

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD
Commissioner



Ned Lamont
Governor
Susan Bysiewicz
Lt. Governor

RE: DECLARATORY RULING CONCERNING THE USE OF THE EMSCULPT NEO MEDICAL DEVICE BY LICENSED CHIROPRACTORS

FINAL DECISION AND ORDER

The parties in the above-referenced matter were provided an opportunity, in accordance with Conn. Gen. Stat. §§ 4-179 and 19a-14(f)(2), to file written exceptions and/or request oral argument to the attached Proposed Declaratory Ruling of the Connecticut Board of Chiropractic Examiners ("the Board") rendered on August 18, 2022 ("Proposed Declaratory Ruling"). Exceptions were due by September 17, 2022. On September 16, 2022, exceptions and a request for oral argument were filed by the Connecticut Chiropractic Association, Inc., a designated party in this matter.

In accordance with Conn. Gen. Stat. § 19a-14(f)(2), on October 11, 2022, the undersigned was designated by Manisha Juthani, MD, the Commissioner of the State of Connecticut's Department of Public Health, to review the Proposed Declaratory Ruling and the entire administrative record in this matter and to render a final determination.

Oral argument was noticed and heard in this matter on January 5, 2022. Attorney Mary Alice Moore Leonhardt appeared on behalf of the Connecticut Chiropractic Association and gave argument in support of the exceptions that were filed. Dr. Alan H. Siegel, DC, also a designated party in this matter, was not present for oral argument and did not file written exceptions.

After reviewing and evaluating the Proposed Declaratory Ruling, the substantive merits of the proposed ruling, the entire administrative record before the Board, and considering the issues and legal arguments presented at hearing and at oral argument, it is clear that, in accordance with Conn. Gen. Stat. § 20-28, the use of the Emsculpt Neo Medical device¹ by licensed chiropractors in Connecticut is not within the scope of chiropractic practice in Connecticut.

The Proposed Declaratory Ruling is supported by the administrative record. Additionally, in making the Proposed Declaratory Ruling, the Board relied on the training, expertise, and specialized

¹ As set forth in footnote 1 of the Proposed Declaratory Ruling, the device that is the subject of this Declaratory Ruling is the Emsculpt Neo Medical Device K202199 (BTL-899ST) and predicate device K192224 (BTL-899), manufactured by BTL Industries.



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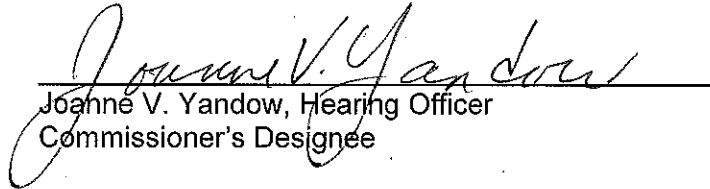
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knowledge of its members in the practice of chiropractic. See *Pet v. Department of Health Services*, 228 Conn. 651, 670 (1994).

Based on the foregoing, I hereby adopt the attached Proposed Declaratory Ruling of the Connecticut Board of Chiropractic Examiners rendered on August 18, 2022, as the Final Declaratory Ruling.

4/25/2023
Date


Joanne V. Yandow, Hearing Officer
Commissioner's Designee

**STATE OF CONNECTICUT
CONNECTICUT BOARD OF CHIROPRACTIC EXAMINERS**

IN RE: DECLARATORY RULING CONCERNING THE USE OF THE
 EMSCUPLT NEO MEDICAL DEVICE BY LICENSED
 CHIROPRACTORS

FOR THE BOARD: Candito Carroccia, DC, Chairperson
 Gina Carucci, DC, Board Member
 Sean Robotham, DC, Board Member
 Karlos Boghosian, DC, Board Member
 Pamela Sawyer, Public Member

PROPOSED DECLARATORY RULING

Procedural Background

On March 31, 2021, Alan H. Siegel, DC (“Petitioner”), petitioned the Connecticut Board of Chiropractic Examiners (the “Board”) to issue a declaratory ruling pursuant to § 4-176 of the Connecticut General Statutes (“Conn. Gen. Stat.”) regarding whether the use of the Emsculpt Neo medical device (“the Emsculpt”)¹ is within the scope of practice for a licensed chiropractor in the State of Connecticut.² Board (“Bd.”) Exhibit (“Ex.”) 1.

