Title 16, Division 14, Article 5, sections 1450 and 1456
California Code of Regulations

Board of Registered Nursing

Final Statement of Reasons

Continuing Education Courses

Sections Affected: California Code of Regulations (CCR), Title 16, Division 14, Article 5, sections 1450 & 1456

Updated Information

The Informative Digest and Initial Statement of Reasons are included in the rulemaking file and incorporated as though set forth herein.

This rulemaking package was noticed on November 12, 2021, and comment was through December 28, 2021. No public hearing was originally set for this proposal and none was requested. Two comments were received. The Board considered these comments and at the May 18-19, 2022 Board Meeting voted to amend the text and notice a 15-day comment period, which ran from June 3 through 28, 2022. No comments were received on the modified text. Based upon the motion of the Board, this text was adopted. A nonsubstantive change to incorporate by reference the two federal regulations used definitionally was made during review by the Office of Administrative Law. The justifications for the modifications are listed as part of the *Objections or Recommendations/Responses*, below.

Objections or Recommendations/Responses

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

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) … ~~(1)~~ (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.

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," the Board's 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 Modified Language in Response to the above comments:

(d)

…

(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; …

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) … (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; …

• **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.

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).

Furthermore, because the Board agrees to use the federal system's nomenclature for a consistent national approach, the Board will incorporate the federal language by reference. The Board defers to the federal government's expertise in this matter and notes that federal regulations go through a similar notice and comment public process to that of this state. For reference, as of the time of OAL's review, the pertinent federal text reads:

> **21 CFR 56.102 (g): Institutional Review Board** (IRB) means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the act.
>
> **45 CFR 46.102 (b): Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
>
> **45 CFR 46.102 (e)**(1) **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:
> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
> (2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
> (3) Interaction includes communication or interpersonal contact between investigator and subject.
> (4) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
> (5) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
> (6) An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
> (7) Federal departments or agencies implementing this policy shall:
> (i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of "identifiable

private information," as defined in paragraph (e)(5) of this section, and "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," as defined in paragraph (e)(5) of this section, or an "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the Federal Register after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

The full text of these two federal regulations would be unduly cumbersome to print in the CCR and may cause confusion as to any perceived difference between the federal and state version; therefore, it is appropriate to incorporate it by reference rather than place the language into the text of the Board's proposed regulatory action. The incorporated documents would be available to the public from the Board on request.

BRN Modified Language in Response to the above comments:

(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 (hereby incorporated by reference as of August 8, 2022) involving a clinical trial or human subject as those terms are defined in Title 45, Code of Federal Regulations, Section 46.102 (hereby incorporated by reference as of August 8, 2022),

…

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

- **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*:

- **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*:

- **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 Board has further elaborated on the definition of “experimental medical procedure or treatment” in the modified version of Section 1450. In addition, a proposed clarification of “generally accepted” which elaborates in the definition with regard to patient health and efficacy, 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 the Board has added "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.

BRN Modified Language in Response to the above comments:

(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.**

A further non-substantive change was made to correct the reference citation in section 1450 and remove the non-existent Business and Professions Code (BPC) section 2811.1.

Finally, a non-substantive change to remove the date was made in section 1456(a)(4). Assembly Bill 241 (Chapter 417, Statutes of 2019) added BPC section 2736.5, which required the board to "adopt regulations to require that, on and after January 1, 2022, all continuing education courses for licensees under this chapter contain curriculum that includes the understanding of implicit bias." Although the text of this regulatory package was noticed in 2021, when an effective date of 2022 was a future date, that date has now passed and is unnecessary.

Incorporation by Reference:

As noted above, the Board is incorporating Title 21, Code of Federal Regulations, Section 56.102 and Title 45, Code of Federal Regulations, Section 46.102 by reference as of the approval date of these regulations for the reasons described above.

Local Mandate:

A mandate is not imposed on local agencies or school districts.