget analysis and reporting requirements; and since 1985, the Boards’ and Commission’s regulations are reviewed every 8 years as a requirement of the State Regulatory Review and Evaluation Act.

These mechanisms already provide accountability and transparency without creating a new commission or restructuring governance.

Additionally, if enacted, SB 858/HB 1369 will establish a Department of Budget and Management, Audit and Finance Compliance Unit, adding yet another layer of oversight.

Boards Are Meeting Performance Metrics

The Department of Legislative Services’ Budget Analysis for the 2026 legislative session indicates that Boards are meeting their **Managing For Results (MFR)** goals, including:

- Timeliness of initial and renewal application processing; and
- Timeliness of complaint resolution/investigative performance

These metrics are reviewed annually during budget hearings, where corrective follow-up is required if deficiencies are identified. Performance trends do not demonstrate systematic failure warranting restructuring.

Proposed Centralization is Premature and Costly

HB 1372 calls for recommendations regarding a single comprehensive licensure system. However, a January 12, 2022, Department of Information Technology (“DoIT”) report estimated implementation costs of approximately \$48.7 million with a minimum four-year implementation timeline. Given this projected cost, the Boards initiated a Request for Proposals (RFP) to identify a more sustainable system. That effort was put on hold by the former Secretary in favor of the Department’s development process with the Board of Nursing.

Most Boards are specially funded. Any large-scale system implementation must be evaluated carefully to protect fiscal autonomy and avoid compromising fee stability, especially in light of BRFA reallocations. Boards are already assessed indirect costs and other statewide assessments for administrative services. As such, authorizing an allocation of the Boards’ regulatory fees to fund a system that does not yet exist is concerning.

Maryland’s Regulatory Model is Functioning

Maryland’s health occupations boards are intentionally structured as semi-independent, peer-regulated bodies accountable to the Secretary and the General Assembly. This structure demonstrates the State’s commitment to public protection in healthcare by pairing subject-matter experts and State representatives to set professional standards and develop enforcement mechanisms.

The available evidence demonstrates:

- Audit findings were limited, demonstrating progressive improvement toward resolution.
- A recently legislatively created Commission examined the Board-Department relationship and did not recommend centralization.
- Oversight mechanisms are already substantial and multi-layered.
- The Boards are not experiencing systemic failure and are meeting performance goals.

Conclusion

HB 1372 is based on audit findings marked by an extraordinary operational period and is not a reflection of performance improvements, ongoing efforts, or the findings of the 2022 Commission.

For these reasons, the Boards and Kidney Commission respectfully request an unfavorable report on HB 1372. Maryland’s current regulatory framework is functioning, accountable, and improving.

The Boards and Kidney Commission welcome further dialogue and may be contacted through our Legislative and Regulatory Liaison Lillian Reese at (443) 794-4757 or Lillian.Reese@maryland.gov.

The opinion of the Boards and Commission expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

HOUSE BILL 1372

J2, J1

EMERGENCY BILL

6lr2541
CF 6lr3598

By: **Delegate Solomon (By Request – Joint Audit and Evaluation Committee)**

Introduced and read first time: February 13, 2026

Assigned to: Health

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Office of Health Care Quality Information and Maryland**
3 **Department of Health Centralization Commission**

4 FOR the purpose of requiring the Maryland Health Care Commission, in collaboration with
5 the Office of Health Care Quality within the Maryland Department of Health, to
6 develop a process to receive and publish certain inspection information on a certain
7 website; establishing the Maryland Department of Health Centralization
8 Commission to provide certain advice and recommendations relating to the
9 relationship between the Department and the health occupations boards; requiring
10 the Secretary of Information Technology to ensure that minimum cybersecurity
11 requirements are met by all health occupations boards; and generally relating to the
12 sharing of inspection information and the oversight of health occupations boards in
13 the State.

14 BY repealing and reenacting, with amendments,
15 Article – Health – General
16 Section 19–109(b)
17 Annotated Code of Maryland
18 (2023 Replacement Volume and 2025 Supplement)

19 BY repealing and reenacting, without amendments,
20 Article – Health Occupations
21 Section 1–102
22 Annotated Code of Maryland
23 (2021 Replacement Volume and 2025 Supplement)

24 BY adding to
25 Article – Health Occupations
26 Section 1–103 and 1–104 to be under the amended subtitle “Subtitle 1. Definitions
27 and Policy”
28 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



(2021 Replacement Volume and 2025 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
That the Laws of Maryland read as follows:

Article – Health – General

19–109.

(b) In addition to the duties set forth elsewhere in this subtitle, the Commission shall:

(1) Adopt rules and regulations that relate to its meetings, minutes, and transactions;

(2) Keep minutes of each meeting;

(3) Prepare annually a budget proposal that includes the estimated income of the Commission and proposed expenses for its administration and operation;

(4) Beginning December 1, 2000, and each December 1 thereafter, submit to the Governor, the Secretary, and, subject to § 2–1257 of the State Government Article, the General Assembly an annual report on the operations and activities of the Commission during the preceding fiscal year, including:

(i) A copy of each summary, compilation, and supplementary report required by this subtitle; and

(ii) Any other fact, suggestion, or policy recommendation that the Commission considers necessary; [and]

(5) Except for confidential or privileged medical or patient information, make:

(i) Each report filed and each summary, compilation, and report required under this subtitle available for public inspection at the office of the Commission during regular business hours; and

(ii) Each summary, compilation, and report available to any other State agency on request; AND

(6) IN COLLABORATION WITH THE OFFICE OF HEALTH CARE QUALITY, DEVELOP A PROCESS TO RECEIVE THE FOLLOWING INFORMATION AND PUBLISH IT ON THE COMMISSION’S MARYLAND QUALITY REPORTING WEBSITE FOR EACH APPLICABLE FACILITY:

- 1 **(I) THE DATE OF THE OFFICE’S MOST RECENT INSPECTION;**
- 2 **(II) ANY ASSOCIATED RATINGS OR OTHER QUALITY METRICS**
3 **CALCULATED BY THE OFFICE BASED ON THE MOST RECENT INSPECTION;**
- 4 **(III) THE DATE OF THE NEXT SCHEDULED INSPECTION; AND**
- 5 **(IV) IF APPLICABLE, A STATEMENT THAT THE FACILITY HAS NOT**
6 **BEEN INSPECTED DURING THE TIME FRAME REQUIRED BY STATUTE OR**
7 **REGULATION.**

8 **Article – Health Occupations**

9 **Subtitle 1. Definitions AND POLICY.**

10 1–102.

11 (a) It is the policy of the State that health occupations should be regulated and
12 controlled as provided in this article to protect the health, safety, and welfare of the public.

13 (b) The health occupations boards established by this article, the majority of
14 whose members are licensed or certified under this article, are created to function as
15 independent boards, with the intent that a peer group is best qualified to regulate, control,
16 and otherwise discipline in a fair and unbiased manner the licensees or certificate holders
17 who practice in the State.

18 1–103.

19 **(A) IN THIS SECTION, “COMMISSION” MEANS THE MARYLAND**
20 **DEPARTMENT OF HEALTH CENTRALIZATION COMMISSION.**

21 **(B) THERE IS A MARYLAND DEPARTMENT OF HEALTH CENTRALIZATION**
22 **COMMISSION.**

23 **(C) THE PURPOSE OF THE COMMISSION IS TO PROVIDE ONGOING ADVICE**
24 **AND RECOMMENDATIONS TO THE GENERAL ASSEMBLY ON HOW BEST TO IMPROVE**
25 **THE RELATIONSHIP BETWEEN THE DEPARTMENT AND THE HEALTH OCCUPATIONS**
26 **BOARDS TO ACHIEVE GREATER EFFICIENCY, TRANSPARENCY, AND**
27 **ACCOUNTABILITY.**

28 **(D) THE COMMISSION CONSISTS OF THE FOLLOWING MEMBERS:**

29 **(1) ONE MEMBER OF THE SENATE OF MARYLAND, APPOINTED BY THE**
30 **PRESIDENT OF THE SENATE;**

1 **(2) ONE MEMBER OF THE HOUSE OF DELEGATES, APPOINTED BY THE**
2 **SPEAKER OF THE HOUSE;**

3 **(3) THE SECRETARY, OR THE SECRETARY'S DESIGNEE;**

4 **(4) THE DEPUTY SECRETARY FOR PUBLIC HEALTH SERVICES;**

5 **(5) THE EXECUTIVE DIRECTOR OF THE STATE BOARD OF NURSING,**
6 **OR THE EXECUTIVE DIRECTOR'S DESIGNEE;**

7 **(6) THE EXECUTIVE DIRECTOR OF THE STATE BOARD OF**
8 **PHYSICIANS, OR THE EXECUTIVE DIRECTOR'S DESIGNEE;**

9 **(7) THE EXECUTIVE DIRECTOR OF THE STATE BOARD OF**
10 **PHARMACY, OR THE EXECUTIVE DIRECTOR'S DESIGNEE;**

11 **(8) THE EXECUTIVE DIRECTOR OF THE STATE BOARD OF SOCIAL**
12 **WORK EXAMINERS, OR THE EXECUTIVE DIRECTOR'S DESIGNEE;**

13 **(9) THE EXECUTIVE DIRECTOR OF THE STATE BOARD OF**
14 **ENVIRONMENTAL HEALTH SPECIALISTS, OR THE EXECUTIVE DIRECTOR'S**
15 **DESIGNEE; AND**

16 **(10) ANY ADDITIONAL MEMBERS APPOINTED BY THE SECRETARY**
17 **THAT THE SECRETARY DETERMINES TO BE NECESSARY TO ACCOMPLISH THE GOALS**
18 **OF THE COMMISSION.**

19 **(E) THE SECRETARY, OR THE SECRETARY'S DESIGNEE, SHALL CHAIR THE**
20 **COMMISSION.**

21 **(F) THE DEPARTMENT SHALL PROVIDE STAFF FOR THE COMMISSION.**

22 **(G) (1) EACH HEALTH OCCUPATION BOARD ESTABLISHED UNDER THIS**
23 **ARTICLE SHALL DESIGNATE A REPRESENTATIVE OF THE HEALTH OCCUPATION**
24 **BOARD TO SERVE AS A LIAISON TO THE COMMISSION.**

25 **(2) EACH HEALTH OCCUPATION BOARD SHALL PROVIDE, AS SOON AS**
26 **PRACTICABLE BUT NOT LATER THAN 10 DAYS AFTER RECEIVING A REQUEST, ANY**
27 **INFORMATION REQUESTED BY THE COMMISSION.**

28 **(H) A MEMBER OF THE COMMISSION:**

1 (1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE
2 COMMISSION; BUT

3 (2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE
4 STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.

