



Agenda Item 5.1

Consideration of public comments, discussion, and possible adoption of modified proposed regulatory text to amend California Code of Regulations, title 16 (CCR), section 1450 (Definitions) and section 1456 (Continuing Education Courses)

BRN Board Meeting | May 18-19, 2022

BOARD OF REGISTERED NURSING
Agenda Item Summary

AGENDA ITEM: 5.1
DATE: May 18-19, 2022

ACTION REQUESTED: Consideration of public comments, discussion, and possible adoption of modified proposed regulatory text to amend California Code of Regulations, title 16 (CCR), section 1450 (Definitions) and section 1456 (Continuing Education Courses)

REQUESTED BY: Loretta Melby RN, MSN
Executive Officer, California Board of Registered Nursing

BACKGROUND:

For CCR 1450 and 1456, the BRN's regulations counsel had drafted proposed regulatory language which was approved by the Board at its May 2021 board meeting. Following review and approval by the DCA Director and the Business, Consumer Services, and Housing Agency Secretary, the regulatory package was noticed on November 12, 2021, with the public comment period ending December 27, 2021. The published regulatory package is available [here](#). No request for a hearing was received for this package, therefore a hearing was not held. Two comment letters were received during the comment period.

BRN management, in consultation with DCA Legal, is now asking for your consideration of those comments and approval of proposed responses to public comments received from the California Hospital Association and Heartbeat International. Further, the Board's consideration and approval for adoption of modified text is sought.

Regarding comments to proposed text for CCR 1450, Definitions, subsection (d), Experimental medical procedure or treatment:

Current Proposed / Noticed Language

(d) "Experimental medical procedure or treatment" means the management and care of a patient involving any of the following: (1) for drugs, the treatment will be considered experimental if the United States Food and Drug Administration approved the drug for use, but the drug is used for a purpose other than that for which it was approved; or, (2) any treatment or procedure for which peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of on-going clinical trials.

Comments and BRN response regarding expansion of the term "drug":

- **Comment by California Hospital Association (CHA)**

Recognizing that the FDA regulates devices in the same way it regulates drugs, CHA suggests using the FDA definition that includes drugs and devices.

Language Suggested by CHA:

(d) "Experimental medical procedure or treatment" means the management and care of a patient involving any of the following: (1) a clinical trial or human subject research approved by an Institutional Review Board as those terms are defined in Title 45 Code of Federal Regulations Section 46.102; ~~(4)~~ (2) for drugs or devices, the treatment will be considered experimental if the United States Food and Drug Administration approved the drug or device for use, but the drug or device is used for a purpose other than that for which it was approved; or ~~(2)~~ (3) any treatment or procedure for which peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of on-going clinical trials."

- **Comment by Heartbeat International**

The definition of "experimental medical procedure or treatment" is drastically overbroad and out of step with the FDA's own guidelines and the practice of medicine.

Under the definition contained in § 1456(d), a drug use is experimental "if the United States Food and Drug Administration approved the drug for use, but the drug is used for a purpose other than that for which it was approved." This definition describes "off-label" drug use, a very common practice in medicine. In fact, according to the American Medical Association Journal of Ethics, "off-label drug use is not the same as experimental or research use," so it is curious for the Board to classify it as such. "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient." Off-label drug use is common, legal, and of particular importance to certain vulnerable patient populations, such as children, the elderly, psychiatric patients, and pregnant women. Nurses need continuing education about the creative and life-saving use of these medications.

Proposed BRN Response: Off-label drug usage can be important to patient care, and may include drugs, devices, or even biological products used in novel applications, and the Board is in favor of its use when generally accepted. The Board is classifying off-label usage as experimental, as stated in the Initial Statement of Reasons, page 4, "...because the FDA has not found such a drug safe and effective for the unapproved use, it is appropriate to consider it experimental under the proposed amendment." No change to the definition is required in response to the practice of off-label drug usage.

In response to the comment to include "devices," modified language is derived from the Health and Safety Code, specifically from section 11548.2 (part of the Right to Try Act, the federal version of which was referenced in the Initial Statement of Reasons), wherein "a manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient pursuant to this article."

