

MEMORANDUM

DATE	May 12, 2023
TO	Board Members California Board of Naturopathic Medicine
FROM	Rebecca Mitchell, Executive Officer California Board of Naturopathic Medicine
SUBJECT	Agenda Item 5.a.: Consideration of Proposed Regulations to Adopt Sections 4237.1, 4237.2, 4237.3, 4237.4 and 4237.5 in Title 16 of the California Code of Regulations (CCR) (Intravenous (IV) and Advanced Injection Therapy, and IV Therapy Course Approval)

Background

Effective 2013, under the provisions of Senate Bill 1446 (“SB 1446” – Stats. 2012, Ch. 333 – **Attachment No. 1**) Section 3640.8 of the Business and Professions Code (BPC) was added to the Naturopathic Doctors Act (“Act”) to require a Naturopathic Doctor (ND), to qualify to administer Intravenous (IV) therapy in their practice pursuant to BPC section 3640.7, to demonstrate that they:

- (A) have a current California ND license, and,
- (B) have completed a qualifying course on IV therapy from a course provider approved by the Naturopathic Medicine Committee.

SB 1446 also authorized the Board, at BPC section 3640.8(d), to “establish regulations regarding IV administration that are consistent with the education and training of a naturopathic doctor.”

The legislative history for SB 1446 considered the following public health and safety issues related to IV therapy administration:

“Depending on the substance and the patient, an IV or IM injection may be preferable to other routes of administration. Many substances have more immediate onset of action when administered via IV or IM.

As with any medical procedure, there are risks with utilizing IV and IM routes. If not trained properly, the practitioner may cause nerve damage when

administering substances via IM. Site selection is also important because the effect of the medication can be enhanced or diminished depending on the site used. In terms of IV administration, infection is the biggest risk because the skin has been broken, giving bacteria access to the body. In most cases, infection is localized, appearing only at the IV site. However, bacteria can spread throughout the bloodstream. Other risks include embolism, caused by blood clots or air bubbles. While potentially life-threatening, this occurs infrequently.”
(Committee Analysis of SB 1446 for Assembly Committee on Business, Professions and Consumer Protection, p. 4, **Attachment 2.**)

Since the enactment of SB 1446, the Board has been developing a regulatory proposal, in coordination with its IV and Advanced Injection Therapy Subcommittee (“Advisory Committee”), to implement the IV administration authority. At its November 2022 Board meeting, the Board made some technical and other changes to a proposal from the Advisory Committee that would:

- (A) set additional training requirements for IV administration for NDs, including re-certification every six years (Section 4237.1),
- (B) set additional training requirements for advanced injection therapy courses (Section 4237.2),
- (C) prescribe minimum requirements for administration for IV therapy and advanced injection therapy that involve IV administration (Section 4237.3),
- (D) set minimum staffing and staff training requirements (Section 4237.4), and,
- (E) specify intravenous therapy course provider approval application and approval requirements (Section 4237.5) (see **Attachment 3**).

The proposal was thereafter referred to counsel in the Department of Consumer Affairs, Legal Affairs’ Division’s Regulations Unit.

The Advisory Committee also held a meeting on March 16, 2023 to discuss possible further amendments to the current proposal at Attachment 3, including amending qualification and training requirements for NDs to administer IV therapy and advanced injection therapy.

Current Status and Recommendations

The Board was recently re-assigned Regulations Counsel to review this proposal, who has raised concerns with some of the proposals in Attachment 3. After reviewing the proposed regulatory language in Attachment 3, Regulations Counsel notified me of the following issues:

- (1) BPC section 3640.8 limits the qualifications requirements to administer IV therapy to two criteria: current licensure and completion of **a** qualifying course meeting the

requirements set forth in Section 3640.8 from a Board-approved provider that includes **25 classroom hours on IV administration** of which at least 14 classroom hours shall be identified as practicum.

As a result, Regulations Counsel advises that any proposal that increases qualifications requirements beyond the 25-hour classroom hours on IV administration required by Section 3640.8 (see proposed Sections 4237.1, 4237.2 and 4237.4) would probably be considered inconsistent with that section of the Act, and may not be approved by the Office of Administrative Law, the agency responsible for reviewing and approving state agency regulations.

- (2) BPC section 3640.8 also does not specify that as a condition of renewal or administration of IV therapy that an ND must complete re-certification after initial training requirements and the Act's continuing education statute does not address any required IV therapy continuing education or training as a condition of renewal. BPC section 3635 states:

“(a) In addition to any other qualifications and requirements for licensure renewal, the board shall require the satisfactory completion of 60 hours of approved continuing education biennially. This requirement is waived for the initial license renewal. The continuing education shall meet the following requirements:

(1) At least 20 hours shall be in pharmacotherapeutics.

(2) No more than 15 hours may be in naturopathic medical journals or osteopathic or allopathic medical journals, or audio or videotaped presentations, slides, programmed instruction, or computer-assisted instruction or preceptorships.

(3) No more than 20 hours may be in any single topic.

(4) No more than 15 hours of the continuing education requirements for the specialty certificate in naturopathic childbirth attendance shall apply to the 60 hours of continuing education requirement.

(5) Course content shall pertain to the practice of naturopathic, osteopathic, or allopathic medicine.

(b) The continuing education requirements of this section may be met through continuing education courses approved by the board, the California Naturopathic Doctors Association, the North American Naturopathic Continuing Education Accreditation Council, the American Association of Naturopathic Physicians, the California State Board of Pharmacy, or the State Board of Chiropractic Examiners, or other courses that meet the standards for continuing education for

licensed physicians and surgeons in California. All continuing education providers shall comply with Section 3635.2. Continuing education providers shall submit an annual declaration to the board that their educational activities satisfy the requirements described in Section 3635.2 and the board shall maintain a list of these providers on its internet website.”

As a result, Regulations Counsel advises that the Board’s continuing education statute at BPC section 3635 does not appear to authorize the Board to prescribe dedicated continuing education or additional training requirements within the 60-hour biennial renewal requirement.

- (3) Finally, Regulations Counsel advises that BPC section 3640.8 (a) and (d) **do** appear to authorize the Board to require an ND to (1) demonstrate compliance with the requirements in Section 3640.8 (i.e., specify types of proof of compliance or other documentary evidence), (2) specify Board approval requirements for IV therapy course providers; and, (3) prescribe IV administration standards.

Based upon the foregoing, Regulations Counsel recommends amending the current proposal to further specify administrative, course approval and minimum standards for IV administration only, and to remove from the current proposal references to additional training, re-certification or course content requirements as criteria for an ND to administer IV therapy at this time. The recommendation would be to refer this proposal back to the Board’s Advisory Committee for further review and development in consultation with Regulations Counsel, and to bring back a new proposal to a future meeting for Board consideration.

Regulations Counsel will be available at the meeting to answer any questions the Board members may have regarding this item.

Attachments

1. SB 1446 (Stats. 2012, Ch. 333)
2. Committee Analysis of SB 1446 for Assembly Committee on Business, Professions and Consumer Protection, dated June 19, 2012
3. Draft Proposed Text to Adopt Sections 4237.1, 4237.2, 4237.3, 4237.4 and 4237.5 in Title 16 of the California Code of Regulations (CCR) (Intravenous (IV) and Advanced Injection Therapy, and IV Therapy Course Approval)