5 (i) THE COMMISSION SHALL:

6 (1) PROVIDE RECOMMENDATIONS REGARDING HOW BEST TO GRANT
7 AUTHORITY TO THE DEPARTMENT TO ENSURE THAT:

8 (i) EACH HEALTH OCCUPATION BOARD REMEDIES AUDIT
9 FINDINGS AND VIOLATIONS OF LAW, REGULATION, OR POLICY; AND

10 (ii) EACH HEALTH OCCUPATION BOARD ESTABLISHES POLICIES
11 AND PROCEDURES FOR, AS APPLICABLE:

12 1. THE TIMELY PROCESSING OF APPLICATIONS;

13 2. RESPONDING TO COMPLAINTS;

14 3. CONDUCTING INVESTIGATIONS AND INSPECTIONS;

15 4. CONDUCTING CRIMINAL HISTORY RECORDS CHECKS,
16 INCLUDING THE RECEIPT OF REVISED CRIMINAL HISTORY INFORMATION FROM THE
17 CENTRAL REPOSITORY AFTER THE DATE OF AN INITIAL CRIMINAL HISTORY
18 RECORDS CHECK;

19 5. THE COLLECTION OF FEES AND THE ACCOUNTING OF
20 FINANCIAL ACTIVITIES, INCLUDING THE ASSESSMENT OF PENALTIES FOR
21 VIOLATIONS OF THOSE POLICIES AND PROCEDURES;

22 6. TAKING APPROPRIATE ACTIONS FOR LICENSE
23 APPLICATION FRAUD, INCLUDING THE ASSESSMENT OF FINES; AND

24 7. ANY OTHER AREAS IN WHICH ACTION IS NEEDED, AS
25 DETERMINED BY THE SECRETARY; AND

26 (2) PROVIDE RECOMMENDATIONS ON HOW BEST TO:

27 (i) ESTABLISH A SINGLE, COMPREHENSIVE LICENSURE
28 SYSTEM TO BE USED BY ALL HEALTH OCCUPATIONS BOARDS;

1 **(II) AUTHORIZE THE USE OF HEALTH OCCUPATION BOARD**
2 **REGULATORY FEES TO SUPPORT THE SINGLE, COMPREHENSIVE LICENSURE**
3 **SYSTEM;**

4 **(III) CONSOLIDATE ADMINISTRATIVE FUNCTIONS TO ESTABLISH**
5 **AND ENHANCE EFFICIENCY AND CONTROL IN ALL AREAS, INCLUDING THROUGH THE**
6 **USE OF EXISTING DEPARTMENT SYSTEMS FOR E-MAIL, FINANCE, AND HUMAN**
7 **RESOURCES SERVICES ACROSS ALL HEALTH OCCUPATIONS BOARDS; AND**

8 **(IV) INCREASE PUBLIC AWARENESS AND USAGE OF THE**
9 **MARYLAND QUALITY REPORTING WEBSITE OF THE MARYLAND HEALTH CARE**
10 **COMMISSION TO ASSIST INDIVIDUALS WITH SELECTING APPROPRIATE HEALTH**
11 **CARE SETTINGS.**

12 **(J) ON OR BEFORE OCTOBER 1 EACH YEAR, BEGINNING IN 2026, THE**
13 **COMMISSION SHALL REPORT ITS FINDINGS AND RECOMMENDATIONS, INCLUDING**
14 **ANY DRAFT LEGISLATION, TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1257**
15 **OF THE STATE GOVERNMENT ARTICLE, THE SENATE FINANCE COMMITTEE, THE**
16 **HOUSE HEALTH COMMITTEE, AND THE JOINT AUDIT AND EVALUATION**
17 **COMMITTEE.**

18 **1-104.**

19 **THE SECRETARY OF INFORMATION TECHNOLOGY SHALL ENSURE THAT**
20 **MINIMUM CYBERSECURITY REQUIREMENTS ARE MET BY ALL HEALTH OCCUPATIONS**
21 **BOARDS ESTABLISHED UNDER THIS ARTICLE.**

22 **SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency**
23 **measure, is necessary for the immediate preservation of the public health or safety, has**
24 **been passed by a ye and nay vote supported by three-fifths of all the members elected to**
25 **each of the two Houses of the General Assembly, and shall take effect from the date it is**
26 **enacted.**



HOUSE BILL 1527

J2

6lr2376

By: **Delegate Arikan**

Introduced and read first time: February 13, 2026

Assigned to: Health

A BILL ENTITLED

1 AN ACT concerning

2 **Complementary and Alternative Health Care – Practice Authorized**
3 **(Complementary and Alternative Health Care Practice Act)**

4 FOR the purpose of authorizing an individual to practice complementary or alternative
5 health care in the State without obtaining a license, certification, or authorization
6 issued under certain provisions of law; establishing certain requirements and
7 limitations regarding the practice of complementary or alternative health care;
8 providing that certain provisions of this Act do not waive certain claims for relief;
9 and generally relating to complementary and alternative health care practitioners.

10 BY repealing and reenacting, without amendments,

11 Article – Health Occupations

12 Section 1A–101(a) and (d), 2–101(a) and (c), 3–101(a) and (b), 4–101(a) and (b),
13 5–101(a) and (b), 6–101(a) and (b), 8–101(a) and (d), 9–101(a) and (d),
14 10–101(a) and (d), 11–101(a) and (b), 12–101(a) and (d), 13–101(a) and (b),
15 14–101(a) and (b), 15–101(a) and (c), 16–101(a) and (b), 17–101(a) and (e),
16 18–101(a) and (b), 19–101(a) and (b), 20–101(a) and (c), and 21–101(a) and (b)

17 Annotated Code of Maryland

18 (2021 Replacement Volume and 2025 Supplement)

19 BY repealing and reenacting, with amendments,

20 Article – Health Occupations

21 Section 1A–301(a), 2–301(a)(1), 3–301(b), 4–301(a), 4–505(c) and (d), 5–301(a),
22 6–301(a), 8–301(a) through (c), 8–6A–02(a) and (f), 8–6B–07(a), 8–6C–06(a),
23 8–6D–02(a), 9–301(a), 9–3A–01(a), 10–301(a), 11–301(a), 11–404.1, 12–301(a),
24 12–6B–01(a), 12–6D–02, 13–301(a), 14–301, 14–5A–08(a), 14–5B–08(a)(1),
25 14–5C–08(a), 14–5D–07(a), 14–5E–08(a), 14–5F–10(a), 14–5G–08(a),
26 15–301(d)(1), 16–301, 17–301(a), 17–401, 17–6A–10(a), 18–301(a), 19–301(a),
27 20–301(a)(1) and (b)(1), and 21–301(a)

28 Annotated Code of Maryland

29 (2021 Replacement Volume and 2025 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY adding to
2 Article – Health Occupations
3 Section 22–101 through 22–204 to be under the new title “Title 22. Complementary
4 and Alternative Health Care Practitioners”
5 Annotated Code of Maryland
6 (2021 Replacement Volume and 2025 Supplement)

7 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
8 That the Laws of Maryland read as follows:

9 **Article – Health Occupations**

10 1A–101.

11 (a) In this title the following words have the meanings indicated.

12 (d) “Board” means the State Acupuncture Board.

13 1A–301.

14 (a) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
15 individual shall be licensed by the Board before the individual may practice acupuncture
16 in this State.

17 2–101.

18 (a) In this title the following words have the meanings indicated.

19 (c) “Board” means the State Board of Examiners for Audiologists, Hearing Aid
20 Dispensers, Speech–Language Pathologists, and Music Therapists.

21 2–301.

22 (a) (1) Except as otherwise provided in this title **OR § 22–201 OF THIS**
23 **ARTICLE**, an individual shall be licensed by the Board before the individual may practice
24 audiology, hearing aid dispensing, speech–language pathology, or music therapy, or assist
25 in the practice of speech–language pathology or audiology in this State.

26 3–101.

27 (a) In this title the following words have the meanings indicated.

28 (b) “Board” means the State Board of Chiropractic Examiners.

29 3–301.

1 (b) Except as otherwise provided in this title **OR § 22-201 OF THIS ARTICLE**, an
2 individual shall be licensed by the Board before the individual may practice chiropractic in
3 this State.

4 4-101.

5 (a) In this title the following words have the meanings indicated.

6 (b) "Board" means the State Board of Dental Examiners.

7 4-301.

8 (a) (1) Except as otherwise provided in this title **OR § 22-201 OF THIS**
9 **ARTICLE**, an individual shall be licensed by the Board to practice dentistry before the
10 individual may practice dentistry on a human being in this State.

11 (2) Except as otherwise provided in this title **OR § 22-201 OF THIS**
12 **ARTICLE**, an individual shall be licensed by the Board to practice dental hygiene before the
13 individual may practice dental hygiene on a human being in this State.

14 4-505.

15 (c) **[After July 1, 1988] EXCEPT AS PROVIDED IN § 22-201 OF THIS ARTICLE**,
16 an individual must be certified by the Board as a dental radiation technologist before a
17 licensed dentist may employ the individual to practice dental radiation technology.

18 (d) **[After July 1, 1988] EXCEPT AS PROVIDED IN § 22-201 OF THIS ARTICLE**,
19 an individual may not practice dental radiation technology unless certified by the Board.

20 5-101.

21 (a) In this subtitle the following words have the meanings indicated.

22 (b) "Board" means the State Board of Dietetic Practice.

23 5-301.

24 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
25 an individual shall be licensed by the Board before the individual may practice dietetics in
26 the State.

27 6-101.

28 (a) In this title the following words have the meanings indicated.

29 (b) "Board" means the State Board of Massage Therapy Examiners.

1 6–301.

2 (a) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**,
3 before an individual may practice massage therapy in the State, the individual shall be:

4 (1) On or before October 31, 2026:

5 (i) Licensed by the Board; or

6 (ii) Registered by the Board to practice massage therapy in a setting
7 that is not a health care setting; or

8 (2) On or after November 1, 2026, licensed by the Board.

9 8–101.

10 (a) In this title the following words have the meanings indicated.

11 (d) “Board” means the State Board of Nursing.

12 8–301.

13 (a) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
14 individual shall be licensed by the Board before the individual may practice registered
15 nursing in this State.

16 (b) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
17 individual shall be licensed by the Board before the individual may practice licensed
18 practical nursing in this State.

19 (c) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
20 individual shall be certified as an advanced practice registered nurse before the individual
21 may practice advanced practice registered nursing in this State.

22 8–6A–02.

23 (a) Subject to subsection (f) of this section and except as otherwise provided in
24 this subtitle **OR § 22–201 OF THIS ARTICLE**, an individual shall be certified by the Board
25 to practice as a nursing assistant, dialysis technician, or medication technician before the
26 individual may practice as a nursing assistant, dialysis technician, or medication
27 technician in the State.

28 (f) **[An] EXCEPT AS PROVIDED IN § 22–201 OF THIS ARTICLE**, AN individual
29 shall be certified by the Board to practice as a nursing assistant and as a dialysis technician

1 before the individual may practice as a dialysis technician in a State-owned hospital or
2 State-owned facility.

3 8-6B-07.

4 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
5 an individual shall be licensed by the Board before the individual may practice electrology
6 or teach an electrology education program in the State.

7 8-6C-06.

8 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
9 an individual shall be licensed by the Board before the individual may practice direct-entry
10 midwifery in the State.

11 8-6D-02.

12 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
13 an individual shall be licensed by the Board before the individual may practice certified
14 midwifery in the State.

15 9-101.

16 (a) In this title the following words have the meanings indicated.

17 (d) "Board" means the State Board of Long-Term Care Administrators.