BRN Proposed Modified Language

(d) "Experimental medical procedure or treatment" means the management and care of a patient involving any of the following:

(1) research approved by an Institutional Review Board as defined in Title 21, Code of Federal Regulations, Section 56.102 involving a clinical trial or human subject as those terms are defined in Title 45, Code of Federal Regulations, Section 46.102,

(2) for drugs, biological products, or devices, the treatment will be considered experimental if the United States Food and Drug Administration approved the drug, biological product, or device for use, but the drug, biological product, or device is used for a purpose other than that for which it was approved; or, ~~(2)~~

(3) any treatment or procedure for which peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of on-going clinical trials.

Comments and BRN response regarding expansion of "clinical trial"

- **Comment by California Hospital Association (CHA)**

CHA's proposed language allows nurses to obtain continued education on the topic of clinical research studies that may not have yet resulted in a published peer review study and allows nurses to obtain continuing education on research that may not be the subject of an on-going clinical trial but rather a future or past clinical trial.

Nurses are often involved in cutting-edge clinical research studies. They need education on the scientific underpinnings of these studies as well as how to care for patients enrolled in these studies. The language recommended allows nurses to obtain continuing education on the topic of clinical research studies that may not have yet resulted in a published, peer-review study. It also allows nurses to obtain continuing education on research that may not be the subject of an on-going clinical trial, but rather a future or past clinical trial.

Language Suggested by CHA:

(d) "Experimental medical procedure or treatment" means the management and care of a patient involving any of the following: (1) a clinical trial or human subject research approved by an Institutional Review Board as those terms are defined in Title 45 Code of Federal Regulations Section 46.102;

~~(4)~~ (2) for drugs or devices, the treatment will be considered experimental if the United States Food and Drug Administration approved the drug or device for use, but the drug or device is used for a purpose other than that for which it was approved; or ~~(2)~~ (3) any treatment or procedure for which

peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of on-going clinical trials.”

- **Comment by Heartbeat International**

To suggest that a treatment or procedure is *per se* "experimental" simply because it is the subject of an on-going clinical trial is drastically overbroad. Even topics that are already broadly accepted can be the subject of clinical trials. Because the text is stunningly overbroad, it would be impossible for CE providers to adhere to the regulations under this definition. CE providers cannot reasonably be expected to stay abreast of each and every on-going clinical trial so that they can ascertain whether a course can be offered due to it being deemed "experimental" under the proposed definition. Whether a topic is subject to an on-going clinical trial could change daily. Further, if the Board wishes to enforce its regulations, it would be tasked with following ClinicalTrials.gov and taking action against CE providers offering courses on topics that are being studied. This is simply not feasible for CE providers or the Board.

Proposed BRN Response: The Board accepts the suggested amendment regarding clinical trials. The Board is not requiring providers to offer continuing education regarding experimental medical procedures or treatment. CE providers are subject to regular audits by the Board, pursuant to BPC 2811.5 and 16 CCR 1454, and if a course was questioned in the audit, the Board would request documentary evidence from the provider that the course met the requirements, including copies of referenced clinical trials or scientific journals. CE providers are required to take responsibility for every course they offer. If the CE provider could not justify a course as meeting the requirements, the Board could take action to withhold or rescind approval from the provider, according to existing Board procedures and BPC 2811.5(d).

BRN Proposed Modified Language

(d) “Experimental medical procedure or treatment” means the management and care of a patient involving any of the following:

(1) **research approved by an Institutional Review Board as defined in Title 21, Code of Federal Regulations, Section 56.102 involving a clinical trial or human subject as those terms are defined in Title 45, Code of Federal Regulations, Section 46.102.**

(2) **for drugs, biological product, or devices, the treatment will be considered experimental if the United States Food and Drug Administration approved the drug, biological product, or device for use, but the drug, biological product, or device is used for a purpose other than that for which it was approved; or, ~~(2)~~**

(3) **any treatment or procedure for which peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of on-going clinical trials.**

Regarding comments to proposed text for CCR 1450, Definitions, subsection (h), Implicit Bias:

Current Proposed / Noticed Language

(h) "Implicit bias" means the attitudes or internalized stereotypes that affect our perceptions, actions, and decisions in an unconscious manner. Implicit bias often contributes to unequal treatment of people based on race, ethnicity, gender identity, sexual orientation, age, disability, and other characteristics.

- **Comment by Heartbeat International**

Heartbeat International ("Heartbeat"), a registered Continuing Education ("CE") provider, does not oppose the inclusion of implicit bias training in CE courses for nurses.

BRN Response: The Board thanks the commenter for this support. No changes to the text are necessary in response to this comment.

