



## MEMORANDUM

<b>DATE</b>	August 23, 2021
<b>TO</b>	Naturopathic Medicine Committee Members
<b>FROM</b>	Rebecca Mitchell, Executive Officer Naturopathic Medicine Committee
<b>SUBJECT</b>	Agenda Item # 4 – IV and Advanced Therapy Regulation

On July 9, 2021, the Naturopathic Medicine Committee (Committee) staff received correspondence from the Department of Consumer Affairs, Legal Affairs, Regulations Unit regarding the Intravenous (IV) and Advanced Therapy Regulation package. Karen Halbo, Regulatory Counsel, advised that the Committee’s IV and Advanced Injection Therapy regulatory text could be questioned by OAL as exceeding the scope of the Committee’s authority to promulgate such regulations. This is because the approved proposed texts require additional training beyond what is set forth in Business and Professions Code (BPC) section 3640.8 and appear to require certification in basic therapies, CPR, or ACLS to qualify to administer IV Therapy.

The statute cited as the basis of the Committee’s authority in the IV and Advanced Injection Therapy regulation package is BCP section 3640.8. In BCP section 3640.8, subdivision (a), licensees must only meet two requirements.

“(a) To qualify to administer intravenous (IV) therapy in his or her practice pursuant to Section 3640.7, a naturopathic doctor shall demonstrate that he or she has complied with both of the following requirements:

- (1) Has a current naturopathic doctor's license in this state.
- (2) Has completed a qualifying course on IV therapy from a course provider approved by the committee.”

BPC section 3640.8 subdivision (b) that immediately follows the above quoted subdivision (a) sets out in detail what must be covered in a qualifying IV therapy course. The best argument supporting the Committee’s authority to require certification and additional training is the catch-all sentence at the end of BPC 3640.8 in subdivision (d), which states:

“(d) Pursuant to subdivision (e) of Section 3640, the committee may establish regulations regarding IV administration that are consistent with the education and training of a naturopathic doctor.”

The IV and Injection therapy regulation package as previously approved by the Committee consists of 4 proposed new sections: 16 CCR 4237.1, 4237.2, 4237.3, and 4237.4, but does not establish the process by which the Committee will approve a qualifying course (the one task in BPC section 3640.8(a)(2) that the committee is clearly authorized to do).

To preserve the considerable time and expertise that went into drafting the previously approved 4 proposed regulation sections, Halbo drafted an additional regulation section on Approval of Course Providers. This section requires, to obtain approval, that a course provider must show the Committee an outline of material that covers everything in BPC §3640.8 and in proposed and already approved 16 CCR section 4237.1 and sets out standard requirements found in other board's regulations for approving course providers.

With a section on Approval of Course providers drafted, the proposed and already approved 16 CCR sections 4237.1 and 4237.2 were then modified to more clearly emphasize that the Committee is just clarifying what an approved provider must teach in a qualifying IV therapy course. Language was added to 16 CCR 4237.2 so all the various injection therapies listed in 4237.2 have additional training requirements and that training must be obtained from an approved continuing education provider. Because as modified the proposed and already approved 16 CCR sections 4237.1 and 4237.2 simply state what a naturopathic doctor must do to perform IV and injection therapy, Legal will argue that those regulations as modified provide additional clarity and consumer protection and thus fall within the Committee's authority granted by BPC section 3640.8 subdivision (d) that the Committee may establish regulations consistent with the education and training of naturopathic doctor, and BPC section 3620.1, prioritizing public protection.

The newly drafted section on Approval of Course Providers could be placed third in the sequence of regulation sections within the package, followed by the already approved 16 CCR sections 4237.3 and 4237.4, on office and staff requirements. These requirements can be characterized as being within the Committee's authority to: “establishing regulations regarding IV administration consistent with the education and training of a naturopathic doctor,” and the Committee's mandate in BPC section 3620.1 to prioritize public protection.

Committee members should review the recommendations and determine if this language is satisfactory for added consumer protections that this regulatory package seeks to provide. All the text sections are new, but underlining has been removed for reading clarity, and so the proposed modifications are seen in struck out and underlined text.