18 9-301.

19 (a) Except as otherwise provided in this section **OR § 22-201 OF THIS ARTICLE**,
20 an individual shall be licensed by the Board before the individual may practice as a nursing
21 home administrator in this State.

22 9-3A-01.

23 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
24 beginning July 1, 2026, an individual must be licensed by the Board before the individual
25 may practice as an assisted living manager in the State.

26 10-101.

27 (a) In this title the following words have the meanings indicated.

28 (d) "Board" means the State Board of Occupational Therapy Practice.

29 10-301.

1 (a) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
2 individual shall be licensed by the Board before the individual may practice occupational
3 therapy or limited occupational therapy in this State.

4 11–101.

5 (a) In this title the following words have the meanings indicated.

6 (b) “Board” means the State Board of Examiners in Optometry.

7 11–301.

8 (a) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
9 individual shall be licensed by the Board before the individual may practice optometry in
10 this State.

11 11–404.1.

12 **(A) THIS SECTION DOES NOT APPLY TO AN INDIVIDUAL AUTHORIZED TO**
13 **PRACTICE OPTOMETRY IN THE STATE UNDER § 22–201 OF THIS ARTICLE.**

14 **[(a)] (B)** Unless certified under this section, a licensed optometrist may not
15 administer or prescribe any therapeutic pharmaceutical agents or remove superficial
16 foreign bodies from a human eye, adnexa, or lacrimal system.

17 **[(b)] (C)** (1) Except as provided in paragraph (2) of this subsection, the Board
18 shall certify a licensed optometrist as a therapeutically certified optometrist if the licensed
19 optometrist submits to the Board evidence satisfactory to the Board that the licensed
20 optometrist:

21 (i) Has successfully completed at least 110 hours of a therapeutic
22 pharmaceutical agents course approved by the Board;

23 (ii) Has successfully passed a pharmacology examination relating to
24 the treatment and management of ocular disease, which is prepared, administered, and
25 graded by the National Board of Examiners in Optometry or any other nationally
26 recognized optometric organization as approved by the Secretary;

27 (iii) Is currently certified by the Board to administer topical ocular
28 diagnostic pharmaceutical agents under § 11–404 of this subtitle; and

29 (iv) Has successfully completed an 8–hour course in the management
30 of topical steroids approved by the Board.

31 (2) (i) Except as provided in subparagraph (ii) of this paragraph, an
32 optometrist who has graduated on or after July 1, 2005 from an accredited school of

1 optometry recognized by the Board is not subject to the requirements of paragraph (1) of
2 this subsection.

3 (ii) If an optometrist who has graduated on or after July 1, 2005 from
4 an accredited school of optometry recognized by the Board is not certified under this section
5 within 3 years of graduation, the optometrist shall successfully complete a therapeutic
6 pharmaceutical agents course and successfully pass a pharmacology exam under paragraph
7 (1) of this subsection before the Board may certify the optometrist.

8 12-101.

9 (a) In this title the following words have the meanings indicated.

10 (d) "Board" means the State Board of Pharmacy.

11 12-301.

12 (a) Except as otherwise provided in this title **OR § 22-201 OF THIS ARTICLE**, an
13 individual shall be licensed by the Board before the individual may practice pharmacy in
14 this State.

15 12-6B-01.

16 (a) Except as otherwise provided in this title **OR § 22-201 OF THIS ARTICLE**, an
17 individual shall be registered and approved by the Board as a pharmacy technician before
18 the individual may perform delegated pharmacy acts.

19 12-6D-02.

20 Except as otherwise provided in this title **OR § 22-201 OF THIS ARTICLE**, an
21 individual shall be registered and approved by the Board as a registered pharmacy intern
22 before the individual may practice pharmacy under the direct supervision of a licensed
23 pharmacist in accordance with this subtitle.

24 13-101.

25 (a) In this title the following words have the meanings indicated.

26 (b) "Board" means the State Board of Physical Therapy Examiners.

27 13-301.

28 (a) Except as otherwise provided in this title **OR § 22-201 OF THIS ARTICLE**, an
29 individual shall be licensed by the Board before the individual may practice physical
30 therapy or limited physical therapy in this State.

31 14-101.

1 (a) In this title the following words have the meanings indicated.

2 (b) "Board" means the State Board of Physicians.

3 14-301.

4 Except as otherwise provided in this title [or], § 13-516 of the Education Article, **OR**
5 **§ 22-201 OF THIS ARTICLE**, an individual shall be licensed by the Board before the
6 individual may practice medicine in this State.

7 14-5A-08.

8 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
9 an individual shall be licensed by the Board before the individual may practice respiratory
10 care in this State.

11 14-5B-08.

12 (a) (1) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS**
13 **ARTICLE**, an individual shall be licensed by the Board before the individual may practice
14 radiation therapy, radiography, nuclear medicine technology, or radiology assistance in this
15 State.

16 14-5C-08.

17 (a) Except as otherwise provided in this subtitle[, on or after October 1, 2013,]
18 **OR § 22-201 OF THIS ARTICLE**, an individual shall be licensed by the Board before the
19 individual may practice polysomnography in this State.

20 14-5D-07.

21 (a) Except as otherwise provided in this subtitle **OR § 22-201 OF THIS ARTICLE**,
22 an individual shall be licensed by the Board before the individual may practice athletic
23 training in the State.

24 14-5E-08.

25 (a) Except as otherwise provided in this subtitle[, on or after October 1, 2013,]
26 **OR § 22-201 OF THIS ARTICLE**, an individual shall be licensed by the Board before the
27 individual may practice perfusion in this State.

28 14-5F-10.

1 (a) [Beginning March 1, 2016, except] **EXCEPT** as otherwise provided in this
2 subtitle **OR § 22-201 OF THIS ARTICLE**, an individual shall be licensed by the Board
3 before the individual may practice naturopathic medicine in the State.

4 14-5G-08.

5 (a) Except as otherwise provided in this subtitle[, on or after January 1, 2024,]
6 **OR § 22-201 OF THIS ARTICLE**, an individual shall be licensed by the Board before the
7 individual may practice genetic counseling in the State.

8 15-101.

9 (a) In this title the following words have the meanings indicated.

10 (c) “Board” means the State Board of Physicians, established under § 14-201 of
11 this article.

12 15-301.

13 (d) (1) Except as otherwise provided in this title **OR § 22-201 OF THIS**
14 **ARTICLE**, an individual shall be licensed by the Board before the individual may practice
15 as a physician assistant.

16 16-101.

17 (a) In this title the following words have the meanings indicated.

18 (b) “Board” means the State Board of Podiatric Medical Examiners.

19 16-301.

20 [An] **EXCEPT AS PROVIDED IN § 22-201 OF THIS ARTICLE**, AN individual shall
21 be licensed by the Board before the individual may practice podiatry in this State.

22 17-101.

23 (a) In this title the following words have the meanings indicated.

24 (e) “Board” means the State Board of Professional Counselors and Therapists.

25 17-301.

26 (a) Except as otherwise provided in subsection (b) of this section **OR § 22-201 OF**
27 **THIS ARTICLE**, an individual may not practice, attempt to practice, or offer to practice
28 clinical alcohol and drug counseling, clinical marriage and family therapy, clinical

1 professional art therapy, or clinical professional counseling in the State unless licensed by
2 the Board.

3 17–401.

4 **(A) THIS SECTION DOES NOT APPLY TO AN INDIVIDUAL AUTHORIZED TO**
5 **PRACTICE ALCOHOL AND DRUG COUNSELING, MARRIAGE AND FAMILY THERAPY,**
6 **PROFESSIONAL ART THERAPY, OR PROFESSIONAL COUNSELING IN THE STATE**
7 **UNDER § 22–201 OF THIS ARTICLE.**

8 **[(a)] (B) (1)** This subsection only applies to individuals certified by the Board
9 as a certified professional counselor or certified professional counselor–marriage and family
10 therapist on or before September 30, 2008.

11 (2) (i) An individual shall be certified as a professional counselor by the
12 Board before the individual may:

- 13 1. Use the title “certified professional counselor”;
- 14 2. Use the initials “C.P.C.” after the name of the individual;
- 15 or
- 16 3. Represent to the public that the individual is certified as
17 a professional counselor.

18 (ii) A certificate to practice professional counseling issued by the
19 Board authorizes the certificate holder to practice professional counseling while the
20 certificate is effective.

21 (3) (i) An individual shall be certified as a professional
22 counselor–marriage and family therapist by the Board before the individual may:

- 23 1. Use the title “certified professional counselor–marriage
24 and family therapist”;
- 25 2. Use the initials “C.P.C.–M.F.T.” after the name of the
26 individual; or
- 27 3. Represent to the public that the individual is certified as
28 a certified professional counselor–marriage and family therapist.

29 (ii) A certificate to practice marriage and family therapy issued by
30 the Board authorizes the certificate holder to practice marriage and family therapy while
31 the certificate is effective.

1 **[(b)] (C)** (1) An individual shall be certified as a certified professional
2 counselor–alcohol and drug by the Board before the individual may:

3 (i) Use the title “certified professional counselor–alcohol and drug”;

4 (ii) Use the initials “C.P.C.–A.D.” after the name of the individual;
5 or

6 (iii) Represent to the public that the individual is certified as a
7 certified professional counselor–alcohol and drug.

8 (2) An individual shall be certified as a certified associate
9 counselor–alcohol and drug by the Board before the individual may:

10 (i) Use the title “certified associate counselor–alcohol and drug”;

11 (ii) Use the initials “C.A.C.–A.D.” after the name of the individual;
12 or

13 (iii) Represent to the public that the individual is certified as a
14 certified associate counselor–alcohol and drug.

15 (3) An individual shall be certified as a certified supervised
16 counselor–alcohol and drug by the Board before the individual may:

17 (i) Use the title “certified supervised counselor–alcohol and drug”;

18 (ii) Use the initials “C.S.C.–A.D.” after the name of the individual;
19 or

20 (iii) Represent to the public that the individual is certified as a
21 certified supervised counselor–alcohol and drug.

22 (4) A certificate to practice alcohol and drug counseling issued by the Board
23 authorizes the certificate holder to practice alcohol and drug counseling while the certificate
24 is effective.

25 17–6A–10.

26 (a) Except as otherwise provided in this subtitle[, beginning January 1, 2015,]
27 **OR § 22–201 OF THIS ARTICLE**, an individual shall be licensed by the Board before the
28 individual may practice behavior analysis in the State.

29 18–101.

30 (a) In this title the following words have the meanings indicated.

1 (b) "Board" means the State Board of Examiners of Psychologists.

2 18–301.

3 (a) Except as otherwise provided in this section **OR § 22–201 OF THIS ARTICLE**,
4 an individual shall be licensed or registered by the Board before the individual may practice
5 psychology as a psychologist or psychology associate in this State.

6 19–101.

7 (a) In this title the following words have the meanings indicated.

8 (b) "Board" means the State Board of Social Work Examiners.

9 19–301.

10 (a) Except as otherwise provided in this title **OR § 22–201 OF THIS ARTICLE**, an
11 individual shall be:

12 (1) Licensed by the Board before the individual may practice social work in
13 this State while representing oneself as a social worker; or

14 (2) Licensed as a certified social worker–clinical before the individual may
15 practice clinical social work in this State.