Regarding comments to proposed text for CCR 1450, Definitions, subsection (i), Direct Patient Care:

Current Proposed / Noticed Language

(i) "Direct patient care" means the provision of health care services directly to individuals being treated for or suspected of having physical or mental illnesses. Direct patient care includes preventative care.

- **Comment by California Hospital Association (CHA).**

We recommend the addition of telehealth in the definition of direct patient care as defined in Section 2290.5 of the Business and Professions Code due to its extreme importance in present and future delivery of health care services.

This definition proposed by BRN is unclear as to whether telehealth is considered "direct patient care." Given the increasing importance of telehealth services, especially to provide care to otherwise underserved individuals and those living in rural areas, CHA recommends clarifying that telehealth is considered direct patient care.

Language Suggested by CHA:

(i) Direct patient care" means the provision of health care services directly to individuals being treated for or suspected of having physical or mental illnesses. Direct patient care includes preventative care and telehealth as defined in Section 2290.5 of the Business and Professions Code.

BRN Response:

The Board appreciates this comment. However, the definition is correct regarding direct patient care, and no changes are necessary in response to this comment.

As indicated in the Board's Initial Statement of Reasons at page 6, telehealth is a delivery modality for providing that direct patient care. Telehealth does not need to be included in this definition for direct patient care because it is only a modality used to provide the direct patient care.

Business and Professions Code section 2290.5, subdivision (a)(6) defines telehealth as:

...the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care.

Telehealth includes telemedicine. Telehealth is not a distinct service, but a way that providers deliver health care to their patients that approximates in-person care. The standard of care is the same whether the patient is seen in-person or through telehealth.

Regarding comments to proposed text for CCR 1456, subsection (b), Generally Accepted:

Current Proposed / Noticed Language

(b) For the purposes of this section, "generally accepted experimental medical procedures or treatments" means the efficacy of the procedure(s) or treatment(s) is supported by at least two peer-reviewed, publicly available scientific journals or studies, is published in medical and/or scientific literature, and is generally accepted as effective by the medical community.

• **Comment by California Hospital Association (CHA)**

We recommend the deletion of the definition of the term generally accepted in that the term experimental medical procedures or treatment is sufficiently clear and may preclude RNs obtaining continuing education credits in cutting-edge studies that may reveal that a particular treatment or procedure is not beneficial after all.

The proposed new term "experimental medical procedure or treatment" in section 1450(d) is sufficiently clear to exclude bogus studies. Including the requirement that the treatment be "generally accepted" would preclude research nurses from obtaining continuing education credit in academic medical centers for education and training related to their role in providing care to patients enrolled in these cutting-edge studies. Nurses are an integral part of these studies, many of which are not yet "generally accepted." In fact, some of these studies may reveal that a particular treatment or procedure is not beneficial after all.

• **Comment by Heartbeat International**

The definition of "generally accepted" is nonsensical, vague, and subjective. Perhaps recognizing the overbreadth of the proposed definition of "experimental," the proposed regulation explicitly allows nurses to receive CE credit for courses on "experimental" procedures or treatments, but only if they are "generally accepted." It appears to contain three elements, all of which must be satisfied: (1) supported by two peer-reviewed, publicly available scientific journals or studies, (2) published

in medical or scientific literature, and (3) generally accepted as effective by the medical community.

The second element causes confusion. It would seem that if the treatment at issue satisfies element (1), then it would automatically satisfy element (2). In other words, if a treatment is supported by two peer-reviewed, publicly available scientific journals or studies, that would necessarily mean that it is "published in medical or scientific literature" - the literature which published the studies in the first place. Yet, "published in medical or scientific literature" appears to be a separate and distinct requirement. This is vague and duplicative.

The third element is also vague and nonsensical. It provides that a treatment is generally accepted if it is "generally accepted as effective by the medical community." The glaring issue with this definition is that these terms are left undefined, i.e., "effective", "medical community", and even "generally accepted," and all could be interpreted subjectively depending upon the composition of the Board. The CE provider is no more likely to be able to comply with these regulations after reading this "definition" than before reading the proposed language.

The Board's proposed language begs the following questions, *inter alia*, in light of the observation that, as in most professional fields, differences of opinion are common in medical science, sometimes even causing controversy: (1) What percentage of providers must accept the treatment for it to be "generally accepted?" (2) How will the Board ascertain whether a treatment is "generally accepted?" (3) How many medical professionals must agree that the treatment at issue is effective? (4) Which types of medical professionals comprise the "medical community?" (5) What if there is staunch disagreement within the "medical community" but both schools of thought are effectively treating patients and California nurses are assisting in such treatment? (6) How many successful cases must exist for the drug to be "effective?" (7) What if the drug achieves its intended effect but with significant side-effects? (8) What if one school of thought holds a treatment as beneficial and "effective" but another insists it is harmful and ineffective?