On May 18, 2021, a Notice of the Declaratory Ruling Proceeding was published in the *Connecticut Law Journal* indicating the Board’s intention to issue a declaratory ruling and hold a hearing.³ Bd. Ex. 5. The Notice further indicated that all persons seeking status to participate were required to petition the Board by June 4, 2021, and that the Board would issue its rulings on the petitions for status by June 17, 2021. Bd. Ex. 5. The Notice further advised that a hearing would be held on August 19, 2021. Bd. Ex. 5.

¹ The specific device referenced in this proceeding is the Emsculpt Neo Medical Devices K202199 (BTL-899ST) and predicate device K192224 (BTL-899), manufactured by BTL Industries. Transcript (“Tr.”), 10/14/21, pp. 84, 85; Siegel Ex. K. According to the manufacture, Emsculpt works by emitting a radio frequency and electromagnetic stimulation that contracts the muscle and breaks down fat. Siegel Exs. B and M.

² On April 22, 2021, Petitioner waived the time requirements to issue a declaratory ruling pursuant to Conn. Gen. Stat. § 4-176(i). Bd. Ex. 3.

³ Pursuant to Conn. Gen. Stat. § 19a-14(f)(2), the Board’s declaratory ruling will be a proposed decision and the Commissioner of the Department of Public Health (“Commissioner”), or the Commissioner’s designee, will render the final determination of the matter. Bd. Ex. 2.

On June 1, 2021, the Connecticut Chiropractic Association, Inc. (“CCA”) requested party status in the declaratory ruling proceeding. Bd. Ex. 6.

On June 24, 2021, Dr. Siegel was designated a party, and the CCA was granted party status pursuant to Conn. Gen. Stat. § 4-177a(a). Bd. Exs. 7 and 8.

On August 3, 2021, a Notice of Declaratory Ruling Proceeding was published in the *Connecticut Law Journal*, indicating a hearing would be held August 19, 2021. Bd. Ex. 10.

At the hearing on August 19, 2021, the Board continued the hearing to allow Dr. Siegel additional time to pre-file testimony and submit documentary evidence in support of his claims and for the CCA to submit its response thereto. Transcript (“Tr.”) 8/16/21, pp. 37-38. On August 25, 2021, Dr. Siegel pre-filed testimony and evidence. The CCA did not pre-file testimony. Bd. Ex. 11.

Dr. Siegel adopted his pre-filed testimony under oath during the hearing on October 14, 2021 and submitted evidence in support of his petition. Siegel Exs. A-N; Tr. 10/14/21, pp. 8, 9.

The hearing in this matter was conducted in accordance with Conn. Gen. Stat. §§ 4-176(g), 4-177c(b), 4-178, 4-179 and §§ 19a-9-24 through 19a-9-29 of the Regulations of Connecticut State Agencies (“the Regulations”).⁴ Bd. Exs. 10, 12, 13. Petitioner appeared *pro se*; Attorney Mary Alice Moore Leonhardt appeared on behalf of the CCA. Tr. 8/19/21, pp. 6-7; Tr., 10/14/21, p. 5.

This Declaratory Ruling is based entirely on the record and the specialized professional knowledge of the Board in evaluating the evidence. *See* Conn. Gen. Stat. § 4-178; *Pet v. Department of Health Services*, 228 Conn. 651, 666 (1994). The Board relied on the training and experience of its members in making this Ruling. *Pet v. Department of Health Services*, 228 Conn. 651, 667 (1994). To the extent that the findings of fact actually represent conclusions of law, they should be so considered, and vice versa. *SAS Inst., Inc. v. S & H Computer Systems, Inc.*, 605 F. Supp. 816 (Md. Tenn. 1985).