16 20–101.

17 (a) In this title the following words have the meanings indicated.

18 (c) "Board" means the State Board for Certification of Residential Child Care
19 Program Professionals.

20 20–301.

21 (a) (1) Except as otherwise provided in this subsection **OR § 22–201 OF THIS**
22 **ARTICLE**, an individual shall receive a certificate from the Board before the individual may
23 be a program administrator in this State.

24 (b) (1) Except as provided in paragraph (2) of this subsection[, on or before
25 October 1, 2015,] **OR § 22–201 OF THIS ARTICLE**, an individual shall receive a certificate
26 from the Board before the individual may be a residential child and youth care practitioner
27 in this State.

28 21–101.

29 (a) In this title the following words have the meanings indicated.

1 (b) "Board" means the State Board of Environmental Health Specialists.
2 21-301.

3 (a) Except as otherwise provided in this title OR § 22-201 OF THIS ARTICLE, an
4 individual shall be licensed by the Board before the individual may practice as an
5 environmental health specialist in this State.

6 **TITLE 22. COMPLEMENTARY AND ALTERNATIVE HEALTH CARE PRACTITIONERS.**

7 **SUBTITLE 1. DEFINITIONS.**

8 **22-101.**

9 IN THIS TITLE, "COMPLEMENTARY OR ALTERNATIVE HEALTH CARE"
10 INCLUDES:

- 11 (1) ACUPRESSURE;
- 12 (2) ANTHROPOSOPHY;
- 13 (3) AROMATHERAPY;
- 14 (4) AYURVEDA;
- 15 (5) CRANIAL SACRAL THERAPY;
- 16 (6) CULTURALLY TRADITIONAL HEALING PRACTICES;
- 17 (7) DETOXIFICATION PRACTICES AND THERAPIES;
- 18 (8) ENERGETIC HEALING;
- 19 (9) POLARITY THERAPY;
- 20 (10) FOLK PRACTICES;
- 21 (11) HEALING PRACTICES USING FOOD, FOOD SUPPLEMENTS,
22 NUTRIENTS, AND THE PHYSICAL FORCES OF HEAT, COLD, WATER, TOUCH, AND
23 LIGHT;
- 24 (12) GERSON THERAPY;

- 1 **(13) COLOSTRUM THERAPY;**
2 **(14) HEALING TOUCH;**
3 **(15) HERBOLOGY OR HERBALISM;**
4 **(16) HOMEOPATHY;**
5 **(17) IRIDOLOGY;**
6 **(18) BODYWORK;**
7 **(19) MEDITATION;**
8 **(20) MIND–BODY HEALING PRACTICES;**
9 **(21) REFLEXOLOGY AND REIKI;**
10 **(22) TRADITIONAL NATUROPATHY;**
11 **(23) NONINVASIVE INSTRUMENTALITIES;**
12 **(24) TRADITIONAL ORIENTAL PRACTICES;**
13 **(25) QIGONG; AND**
14 **(26) ENERGY HEALING.**

15 **SUBTITLE 2. AUTHORIZATION TO PRACTICE.**

16 **22–201.**

17 **SUBJECT TO THE REQUIREMENTS AND LIMITATIONS OF THIS TITLE, AN**
18 **INDIVIDUAL MAY PRACTICE COMPLEMENTARY OR ALTERNATIVE HEALTH CARE**
19 **WITHOUT OBTAINING A LICENSE, CERTIFICATION, OR OTHER AUTHORIZATION**
20 **ISSUED UNDER THIS ARTICLE.**

21 **22–202.**

22 **UNLESS THE INDIVIDUAL HOLDS A LICENSE, CERTIFICATION, OR OTHER**
23 **AUTHORIZATION ISSUED UNDER THIS ARTICLE THAT AUTHORIZES THE INDIVIDUAL**
24 **TO DO SO, AN INDIVIDUAL PRACTICING COMPLEMENTARY OR ALTERNATIVE HEALTH**
25 **CARE MAY NOT:**

1 **(1) REPRESENT TO THE PUBLIC THAT THE INDIVIDUAL IS A LICENSED**
2 **HEALTH CARE PRACTITIONER;**

3 **(2) RECOMMEND TO ANOTHER INDIVIDUAL TO DISCONTINUE**
4 **PRESCRIBED MEDICAL TREATMENT;**

5 **(3) PERFORM SURGERY;**

6 **(4) EXPOSE ANOTHER TO X-RAY RADIATION;**

7 **(5) SET A FRACTURE;**

8 **(6) PRESCRIBE OR DISPENSE A PRESCRIPTION DRUG OR**
9 **CONTROLLED SUBSTANCE, AS DEFINED BY 21 U.S.C. § 812; OR**

10 **(7) MANIPULATE A SPINE OR OTHER JOINT.**

11 **22-203.**

12 **(A) AN INDIVIDUAL ACTING WITHIN THE SCOPE OF A LICENSE,**
13 **CERTIFICATE, OR OTHER AUTHORIZATION ISSUED UNDER THIS ARTICLE IS NOT**
14 **SUBJECT TO THE REQUIREMENTS OF THIS SECTION.**

15 **(B) A COMPLEMENTARY OR ALTERNATIVE HEALTH CARE PRACTITIONER**
16 **SHALL:**

17 **(1) PROVIDE EACH OF THE PRACTITIONER'S CLIENTS WITH A**
18 **WRITTEN NOTICE THAT CONTAINS:**

19 **(I) THE NAME, TITLE, BUSINESS ADDRESS, AND TELEPHONE**
20 **NUMBER OF THE PRACTITIONER;**

21 **(II) A STATEMENT INDICATING WHETHER THE PRACTITIONER**
22 **HOLDS A LICENSE, CERTIFICATE, OR OTHER AUTHORIZATION ISSUED BY A HEALTH**
23 **OCCUPATIONS BOARD UNDER THIS ARTICLE;**

24 **(III) A DESCRIPTION OF THE COMPLEMENTARY OR**
25 **ALTERNATIVE HEALTH CARE SERVICE THAT THE PRACTITIONER PROVIDES; AND**

26 **(IV) ANY EDUCATIONAL CREDENTIAL, TRAINING, EXPERIENCE,**
27 **OR OTHER QUALIFICATION HELD BY THE PRACTITIONER;**

1 **(2) OBTAIN A SIGNED WRITTEN ACKNOWLEDGEMENT THAT THE**
2 **CLIENT HAS RECEIVED THE NOTICE REQUIRED UNDER ITEM (1) OF THIS**
3 **SUBSECTION;**

4 **(3) RETAIN THE ACKNOWLEDGEMENT REQUIRED UNDER ITEM (2) OF**
5 **THIS SUBSECTION AT LEAST 2 YEARS AFTER THE DATE THE ACKNOWLEDGEMENT IS**
6 **SIGNED; AND**

7 **(4) PROVIDE THE CLIENT WITH A COPY OF THE ACKNOWLEDGEMENT**
8 **REQUIRED UNDER ITEM (2) OF THIS SUBSECTION.**

9 **22-204.**

10 **THIS TITLE MAY NOT BE CONSTRUED TO WAIVE OR LIMIT ANY COMMON LAW**
11 **OR STATUTORY CLAIM FOR RELIEF THAT A PERSON MAY BRING AGAINST A**
12 **COMPLEMENTARY OR ALTERNATIVE HEALTH CARE PRACTITIONER.**

13 **SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect**
14 **October 1, 2026.**

----- Forwarded message -----

From: [redacted]@neuralacemedical.com>
Date: Mon, Feb 16, 2026 at 12:02 PM
Subject: Scope of Practice Inquiry
To: eva.schwartz@maryland.gov <eva.schwartz@maryland.gov>



Neuralace Medical

February 16, 2026

Maryland Board of Podiatric Medical Examiners 4201 Patterson Avenue Baltimore, MD 21215

Re: Request for Advisory Opinion – Scope of Practice Inquiry Regarding Magnetic Peripheral Nerve Stimulation (mPNS) Therapy

Dear Members of the Board:

For Neuralace Medical, the manufacturer of Axon therapy, I am writing to request an advisory opinion regarding whether the administration of magnetic peripheral nerve stimulation (mPNS) Axon therapy falls within the scope of practice for licensed podiatrists in Maryland.

Background on the Treatment:

Axon Therapy® (manufactured by Neuralace Medical, Inc.) is FDA cleared for painful diabetic neuropathy of the lower extremities. This therapy utilizes the following characteristics:

- Clearance Status: FDA-cleared for chronic painful diabetic neuropathy (PDN) of the lower extremities, as well as chronic intractable pain, post-surgical pain, and post-traumatic pain

Mechanism of Action: Non-invasive magnetic peripheral nerve stimulation that delivers magnetic pulses through the skin to stimulate peripheral nerves

- Treatment Protocol: Painless, 13.5-minute outpatient sessions with no needles, incisions, or implants

- Clinical Evidence: Published randomized controlled trials demonstrate significant efficacy in reducing neuropathic pain in the lower extremities (see attachments)

Scope of Practice Analysis:

Under Maryland Health Occupations Code § 16-101(f)(1), "practice podiatry" is defined as diagnosing or surgically, medically, or mechanically treating any ailment of the human foot or ankle, or any ailment of the anatomical structures that attach to the human foot.

I believe Axon therapy may fall within the scope of podiatric practice for the following reasons:

1. Anatomical Focus: The FDA-cleared indication specifically addresses painful diabetic neuropathy of the lower extremities (foot and ankle region)
2. Treatment Modality: The therapy constitutes "medical" or "mechanical" treatment of foot and ankle ailments, similar to currently accepted modalities such as transcutaneous electrical nerve stimulation (TENS)
3. Clinical Need: Painful diabetic neuropathy is a common condition encountered in podiatric practice, and this represents a non-invasive treatment option for patients who have not responded to conventional

therapies.

4. Current Practice Patterns: Maryland podiatrists currently utilize various forms of electrical nerve stimulation and physical modalities for peripheral neuropathy treatment.

Specific Questions:

I respectfully request the Board's guidance on the following questions:

1. Does the administration of FDA-cleared magnetic peripheral nerve stimulation (mPNS) therapy for painful diabetic neuropathy of the lower extremities fall within the scope of practice for licensed podiatrists in Maryland?
2. Are there any specific training, certification, or credentialing requirements the Board would recommend or require before a podiatrist administers this therapy?
3. Are there any regulatory restrictions or limitations the Board is aware of that would preclude podiatrists from offering this treatment modality?
4. Would the Board recommend any specific documentation, informed consent, or patient selection protocols for this therapy?

Request for Formal Advisory Opinion:

I would greatly appreciate a formal written advisory opinion from the Board on this matter. This guidance will help ensure we, as a Company, respond to the inquiries we are fielding in a well-informed manner.

I am available to provide any additional information the Board may require, as well as provide initial attachments that may be useful in your deliberations.