In short, whether CE credit can be awarded for "experimental medical procedures or treatments" hinges entirely on whether the procedure or treatment at issue is "generally accepted." But even the most diligent CE providers will be unable to ascertain whether content on a given drug, procedure, or treatment is "generally accepted" under the proposed regulations.

Because "generally accepted" is vague, the proposed regulation leaves room for discriminatory, selective enforcement. It is unclear how this regulation will be implemented and enforced.

BRN Response:

The Board appreciates this comment. However, the term "generally accepted" is appropriate in this regulation given the previous issues with continuing education providers not being clear on the interpretation of this regulation, which has caused harm.

That said, the staff has further elaborated on the definition of “experimental medical procedure or treatment” in the new version of Section 1450 proposed text which staff has placed before the Board for approval. In addition, a proposed clarification of “generally accepted” which elaborates in the definition with regard to patient health and efficacy, is presented for Board approval. This proposed language modification is derived from the Health and Safety Code, specifically from section 1367.21, subdivision (a)(3)(C), where off-label use of drugs cannot be denied coverage if, among other things, the drug is recognized by “Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.” The articles are already covered in section 1450 but staff proposes adding “or” to include those “cutting-edge” studies that have been peer-reviewed but not yet published in literature, which expands the options. Under the proposed regulation, as revised, RNs would be able to **participate** in research and receive continuing education credit in academic medical centers for education and training related to their role in providing care to patients enrolled in these cutting-edge studies. The below modification also expands on safety and clarifies that a procedure or treatment would no longer be generally accepted if a major peer-reviewed article showed that the procedure or treatment was not safe and effective, which furthers the Board’s mission of public protection.

Proposed Modified Language

(b) For the purposes of this section, “generally accepted experimental medical procedures or treatments” means:

(1) the efficacy of the procedure(s) or treatment(s) is supported by at least two peer-reviewed, publicly available scientific journals or studies, **or** is published in medical and/or scientific literature, and

~~(2) is generally accepted as effective by the medical community. there is no clear and convincing contradictory evidence presented in a major peer reviewed medical journal that the treatment or procedure is not safe and effective.~~

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Note: Comments noted and addressed here are specific to CCR 1450 and 1456 and are not in the scope of the 1427 or the 1423/1432 changes which will be summarized and responded to in their related packages.

NEXT STEPS:

If approved, notice the proposed modified text for a 15-day public comment period. If no relevant, adverse comments are received, submit the regulatory package to the DCA Director, Agency, DOF, and OAL.

FISCAL IMPACT, IF ANY:

Staff estimates that there will be no fiscal impact to the Board.

PERSON TO CONTACT:

Ras Siddiqui
Regulatory Analyst
California Board of Registered Nursing
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Action Requested:

Staff requests the Board to consider the comments received and provide any feedback as is deemed necessary, adopt the new language presented for CCR section 1450 and CCR section 1456 (the regulatory text) and send it out for notice for a 15-day comment period. Delegate to the Executive Officer the authority to make any technical or non-substantive changes required by the control agencies as this regulation is being finalized.

If the Board wishes to change any text, then once the language is agreed upon, delegate to the Executive Officer authority to adopt the modified text in the absence of any negative comments and continue with the process to finalize the regulatory package, including making any non-substantive changes.

Possible Motion:

Approve the responses to comments and the modifications to text proposed by staff. Direct staff to send the modified text out for a 15-day comment period and, if no relevant, adverse comments are received, adopt the text as noticed. Delegate authority to the Executive Officer to finalize the regulatory package, including making any technical or non-substantive changes required.

Reference Material

Attachment A: Notice of Proposed Rulemaking:

<https://www.rn.ca.gov/pdfs/regulations/notice-ce.pdf>

Attachment B: Initial Statement of Reasons:

[Initial Statement of Reasons - Continuing Education Courses](#)

Attachment C: Noticed Regulatory Language:

<https://www.rn.ca.gov/pdfs/regulations/proposedlang-ce.pdf>

Attachment D: Comments received during the 45-day comment period

Attachment E: Proposed Modified CCR 1450 & 1456, with new language incorporating responses to comments.