Discussion

Conn. Gen. Stat. § 4-176 authorizes the Board to issue a declaratory ruling regarding, among other things, the applicability of the statutes or regulations to specified circumstances on matters within the agency’s jurisdiction. By law, a declaratory ruling constitutes a statement of

⁴ During the Board’s meeting on April 22, 2021, Petitioner waived the time requirements to issue a declaratory ruling pursuant to § 4-176(i) of the Conn. Gen. Stat.

agency law and may also be utilized by the Board, on a case-by-case basis, in future proceedings before the Board concerning the practice of chiropractic.

In accordance with Conn. Gen. Stat. § 20-24, the practice of chiropractic means:

the practice of that branch of the healing arts consisting of the science of adjustment, manipulation and treatment of the human body in which vertebral subluxations and other malpositioned articulations and structures that may interfere with the normal generation, transmission and expression of nerve impulse between the brain, organs and tissue cells of the body, which may be a cause of disease, are adjusted, manipulated or treated.

Conn. Gen. Stat. § 20-28(b) provides that any chiropractor who has complied with Chapter 372 of the Statutes may:

(1) Practice chiropractic as defined in section 20-24, but shall not prescribe for or administer to any person any medicine or drug included in materia medica, except vitamins, or perform any surgery or practice obstetrics or osteopathy;

(2) Examine, analyze and diagnose the human living body and its diseases, and use for diagnostic purposes the x-ray or any other general method of examination for diagnosis and analysis taught in any school or college of chiropractic which has been recognized and approved by the State Board of Chiropractic Examiners;

(3) Treat the human body by manual, mechanical, electrical or natural methods, including acupuncture, or by use of physical means, including light, heat, water or exercise in preparation for chiropractic adjustment or manipulation, and by the oral administration of foods, food concentrates, food extracts or vitamins;

(4) Administer first aid and, incidental to the care of the sick, advise and instruct patients in all matters pertaining to hygiene and sanitary measures as taught and approved by recognized chiropractic schools and colleges.

The Board is unpersuaded that use of the Emsculpt device is within the scope of practice of chiropractic. Based on the evidence in the record, the Board finds Emsculpt is used primarily for cosmetic purposes and not in preparation for chiropractic adjustment or manipulation. See Tr., 10/19/21, pp. 27, 28, 30, 32, 22. In evaluating the evidence before it, the Board finds, based on its specialized knowledge, that the Emsculpt device does not provide a chiropractic benefit. The evidence in the record is insufficient to establish that Emsculpt inhibits or decreases adipose tissue, strengthens muscles or reduces a person's body mass index to provide for a chiropractic benefit.

Petitioner provided excerpts of various studies from the manufacturer's promotional materials that he claims support the use of the Emsculpt device in chiropractic care. Tr. 10/19/21, p. 83; Siegel Ex. B. The Board does not find these excerpts persuasive to allow for the use of this device for chiropractic care. The record is devoid of any studies or peer review articles that support the use of Emsculpt for chiropractic care within the scope of practice as set forth in Conn. Gen. Stat. § 20-28.

Additionally, the evidence in the record indicates there is no training on the use of the Emsculpt device in any chiropractic colleges. Tr., 10/14/21, pp. 45, 65. The Board finds that the evidence weighs heavily in support of the Emsculpt device for aesthetic purposes but fails to sufficiently establish any chiropractic purpose as set forth in Conn. Gen. Stat. § 20-24 or treatment within the scope of practice as set forth in Conn. Gen. Stat. § 20-28.

Ruling

Based on the foregoing record, the Board concludes that in accordance with Conn. Gen. Stat. § 20-28, the use of the Emsculpt device is not within the scope of chiropractic practice in Connecticut.

8/18/2022
Date

Karlos Boghosian, DC
Karlos Boghosian, DC
Board Member