Safety and Efficacy of Magnetic Peripheral Nerve Stimulation for Treating Painful Diabetic Neuropathy

Lora Brown, MD¹; Emmanuel Gage, MD²; Harold Cordner, MD³;
Leonardo Kapural, MD, PhD^{4,5}; Jason Rosenberg, MD⁶;
Marshall Bedder, MD^{7,8}

ABSTRACT

Objectives: Current treatments for painful diabetic neuropathy (PDN) have variable effectiveness and known side effects. Noninvasive magnetic peripheral nerve stimulation (mPNS) provides effective pain relief without the side effects associated with interventional approaches. This study measured the differences in pain relief, sensory, and quality of life improvements using mPNS and conventional medical management (CMM) compared with sham and CMM in patients with PDN.

Materials and Methods: A multicenter, randomized clinical trial was conducted from December 2022 to November 2023. Patients were randomized to receive either mPNS and CMM or sham and CMM. Subjects were randomized to treatment groups in a 3:1 ratio to mPNS+CMM or Sham+CMM and observed for 30 days during the double-blinded phase (phase 1). At 30 days, the subjects in the Sham+CMM group could cross over to the mPNS group, initiating phase 2. All patients were followed up for 90 days after the first mPNS treatment. The primary end point was the between-group comparison of the proportion of responders, a subject who experienced $\geq 50\%$ reduction from baseline in neuropathic pain measured by visual analog scale on day 30. Secondary end points included between-group comparison of percentage change from baseline for pain and numbness scores (days 30/90), responders to mPNS (day 90), and results from other quality-of-life measures (day 90).

Results: After 92 subjects were screened, 71 met the study inclusion/exclusion criteria and were treated. Subjects were similar in the groups, except for sex: 24 men (48%) in the mPNS group ($n = 50$) and 18 (85.7%) in the sham group ($n = 21$) ($p = 0.0096$). In the per-protocol analysis set, the mPNS group had a 72.3% responder rate (day 30) compared with 0% for sham (72.3% difference; 95% CI, 54.3–84.8; $p < 0.0001$), and 57.8% pain reduction from baseline, with 12.1% for sham. At day 90, mPNS had an 81.4% responder rate with 75.7% average pain reduction.

Conclusions: The data revealed that mPNS+CMM is superior to Sham+CMM at day 30 when used for treating pain from PDN. mPNS should be considered earlier in the treatment algorithm for PDN.

Clinical Trial Registration: The Clinicaltrials.gov registration number for the study is NCT05620225 (<https://clinicaltrials.gov/study/NCT05620225>). The study was first posted on November 9, 2022, and the first patient was enrolled on December 15, 2022.

Keywords: Magnetic peripheral nerve stimulation, noninvasive, pain relief, painful diabetic neuropathy, side-effect free

Address correspondence to: Marshall Bedder, MD, Department of Surgery, Pain Medicine Service, Charlie Norwood Veterans Administration Medical Center, 950 15th Street, Augusta, GA, 30904 4C-125, USA. Email: marshall.bedder@va.gov

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² Centurion Spine and Pain Centers, Brunswick, GA, USA;

³ Florida Pain Management Associates, Vero Beach, FL, USA;

⁴ Carolinas Pain Institute, Winston-Salem, NC, USA;

⁵ Atrium Health, Wake Forest Baptist Pain Center-Premier, Winston Salem, NC, USA;

⁶ South Carolina Pain and Spine Specialists, Murrell's Inlet, SC, USA;

⁷ Department of Surgery, Pain Medicine Service, Charlie Norwood Veterans Administration Medical Center, Augusta, GA, USA; and

⁸ Department of Psychiatry and Health Behavior, Addiction Medicine Service, Wellstar/Medical College of Georgia, Augusta, GA, USA

For more information on author guidelines, an explanation of our peer review process, and conflict of interest informed consent policies, please see the journal's Guide for Authors.

Source(s) of financial support: This study was supported and funded by NeuraLace Medical, Inc.

INTRODUCTION

Painful diabetic neuropathy (PDN) is a debilitating condition characterized by chronic neuropathic pain resulting from damage to the myelin sheath of peripheral nerves and axonal loss, primarily affecting the lower extremities.¹ PDN may affect quality of life (QoL), contributing to psychologic distress and social dysfunction. Initial PDN treatment typically includes glycemic control and pharmacologic interventions, such as over-the-counter pain relievers (ibuprofen, aspirin), anticonvulsants (membrane stabilizers), and antidepressants (conventional medical management, CMM).² These treatments often provide incomplete relief, sometimes with significant side effects.³ More invasive therapies, such as spinal cord stimulation (SCS), are used later in the treatment algorithm.⁴ A systematic review reported 67% to 100% of patients experienced >50% pain relief 12 months after initiation of SCS therapy. However, SCS involves surgical implantation and risks such as lead migration, infection, pocket irritation, and explantation.⁵ The increased risks and limited effectiveness of current therapies underscore the need for innovative, evidence-based PDN treatments.²

Magnetic peripheral nerve stimulation (mPNS) is Food and Drug Administration-approved for treating chronic and intractable post-traumatic and postsurgical pain and chronic PDN in the lower extremities. mPNS delivers biphasic, time-varying magnetic pulses that induce strong electrical fields in nerve bundles. These pulses are delivered at 0.2 to 5 Hz, typically 0.5 Hz.⁶ Low-frequency pulses aim to induce action potentials and neuronal activity in the ascending and descending pathways of the peripheral and central nervous systems.⁷

mPNS treatment does not recruit smaller pain fibers, making it a more attractive option for patients with hypersensitivity. This lack of induced pain is due to the physics of the induced fields and the differential recruitment of nerve fibers within a bundle. mPNS recruitment is proportional to the inverse square of the fiber diameter.⁸ A typical fiber diameter ratio of A- β (sensory) to A- Δ (pain) fibers is 3:1, yielding a recruitment ratio of 9:1. In contrast, other therapies, such as electrical PNS (ePNS) and transcutaneous electrical nerve stimulation, recruit A- β fibers in proportion to the inverse of the fiber diameter, at a 3:1 ratio.⁹ This generates a higher proportion of undesirable A- Δ recruitment, reducing the beneficial A- β recruitment based on the patient's pain tolerance.

Each mPNS treatment lasted for approximately 13 minutes and at times induced slight motor contraction. Motor activity in the ascending and descending pathways of the PNS and CNS may increase plasticity changes in the brain as afferent neuronal signals are suppressed.⁷ Competing treatments, such as percutaneous ePNS or implanted SCS, must function below the motor threshold to prevent discomfort. Moreover, neuromodulation with ultralow frequency waveforms (0.5–1 Hz) can reversibly block axonal conduction and chronic pain.¹⁰

In the recently published Safety and Efficacy of Axon Therapy (SEAT) study (which studied posttraumatic and postsurgical chronic neuropathic pain), mPNS showed superior efficacy to CMM. At three months, 71% of the subjects were deemed responders (>50% pain relief) in the mPNS+CMM group vs 13% of subjects in the CMM group.¹¹

A pivotal multicenter, double-blind, randomized, sham-controlled clinical trial (RCT) was conducted to determine the pain relief, sensory, and QoL improvements derived from mPNS+CMM (the "mPNS Treatment") in the treatment of PDN, in comparison with Sham+CMM (the "Sham Treatment").

MATERIALS AND METHODS

Approvals and Informed Consent

This study adhered to the Declaration of Helsinki and good clinical practice guidelines. The protocol and informed consent forms were approved by the Western Institutional Review Board-Copernicus Group (WCG[®] IRB), Puyallup, WA, on November 8, 2022. The trial was registered at ClinicalTrials.gov with the unique identifier NCT05620225 (<https://clinicaltrials.gov/study/NCT05620225>). The study was first posted on November 9, 2022, and the first patient was enrolled on December 15, 2022.

Study Design and Population

The mPNS-PDN study was conducted in two phases. In phase 1, subjects were blinded and randomized 3:1 to mPNS Treatment or Sham Treatment and evaluated for 30 days. After unblinding in phase 2, participants in mPNS could continue treatment and be observed for another 60 days, whereas participants in Sham had the option to cross over to mPNS Treatment and be observed for 90 days to assess extended treatment effects. Consenting subjects were assessed for eligibility on the basis of the inclusion and exclusion criteria and randomized across six US sites. The key inclusion criteria were PDN for \geq six months (diagnosed by the subject's primary care or pain physician), being refractory to conservative treatment for \geq three months (including pain medications, physical therapy, and behavioral treatment), a pain intensity score of \geq 5 of 10 on the visual analog scale (VAS), and no pain medications or a stable regimen (over-the-counter pain medications, prescription opioids, nonsteroidal antiinflammatory drugs, and anticonvulsants) for \geq 28 days before enrollment. The key exclusion criteria included neuropathic pain due to postherpetic neuropathy, HIV, trigeminal neuralgia, carpal tunnel syndrome, central pain (eg, spinal cord injury), active psychologic or psychiatric disorders, and conditions affecting pain perception. Additional exclusion criteria included progressive neurologic diseases (eg, multiple sclerosis, brain or spinal cord tumors), body mass index >40, or A1C \geq 9.0%. Although this A1C is too high for elective surgery such as SCS, and the high A1C group might be a very good target for this noninvasive alternative, the investigators concluded that an A1C of this magnitude might reflect a lack of glucose control and confound the study results.

Sample Size Calculation

The primary efficacy end point was a \geq 50% reduction in diabetic neuropathy pain intensity at day 30, with no increase in baseline pain medication within four weeks before day 30. Pain intensity was measured using a ten-point VAS scale. Pilot data suggested 60% to 65% of responders in the mPNS+CMM group compared with 0% to 15% in the Sham+CMM group. Powering to the smallest difference (60%:15%) and assuming a 3:1 subject ratio in the mPNS+CMM to Sham+CMM group, with 90% power, 60 subjects (45:15) were needed to complete the study. Approximately 80 subjects were to be enrolled to account for \geq 20% attrition.

Randomization and Blinding

Subjects diagnosed with PDN were randomized in a 3:1 ratio to either the mPNS+CMM or Sham+CMM group after final eligibility. An unbalanced group size was selected to expose more subjects to the therapy during phase 1 of the study and to minimize the risk to the study from excessive attrition in the Sham arm. Randomization

was generated using a permuted block size of four, stratified by site, to ensure within-site balance. It was assigned through the electronic data capture (EDC) system and was visible only to the “blinding operator,” a designated clinical study team member (not the investigator or a therapy administrator) at each site. The blinding operator configured the EDC system to administer either mPNS or sham therapy on the basis of an automated blinding algorithm. All treatments were administered by the physician investigator (PI) or under the PI’s supervision by another team member other than the blinding operator.

Both the participants and clinical staff (except the blinding operator) were blinded to the treatment. Device application appeared identical whether the subjects received sham or mPNS. Sham treatment was achieved by obscuring the coil and having the blinding operator reverse its orientation from active (toward the subject) to sham (away) on a per-subject basis. Blinding was maintained through strict permissions granted only to the blinding operator. At the day-30 visit, after the blinding effectiveness assessment, the subjects and treatment operator were unblinded. Participants were asked the following question: “What treatment

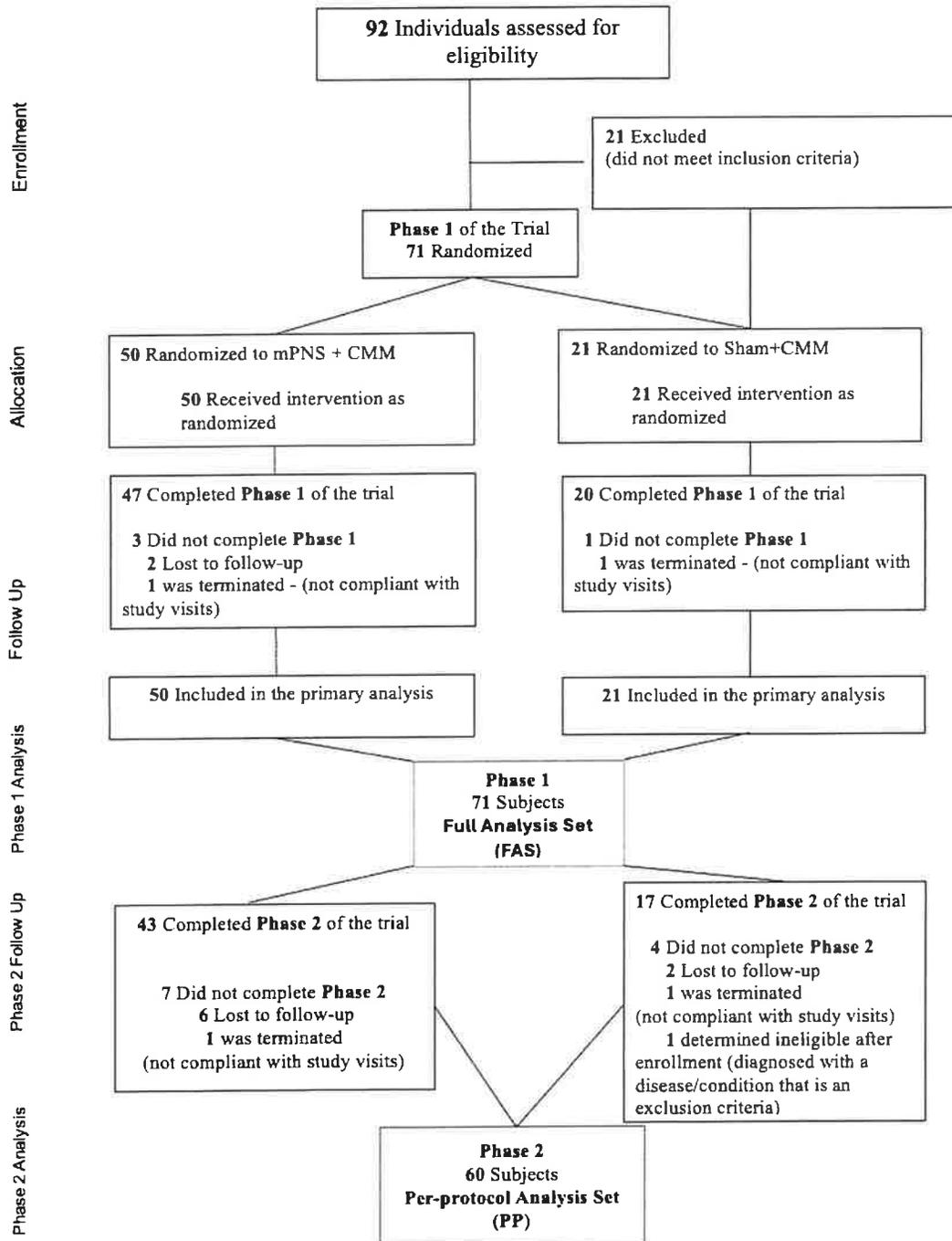


Figure 1. Consolidated Standards of Reporting Trials diagram.

group do you believe you were in?" They were then asked to choose one of the following three possible responses: Treatment, Sham, or not sure. If the 95% confidence interval (CIs) based on the James Blinding Index (BI) had an upper bound >0.5, blinding could be inferred.

Interventions

Per protocol, the participants first completed a seven-day self-assessment to measure pain scores, followed by a baseline clinical examination for those who met the inclusion criteria. Subjects scoring ≥ 5 on the VAS were randomized to receive mPNS or Sham Treatment. Analgesics were stabilized at a fixed dose 28 days before enrollment and monitored throughout the study, with adjustments allowed by the investigator, as needed.

At 30 days, the subjects in the Sham+CMM group could cross over to the mPNS group (the "Cross-Over mPNS"). The study continued to observe subjects from both the original mPNS and Cross-Over mPNS groups for 90 days.

Nerve Stimulation Procedure

The participants in the mPNS or Cross-Over mPNS groups received three treatments in the first week, followed by weekly treatments for the rest of the month. Biweekly treatments were administered for the next 60 days. Each mPNS procedure lasted 13.33 minutes per peripheral nerve (lower extremity nerves only), and PDN treatment was often bilateral, requiring two treatments per session. Investigators could adjust the intensity on the basis of the subject's needs and customize the treatment to target each subject's area of nerve damage.

During each treatment, subject information was entered in the mPNS system, including the pretreatment pain score and treatment location. A mapping procedure refined the exact treatment location and intensity, guided by the subject's feedback. Subsequently, 400 pulses were delivered while the locking arm held the coil in place. The operator could adjust the stimulus amplitude on the basis of feedback. The posttreatment pain score was then recorded.

Statistical Analysis

The full analysis set (FAS) adhered to the intent-to-treat principle, whereby all available data were included; subjects were analyzed according to their randomized group, irrespective of the treatment received. The per-protocol (PP) analysis set included all subjects who completed the day-30 visit (phase 1) without protocol deviations or missing visit data. For phase 2, the PP set included all subjects who completed the day-90 (or day 120 for Cross-Over mPNS) visit.

A fixed-sequence hierarchical testing strategy was applied to perform a confirmatory analysis of the primary and secondary efficacy end points in the FAS and PP populations. The primary end point was the proportion of responders, as measured by in-clinic VAS pain scores. Secondary end points included change in mean scores from baseline for VAS pain, European Quality of Life 5 Dimension 3 Level Scale (EQ-5D-3L), Patient Global Impression of Change, Norfolk Quality of Life-Diabetic Neuropathy (QOL-DN), Pain Disability Index (PDI), Brief Pain Inventory (BPI), Depression Anxiety Stress Scales (DASS), VAS numbness, and any increase in baseline pain medication within four weeks of day 90 (day 120 for Cross-Over mPNS).

The primary end point at days 30 and 90 (day 120 for Cross-Over mPNS) was evaluated in the FAS and PP populations using a two-sided z-test of proportions. Effect sizes were calculated using Cohen's *h* for proportions, and two-sided exact 95% CIs were determined. Secondary end point testing followed a fixed-sequence approach, as specified. Statistically significant secondary end points underwent post hoc testing for subgroup differences (age, sex, and race) with Bonferroni correction. The primary efficacy outcome of VAS pain responder and two secondary outcomes (VAS pain and EQ-5D-3L change scores) were analyzed in sensitivity analyses and tested for treatment effect consistency using logistic regression or analysis of covariance models with a treatment-subgroup interaction term.

The incidence of adverse events (AEs) was summarized at days 30 and 90 (day 120 for Cross-Over mPNS) in the Safety Analysis Set/FAS. The χ^2 or Fisher exact test was used depending on the AE proportions. However, only one AE was reported (detailed in the safety results section); therefore, no statistical analysis was necessary.

Primary and secondary outcomes in subjects in the mPNS group across all three time points (0, 30, and 90 days) were modeled using mixed-effect models with repeated measures (MMRM), provided enough subjects remained in the study through phase 2. This exploratory analysis evaluated the potential differences in outcomes at 30 and 90 days. An α value of 0.05 was used. All analysis data sets and statistical outputs will be produced by the statisticians at EpidStrategies, Inc (Ann Arbor, MI), using the SAS system version 9.4 for Windows (SAS Institute Inc, Cary, NC).

RESULTS

The trial was conducted at six sites, with the first and last subjects enrolled in December 2022 and June 2023, respectively. The trial concluded when the final participant in Cross-Over mPNS

Table 1. Summary of Demographics, PP Population.

	CMM+mPNS (n = 43)	CMM+Sham (n = 17)	p Value
	n (%)	n (%)	
Age, mean (SD)	64.0 (9.0)	65.5 (7.8)	0.53
Sex			
Male	19 (44.2%)	14 (82.4%)	0.0096
Female	24 (55.8%)	3 (17.6%)	
Race			
White	35 (81.4%)	15 (88.2%)	0.71
Black or African American	8 (18.6%)	2 (11.8%)	
Not reported	0 (0%)	0 (0%)	

Table 2. Primary End Point in PP Population at Day 30.

	CMM+mPNS (n = 50) n (%)	CMM+Sham (n = 21) n (%)	Proportion difference (95.3% CI)	p Value
VAS pain responders	34 (72.3%)	0 (0.0%)	72.3% (54.3%, 84.8%)	<0.0001

An unpooled z-test for two proportions without continuity correction was used.

completed the 90-day visit in October 2023. Of the 92 subjects screened, 21 were excluded; 71 subjects were randomized, of whom 50 received mPNS+CMM and 21 received Sham+CMM. Through day 30, all subjects who completed the day-30 visit received six treatments (either mPNS or sham). Through day 90, all subjects receiving mPNS who completed the day-90 visit received ten treatments. From day 30 to day 120, all participants who crossed over group and completed the day-120 visit received ten mPNS treatments. All 71 subjects had PDN in the lower extremities. Of the 21 subjects in the Sham group, 20 chose to cross over on day 30; 60 subjects completed the study by day 90. Eight subjects (six mPNS, two Sham) were lost to follow-up, and three (one mPNS, two Sham) had their participation terminated before completion (Fig. 1). No protocol deviations were observed.

The demographics (Table 1) were generally similar in the two treatment groups. However, in the Sham+CMM group, there was an uneven majority of men in the PP group (82.4% male). Results from sensitivity subgroup analyses (data not shown) showed no statistically significant differences in treatment effects based on sex for the VAS responder rates, VAS change score, or EQ-5D-3L change score ($p = 0.85$, $p = 0.64$, and $p = 0.25$, respectively). Baseline characteristics, physical examination, medical history, and surgical history also were similar in the groups (data not shown).

Primary Outcomes End Point Evaluation

The primary end point was defined as $\geq 50\%$ reduction in the VAS pain score on day 30 without an increase in pain medication within the previous four weeks. No subjects in the mPNS or Sham group reported increased pain medication use at days 30 or 90. In the PP populations, 34 of 50 participants (72.3%) with mPNS were responders, with 0 responders (0%) in the Sham group (day 30), yielding a 72.3% responder difference (95% CI, 54.3–84.8; $p < 0.0001$) (Table 2). This result should not be taken to indicate that

there was no sham response; the later results present the mean VAS score for Sham.

Secondary End Point Evaluations

At day 30, for the mPNS treatment group, the mean change in VAS pain score (in clinic) from baseline was -4.04 (SD = 2.45; 95% CI, -4.76 , -3.32) for the PP population. For the Sham group, the mean VAS score change was -0.81 (SD = 1.76; 95% CI, -1.63 , 0.02), indicating that a placebo effect was observed in the study. The difference in the mean change from baseline between the two groups was -3.23 ($p < 0.0001$) (Table 3). The percentage reduction in VAS pain scores showed a -57.6% reduction for mPNS vs -12.5% for Sham (for a difference of -45.1%). In the FAS and PP populations, 35 subjects with mPNS (70.0% and 81.4%, respectively) and 15 subjects in the mPNS Cross-Over group (75% and 88.2%, respectively) were responders at day 90 (data not shown).

The mean VAS pain scores in the PP population are presented in Figure 2. At day 90, the change from baseline in the mPNS group was -5.28 (SD = 2.37; 95% CI, -6.01 , -4.55). In the PP population, the mean change from baseline VAS pain score (day 30) was -4.11 (SD = 2.28; 95% CI, -4.81 , -3.41) in the mPNS group and -0.82 (SD = 1.78; 95% CI, -1.74 , 0.09) in the Sham group, a difference of -3.29 (95.3% CI, -4.54 , -2.03 ; $p < 0.0001$) (Fig. 2).

MMRM for VAS pain score (day 30), which was adjusted for baseline VAS pain score and opioid use at baseline, revealed significant differences between mPNS and Sham in both FAS and PP ($p < 0.0001$ FAS and PP): FAS mPNS (-3.95 ; SD = 0.29; 95% CI, -4.54 , -3.36) versus FAS Sham (-1.01 ; SD = 0.45; 95% CI, -1.92 , -0.11) and PP mPNS (-4.04 ; SD = 0.29; 95% CI, -4.61 , -3.47) versus PP Sham (-1.00 ; SD = 0.46; 95% CI, -1.92 , -0.09). MMRM for VAS pain score through day 90 in mPNS also was significant in both FAS (-5.24 ; SD = 0.34; 95% CI, -5.93 , -4.56 ; $p = 0.0006$) and PP (-5.28 ; SD = 0.32; -5.93 , -4.63 ; $p = 0.0007$), suggesting continued improvement through 90 days.

Table 3. Secondary End Points in PP Population at Day 30.

	CMM+mPNS (n = 47) n Mean change from baseline (SD)	CMM+Sham (n = 20) n Mean change from baseline (SD)	Difference ^a	p Value
Change in VAS pain scores (in clinic)	47 -4.04 (2.45)	20 -0.81 (1.76)	-3.23 (-4.46 , -2.01)	<0.0001
Change in VAS numbness	47 -2.29 (3.01)	20 -0.13 (2.44)	-2.16 (-3.68 , -0.64)	0.0061
Change in EQ-5D-3L	47 0.08 (0.19)	20 0.01 (0.15)	0.07 (-0.03 , 0.17)	0.16
Change in QOL-DN (total)	45 -8.36 (15.57)	19 -0.05 (13.62)	-8.30 (-16.5 , -0.08)	0.048
PGIC Status (n (%))				
Improved	38 (80.9%)	7 (35.0%)	45.9% (19.1%, 67.5%)	0.0005
Nonimproved	9 (19.1%)	13 (65.0%)		

Improved, much better and slightly better; nonimproved, no change, slightly worse, and much worse.

PGIC, Patient Global Impression of Change.

^a95% or 95.3% CIs.

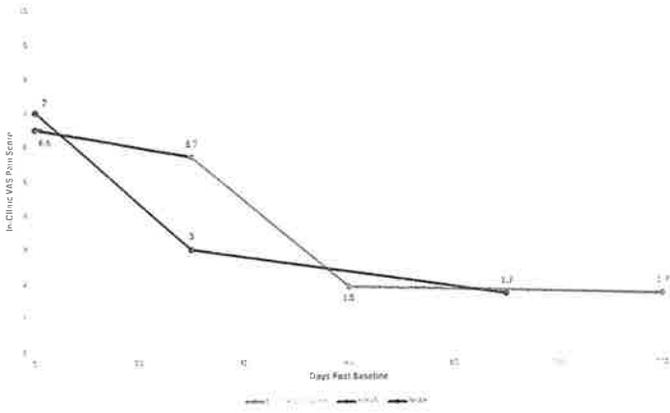


Figure 2. Mean VAS pain scores—mPNS vs Sham+Crossover, PP population.

At day 90, in both the FAS and PP, the EQ-5D-3L score change from baseline in the mPNS group was 0.14 (SD = 0.21). MMRM of the EQ-5D-3L score through day 90 in mPNS was significant in both FAS (0.15; SD = 0.03; 95% CI, 0.09–0.20; *p* = 0.019) and PP (0.14; SD = 0.03; 95% CI, 0.09–0.20; *p* = 0.023), indicating continued improvement throughout the study.

In the PP population, the mean change from baseline in the VAS numbness score at day 30 was –2.46 (SD = 3.00; 95% CI, –3.39, –1.54) in the mPNS group and –0.17 (SD = 2.53; 95% CI, –1.47, 1.13) in the Sham group, a difference of –2.29 (95% CI, –3.94, –0.64; *p* = 0.0073). At day 90, the change from baseline in the PP mPNS group was –3.54 (SD = 3.29; 95% CI, –4.55, –2.52), identical to the FAS, a 52% reduction (Fig. 3). After adjusting for baseline score and opioid use at baseline, MMRM from day 30 through day 90 in the mPNS group was significant in both FAS (–3.43; SD = 0.40; 95% CI, –4.25, –2.62; *p* = 0.0024) and PP (–3.54; SD = 0.42; 95% CI, –4.38, –2.70; *p* = 0.0033), suggesting continued improvement through 90 days.

After 90 days of treatment, the mPNS+CMM group showed improvements in other key secondary outcomes (Table 4). Subjects in the Cross-Over mPNS group also showed significant improvements in numbness, QOL-DN, PDI, and BPI scores after 90 days, whereas DASS scores remained stable across the depression, anxiety, and stress dimensions. The blinding effectiveness assessment showed that it was effective, and blinding could be inferred, with the James BI having an upper CI of 0.520 (Table 5).

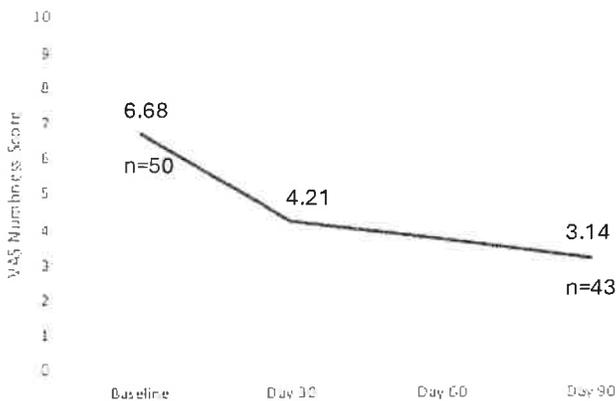


Figure 3. Mean VAS numbness scores, PP population.

Table 4. Change in Sensory and QoL Measures From Baseline to Day 90, PP Population.

	mPNS+CMM	Crossover to mPNS+CMM
	Mean change (95% CI)*	Mean change (95% CI)*
VAS numbness (in-clinic)	–3.54 (–4.55, –2.52)	–2.42 (–3.95, –0.90)
QOL-DN	–12.07 (–18.47, –5.67)	–15.53 (–25.40, –5.66)
PDI	–11.17 (–17.41, –4.93)	–15.59 (–21.46, –9.71)
BPI	–2.52 (–3.29, –1.75)	–1.84 (–2.78, –0.90)
DASS—depression	–2.33 (–4.48, –0.17)	–2.24 (–5.57, 1.09)
DASS—anxiety	–2.47 (–4.48, –0.45)	–2.29 (–4.84, 0.25)
DASS—stress	–4.65 (–7.78, –1.52)	–1.88 (–4.72, 0.96)

*Negative change score values indicate improvement in all sensory and QoL measures.

Safety

No treatment- or device-related AEs or AEs leading to withdrawal or death were reported in either group. One participant (2%) in the mPNS group with an extensive history of cardiovascular morbidity reported the only AE, a serious AE that occurred three months after enrollment and was unrelated to the device or treatment. The patient was hospitalized for myocardial infarction, leading to quadruple coronary artery bypass graft surgery. Before this event, the subject had been a responder with a baseline in-clinic VAS pain score of 7.5 and day 30 in-clinic VAS pain score of 1.1. The VAS pain score after the patient’s last recorded mPNS treatment was 0.0.

DISCUSSION

To our knowledge, this mPNS-PDN study is the first prospective, multicenter RCT to indicate the superiority of mPNS+CMM to Sham+CMM. Although there was a measurable Sham response of a mean VAS score change of –0.81 (for Sham+CMM), the mean VAS score change of –4.04 for mPNS+CMM was a statistically significant difference. The high pain responder rate at 90 days (FAS 70.0%; PP 81.4%) and pain reduction (FAS 75.7%; PP 75.5%) were statistically significant. These findings are similar to those of the recently published SEAT study.¹¹ The SEAT study was the first multicenter RCT to show the superiority of mPNS+CMM to CMM alone. In the PP analysis, 22 subjects (71.0%) in the mPNS+CMM group and three subjects (13.0%) in the CMM group were responders (>50% pain relief; *p* < 0.0001). At day 90, the mean change in VAS pain score was –3.76 (SD: 2.16) in mPNS+CMM compared with –0.70 (SD: 2.16) in CMM; *p* < 0.0001.

These results rival the effectiveness of invasive procedures such as temporary or implanted peripheral nerve stimulators and spinal cord stimulators^{2,4,5,12} but without their peri-procedural pain or surgical risks.⁹ No participants in the mPNS group in the study

Table 5. Blinding Effectiveness at Day 30, PP Population.

James BI*	Estimate	SE	95% CI
	0.40	0.0623	(0.27, 0.52)

*Computed using the BI package in R.

increased their pain medication usage, indicating a potential benefit in avoiding the side effects of higher CMM dosages and opioid dependency.³ The mPNS-PDN study results mirror those from the Bedder mPNS retrospective analysis.¹³

The mPNS-PDN study yielded statistically significant relief of pain and numbness, and improvements in QoL, warranting further investigation in larger populations. These results, achieved without side effects, suggest that mPNS could play a greater role in earlier PDN intervention. Additional neuropathic pain conditions, such as chemotherapy-induced peripheral neuropathy, should be explored.

Limitations

A review of QOL-DN data collection revealed that questions related to the QOL-DN symptoms domain intended for multiple body areas were only collected for one area. Consequently, the total QOL-DN and symptoms domain scores cannot be interpreted within the context of the validated QOL-DN questionnaire and published scores from other trials. Therefore, the QOL-DN results should be interpreted with this limitation in mind. Another consideration is the interaction between pain medication and mPNS. Investigators could adjust the subjects' pain medications during the study. Although no increases were observed in the mPNS group, changes in opioid analgesics could potentially confound the effects of mPNS. Because the study was not designed to address medication or psychologic issues related to chronic pain medication use, the impact of mPNS on chronic opioid use warrants further investigation. Finally, the study duration of 90 days limited the time the participants were observed. In a longer study of mPNS and PDN, once-per-month maintenance treatments would be required to maintain durable pain relief.

CONCLUSIONS

The mPNS-PDN study results at 30 and 90 days are both statistically and clinically significant. Pain relief, sensation, and QoL improvements were shown with high confidence. Pain responder rates ranged from 70.0% to 81.4%, a level previously only achieved by invasive treatments. As a noninvasive procedure, mPNS offers the benefits of neuromodulation with a significantly lower risk. This new evidence reinforces the value of mPNS, supported by the recently published Systematic Guideline by the ASPN Workgroup on the Evidence, Education, and Treatment Algorithm for Painful Diabetic Neuropathy (SWEET) guideline,² which suggest that mPNS should be considered early in the chronic PDN treatment algorithm, directly after CMM and before any invasive procedures.

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Data Availability

The Principal Investigator takes responsibility for the integrity of the data and the accuracy of the data analysis, and once unblinded, had full access to all the data in the study. The data supporting the findings of this study are available from the Principal Investigator on request.

Authorship Statements

Lora Brown, Emmanuel Gage, Harold Cordner, Leonardo Kapural, and Jason Rosenberg designed and conducted the study, including patient recruitment, data collection, and data analysis. Leonardo Kapural and Marshall Bedder designed the study and prepared the manuscript draft with important intellectual input from Lora Brown and Harold Cordner. Leonardo Kapural and Marshall Bedder provided input in analyzing the data. Lora Brown, Emmanuel Gage, Harold Cordner, Leonardo Kapural, Jason Rosenberg, and Marshall Bedder had complete access to the study data. All the authors approved the final manuscript.

Conflict of Interest

Marshall Bedder is a paid consultant for NeuraLace Medical, Inc and a consultant for Boston Scientific; and chairs the Advisory Board for Neuralace Medical. Jason Rosenberg is a consultant for Neuralace Medical. Leonardo Kapural serves on the advisory boards of Biotronik, Gimer, Neuralace, PainTEQ, and Presidio and has research agreements with Neuros, Nevro, FUS Mobile, Saluda, and Nalu. The remaining authors reported no conflict of interest.

How to Cite This Article

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January 10, 2024

NeuraLace Medical Inc.

PhD, RAC

MedTech Innovation

RQM+

2251 San Diego Ave,

Suite B-257

San Diego, California 92110

Re: K233364

Trade/Device Name: Axon Therapy

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief

Regulatory Class: Class II

Product Code: QPL, IPF

Dated: September 29, 2023

Received: October 2, 2023

Dear Dr.

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for _____ Ph.D.

DHT5B: Division of Neuromodulation

Indications for Use

510(k) Number (if known)
K233364

Device Name
Axon Therapy

Indications for Use (Describe)

The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on patients 18 and older.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K233364

DATE PREPARED

January 10, 2024

MANUFACTURER AND 510(k) OWNER

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DEVICE INFORMATION

Proprietary Name/Trade Name: Axon Therapy
Common Name: Electromagnetic stimulator, pain relief
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Class: Class II
Product Code: QPL
IPF
Review Panel: Neurology
Physical Medicine

PREDICATE DEVICE IDENTIFICATION

The Axon Therapy is substantially equivalent to the following predicates:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K210021	Axon Therapy / NeuraLace	✓

The predicate device has not been subject to a design related recall.

DEVICE DESCRIPTION

The Axon Therapy is a magnetic stimulator system that provides brief and focused magnetic pulses in order to non-invasively stimulate peripheral nerves and provide chronic nerve pain relief. The subject device is intended to be used in clinics such as pain management clinics and physical therapy clinics. The device consists of Magnetic Stimulator, Stimulation Coil, Liquid Cool Unit, and a Cart. The Axon Therapy includes a thermal shutdown feature which is activated once the inside temperature of the stimulation coil either: (A) reaches 45°C or (B) exceeds 41°C for a total of nine minutes during a 20-minute session.

INDICATIONS FOR USE

The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on patients 18 and older.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

NeuraLace believes that the Axon Therapy is substantially equivalent to the predicate device based on the information summarized here:

The subject device has an identical design and dimensions, and uses identical materials as the device cleared in K210021. The subject device has the same intended use and identical technological characteristics to the device cleared in K210021. The device has identical instrumentation to the device cleared in K210021.

Comparison Topic	Subject Device	Predicate Device	Statement of Equivalence
Company Name / Device Name	NeuraLace Medical Inc. Axon Therapy	NeuraLace Medical Inc. Axon Therapy	N/A
Indications for Use	The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable pain, post-traumatic pain, post-surgical pain and/or for relief of chronic painful diabetic peripheral neuropathy in the lower extremities. The Axon Therapy is for use on patients 18 and older.	The Axon Therapy is intended to stimulate peripheral nerves for relief of chronic intractable, post-traumatic and post-surgical pain for patients 18 and older.	Substantially equivalent to the predicate device. Clinical testing demonstrates that there is no impact on safety and effectiveness for expanded indication.
Product Codes / Regulation Numbers	QPL / 21 CFR 882.5890 IPF / 21 CFR 890.5850	QPL / 21 CFR 882.5890 IPF / 21 CFR 890.5850	Identical to predicate device with no impact on safety and effectiveness.
Technological Characteristics			
Power Source	Power Supply: 110V to 240V ac, 50/60Hz Power consumption: 800VA maximum, 115W idle	Power Supply: 110V to 240V ac, 50/60Hz Power consumption: 800VA maximum, 115W idle	Identical to predicate device with no impact on safety and effectiveness.

Comparison Topic	Subject Device	Predicate Device	Statement of Equivalence
Company Name / Device Name	NeuraLace Medical Inc. Axon Therapy	NeuraLace Medical Inc. Axon Therapy	N/A
User Interface	LED display	LED display	Identical to predicate device with no impact on safety and effectiveness.
Waveform	Biphasic wave	Biphasic wave	Identical to predicate device with no impact on safety and effectiveness.
Software / Firmware / Microprocessor Control?	Yes	Yes	Identical to predicate device with no impact on safety and effectiveness.
Indication Functions	On/off status Ready status	On/off status Ready status	Identical to predicate device with no impact on safety and effectiveness.
Time Range	800 seconds (400 pulses at 0.5 Hertz)	800 seconds (400 pulses at 0.5 Hertz)	Identical to predicate device with no impact on safety and effectiveness.
Housing Materials Construction	Stimulator: AL sheet EN AW 5754 H111 Coil: ABS	Stimulator: AL sheet EN AW 5754 H111 Coil: ABS	Identical to predicate device with no impact on safety and effectiveness.
Applied Part(s)	Coil 60BF-NL	Coil 60BF-NL	Identical to predicate device with no impact on safety and effectiveness.
Applied Part Area	16 cm ²	16 cm ²	Identical to predicate device with no impact on safety and effectiveness.
Treatment Area	Any area, such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, Back and low back etc.	Any area, such as Hand, Arm, Chest, Waist, Buttock, Thigh, Calf, Back and low back etc.	Identical to predicate device with no impact on safety and effectiveness.
Weight	Stimulator: 17 kg Coil: 3.2 kg Full system (with cart): 54 kg	Stimulator: 17 kg Coil: 3.2 kg Full system (with cart): 54 kg	Identical to predicate device with no impact on safety and effectiveness.
Unit Dimensions	485 x 380 x 165 mm	485 x 380 x 165 mm	Identical to predicate device with no impact on safety and effectiveness.
Pulse Frequency	0-2 Hz	0-2 Hz	Identical to predicate device with no impact on safety and effectiveness.
Pulse Amplitude	0 to 100% A maximum of 80% intensity is recommended to reduce the risk of coil overheating	0 to 100% A maximum of 80% intensity is recommended to reduce the risk of coil overheating	Identical to predicate device with no impact on safety and effectiveness.
On-Cycle Duty Period	2-800 seconds	2-800 seconds	Identical to predicate device with no impact on safety and effectiveness.
Maximum Repetition Rate	2 pulses per second (pps)	2 pulses per second (pps)	Identical to predicate device with no impact on safety and effectiveness.
Pulse Mode	Standard	Standard	Identical to predicate device with no impact on safety and effectiveness.

Comparison Topic	Subject Device	Predicate Device	Statement of Equivalence
Company Name / Device Name	NeuraLace Medical Inc. Axon Therapy	NeuraLace Medical Inc. Axon Therapy	N/A
Pulse Width	Biphasic (290 μ sec)	Biphasic (290 μ sec)	Identical to predicate device with no impact on safety and effectiveness.
Maximum Output Power	100% at 2 pps	100% at 2 pps	Identical to predicate device with no impact on safety and effectiveness.
Testing			
Non-Clinical Testing	Electrical safety per IEC 60601-1 EMC testing per IEC 60601-1-2 Software testing per IEC 62304 Usability testing per IEC 62366-1	Electrical safety per IEC 60601-1 EMC testing per IEC 60601-1-2 Software testing per IEC 62304 Usability testing per IEC 62366-1	Identical to predicate device, no new elements proposed for subject device requiring new non-clinical testing. No impact to safety and effectiveness.
Clinical Testing	Three previous studies that evaluated the effectiveness and safety of the subject device. One additional study for patients with diabetic peripheral neuropathy (PDN) for the subject device.	Three studies that evaluated the effectiveness and safety of the subject device.	Substantially equivalent to the predicate device. Performance and clinical testing demonstrate that there are no new questions of safety and effectiveness.

SUMMARY OF NON-CLINICAL TESTING

The Axon Therapy subject device had no design changes from the predicate device cleared in K210021 that required additional non-clinical testing for this submission to demonstrate safety and effectiveness:

Software Verification: The subject device did not undergo any new software verification testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

Electromagnetic Compatibility and Electrical Safety: The subject device did not undergo any new electromagnetic compatibility and electrical safety testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

Usability: The subject device did not undergo any new usability testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

Performance Testing: The subject device did not undergo any new performance testing due to substantial equivalence of the predicate device and no new questions of safety and effectiveness.

SUMMARY OF CLINICAL TESTING

The goal of the Axon Therapy PDN clinical study was to expand the indications to include painful diabetic peripheral neuropathy. Axon Therapy was demonstrated to be effective and safe in the original clinical studies for chronic intractable post-traumatic and post-surgical pain. The primary efficacy objective of this trial was to compare the proportion of responders in the Axon Therapy plus CMM group, (responder is defined as a subject who experiences 50% or greater reduction from baseline in neuropathic pain intensity as measured by an in-clinic visual analog score (VAS) for the primary area of pain at Day 30, with no increase over baseline pain medications within four weeks of the Day 30 visit), to the Sham plus CMM group.

The results of the study demonstrate effectiveness of this non-invasive Treatment at statistically significant levels. The % reduction in VAS pain scores showed a -57.6% reduction for Treatment vs -12.5% for Sham at a p value of <0.00001. The -45.1% VAS pain reduction from Sham supports the argument that these are statistically significant improvements in patient care and not a placebo effect. In addition to pain relief, both the QoL-DN and PGIC scales show that this pain relief manifests into better quality of life outcomes at a statistically significant level.

CONCLUSION

The Axon Therapy is considered substantially equivalent to the predicate device based on the testing performed, the similar indications for use, and identical technological characteristics. Based on the testing performed it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices.