

**BOARD OF REGISTERED NURSING
CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS**

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing has been scheduled.

Subject Matter of Proposed Regulation(s): Continuing Education Courses

Section(s) Affected: Sections 1450 and 1456 of Title 16, California Code of Regulations (CCR)

Introduction/Background

The Board of Registered Nursing (Board) regulates the practice of registered nursing (RN) in the State of California. Protection of the public is the highest priority of the Board in exercising its licensing, regulatory, and disciplinary functions. (Bus. & Prof. Code (BPC), § 2708.1.)

In addition to its licensing and certification functions, the Board regulates and approves California educational prelicensure RN programs, nurse midwife programs, and nurse practitioner programs. The Board also establishes requirements for continuing education (CE) programs.

Specific Purpose of Each Adoption, Amendment, or Repeal:

1. Problem Being Addressed/Purpose of the Amendment:

All licensees are required by statute to complete 30 hours of CE during each two-year renewal cycle to ensure continued competence. BPC section 2811.5 requires the Board to establish regulations ensuring that CE courses are either related to the scientific knowledge or technical skills required for the practice of nursing, or to direct or indirect patient care. Existing regulations specify examples of appropriate coursework and include a requirement that all content be relevant to the practice of nursing. According to current practice, the Board approves CE providers based on the evaluation of a single course. Providers are then required to ensure the balance of their offerings meet established criteria. The Board is the sole agency tasked with defining and interpreting the practice of nursing and is required to exercise its discretion to “withhold or rescind approval from any [CE] provider that is in violation of the regulatory requirements.” (Bus. & Prof. Code, § 2811.5, subd. (d).)

On October 5, 2017, Governor Edmund G. Brown signed Senate Bill 799 (Chapter 520, Statutes of 2017) (SB 799) into law. This bill amended BPC section 2811.5 and required the Board to: (1) by January 1, 2019, deliver a report to the appropriate legislative policy

committees detailing a comprehensive plan for approving and disapproving CE opportunities; and (2) by January 1, 2020, report to the appropriate legislative committees on its progress implementing this plan. The Senate Analysis of SB 799 expressed a concern that “BRN continues to be lax in its approval standards for [CE providers] ... approving courses with dubious scientific merit and not directly relating to patient care.” (Senate Committee on Business, Professions and Economic Development, April 20, 2017.)

The enactment of SB 799 prompted the Board to re-evaluate its standards for CE content and its approval process for CE course content. Currently, CE courses must be related to the scientific knowledge and/or technical skills required for the practice of nursing, or to direct and/or indirect patient/client care. Concerns have been raised that the regulation does not adequately prescribe the educational standards applicable to experimental medical procedures or treatments.

On October 2, 2019, Governor Gavin Newsom signed Assembly Bill 241 (Chapter 417, Statutes of 2019) (AB 241) into law. This bill added BPC section 2736.5 and 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.”

In this regulatory proposal, the Board proposes to establish criteria for CE content relating to experimental medical procedures and treatments as well as implicit bias. Under existing regulation at 16 CCR section 1456, all CE courses must be relevant to the practice of nursing and either (1) be related to the scientific knowledge and/or technical skills required for the practice of nursing, or (2) be related to direct and/or indirect patient/client care.

The Board proposes to amend sections 1450 and 1456 to define the regulatory criteria applicable to CE with content relating to experimental medical procedures or treatments and implicit bias, and to define direct patient care. This proposal would provide that course material related to experimental medical procedures or treatments is among the types of appropriate CE course content. However, the proposal would qualify that this course content is not relevant to the practice of nursing unless: (1) the underlying treatment’s efficacy is supported by at least two peer-reviewed publicly available scientific journal or studies, published in medical and scientific literature; and (2) the procedure or treatment is generally accepted as effective by the medical community. It will also implement the legislative mandate that as of January 1, 2022, curriculum include an understanding of implicit bias.

In a subsequent rulemaking proposal, the Board will propose to reformulate its process for approving CE course content. Specifically, the Board intends to promulgate regulations requiring it to review and approve all CE course content before providers make the courses available to licensees.

2. Anticipated Benefits from this Regulatory Action:

Under current section 1456, CE courses must be related to the scientific knowledge and/or technical skills required for the practice of nursing, or to direct and/or indirect patient/client care. However, it is important for RNs to be educated about experimental medical procedures or treatments so they can understand what alternative treatments and therapies are directly related to nursing and those that are not.

This regulatory proposal will clarify requirements for CE course content relating to experimental medical procedures or treatments. It will ensure that content meets specified standards for reliability and efficacy before it will qualify for approval by the Board. Ensuring that such procedures are reliable and effective before being taught will protect public health and safety because Board licensees will not be studying unsupported and unproven procedures and treatments. These standards will also clarify to CE providers what content is appropriate for CE courses relating to experimental medical procedures or treatments.

This regulatory proposal will also clarify the requirements of implicit bias for curriculum beginning January 1, 2022. This legislative implementation is important for CE courses to contain content regarding implicit bias, so that potential harms to patients can be recognized and corrected, furthering consumer protection.

Factual Basis/Rationale:

Amend 1450

Renumbering is done within 1450 for ease of reading. The Authority and Reference citations are amended to reflect the new material.

Add section 1450(d)

Proposed subdivision (d) provides:

(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.

According to the Food and Drug Administration (FDA), 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. However, if a healthcare

provider decides to use an approved drug for an unapproved use to treat a disease or medical condition, it means that the FDA has not determined that the drug is safe and effective for the unapproved use.

The Board proposes to classify the use of a drug as experimental if the drug is used for a purpose other than that for which it was approved. Under the FDA's guidance, 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.

The Board proposes to further define medical procedures and treatments as experimental if peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of ongoing clinical trials. If such procedures and treatments are the subject of ongoing clinical trials, this would tend to show that they have not been accepted as generally effective by the medical community. As discussed above, if a medical treatment or procedure has not been accepted as generally effective by the medical community, RNs could potentially learn about treatments and procedures that could put patients at risk and cause harm to the public.

Add section 1450(h)

Proposed subdivision (h) provides:

(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.

This mirrors AB 241's intent language:

AB 241: SECTION 1. The Legislature finds and declares all of the following:

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

(b) Implicit bias contributes to health disparities by affecting the behavior of physicians and surgeons, nurses, physician assistants, and other healing arts licensees.

The partial duplication of legislative intent language is necessary because section 1 is uncodified text and may be difficult for readers to find.

Add section 1450(i)

Proposed subdivision (i) provides:

(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.

This new subdivision is necessary to clarify what “Direct patient care” means, and to eliminate any confusion on how it is viewed in nursing education.

According to the Office of Statewide Health Planning and Development, for *vocational nurses* to be eligible for scholarships or loan repayment programs,:

“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 first line supervision.”¹

This definition is backed by California Code of Regulations Title 22 - Social Security, Division 7 - Health Planning and Facility Construction, Chapter 16 - Vocational Nurse Scholarship and Loan Repayment Program, Article 1 - General Provisions, section 97900 - Chapter Definitions, which states that “The first line supervision of direct patient care shall be considered “direct patient care.”² Registered nurses have a similar definition at 22 CCR 97700.17 for purposes of scholarships.

However, the Office of Statewide Health Planning and Development Grant Guide for *physicians* to be eligible for scholarships or loan repayment programs have a different take, where “Administrative duties do not fall under direct patient care.”³

The State Department of Health Services, in their regulations regarding laboratories and licensure of clinical laboratory personnel, describe “Direct patient care” to mean:

¹ *Vocational Nurse Scholarship Grant Guide, Fiscal Year 2020-21*. <https://oshpd.ca.gov/wp-content/uploads/2021/01/VNSP-Grant-Guide-FY-2020-21.pdf>, page 5.

² 22 CCR 97900. Chapter Definitions. (Chapter 16. Vocational Nurse Scholarship and Loan Repayment Program, Article 1. General Provisions)

(d) “Direct patient care” means the provision of health care services directly to individuals being treated for, or suspected of having, physical or mental illness. Direct patient care includes preventative care. The first line supervision of direct patient care shall be considered “direct patient care.”

³ G. Direct Patient Care

Direct patient care means the provision of healthcare services provided directly to individuals being treated for, or suspected of having, physical illnesses. Direct patient care includes preventative care and the first line supervision of direct patient care. Direct patient care includes hands on, face-to-face contact with patients for the purpose of diagnosis, treatment and monitoring. Administrative duties do not fall under direct patient care.

Steven M. Thompson Physician Corps Loan Repayment Program Grant Guide, Fiscal Year 2020-21. <https://oshpd.ca.gov/wp-content/uploads/2020/12/STLRP-Grant-Guide-FY-2020-21.pdf>, page 6.

...medical, psychiatric, nursing, or other health care that is legally provided by a care giver or healthcare provider directly to a patient, and that includes observation of the patient's physical or mental condition to enable the care giver or healthcare provider to report changes in the patient's condition.

(17 CCR § 1029 (a)). This definition does not include an administrative component in providing patient care.

Direct patient care includes hands on, face-to-face contact with patients for the purpose of diagnosis, treatment, and monitoring. However, direct patient care is more than just “bedside” or “hands-on” but also may encompass other modalities that include technology, such as telephone consultations.

As the Board noted that administrative duties do not fall under direct patient care in the practical application of services, the Board elected and voted to remove “and first line supervision” from its definition of Direct Patient Care for registered nurses at the May 12, 2021 Board Meeting.

Amend section 1456

Renumbering is done within 1456 for ease of reading. The Authority citations are amended to reflect the new material.

Amend section 1456(a)(3)

This proposal would add “experimental medical procedures and treatments” to the list of related and permissible subject matter areas the Board considers appropriate for CE.

This amendment is necessary because there is an increased awareness and demand for the utilization of alternate therapies in the health care field. Developments driving this demand include:

- Expanded Access/Compassionate Use – Expanded access, also called “compassionate use,” provides a pathway for patients to gain access to investigational drugs, biologics, and medical devices used to diagnose, monitor, or treat patients with serious diseases or conditions for which there are no comparable or satisfactory therapy options available outside of clinical trials.
- The Right to Try Act – The federal Right to Try Act was signed into law May 30, 2018. This law is another way for patients who have been diagnosed with life-threatening diseases or conditions who have tried all approved treatment options and who are unable to participate in a clinical trial to access certain unapproved treatments.

- Websites and Social Media – The convenience of the Internet for accessing information is an advantage to health care professionals and patients. Full prescribing information for most approved drugs can be found on the internet. People may access the internet for information and consider this information as expert advice. However, such information can be unreliable and misleading.

Given this landscape, it is important that CE coursework acquaint nurses with experimental medical procedures and treatments. As set forth below, the Board proposes to limit course content to those procedures and treatments that have been shown to be effective in the scientific community.

Add section 1456(a)(4)

The Board proposes to add a new subsection (a)(4) to section 1456.

Beginning January 1, 2022, contain curriculum that includes the understanding of implicit bias pursuant to Section 2736.5 of the code, unless the course is dedicated solely to research or other issues that do not include a direct patient care component.

This addition is necessary as it reiterates the date in BPC 2736.5⁴ which sets the timeframe by which all CE courses for practicing nurses must contain curriculum that includes an understanding of implicit bias (unless the course is dedicated solely to research or other issues not including a direct patient care component). By January 1, 2023, CE providers will need to ensure compliance with this regulation and include an understanding of implicit bias in the coursework, as the Board shall start to audit CE providers pursuant to Sections 2736.5 and 2811.5 at the same time. By adding the statutory components to this subsection, the regulation becomes more comprehensively clear.

⁴ BPC 2736.5, as added by AB 241:

- (a) (1) The board shall 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.
- (2) Beginning January 1, 2023, continuing education providers shall ensure compliance with paragraph (1). Beginning January 1, 2023, the board shall audit continuing education providers, pursuant to Section 2811.5.
- (b) Notwithstanding the provisions of subdivision (a), a continuing education course dedicated solely to research or other issues that does not include a direct patient care component is not required to contain curriculum that includes implicit bias in the practice of nursing.
- (c) In order to satisfy the requirements of subdivision (a), continuing education courses shall address at least one or a combination of the following:
 - (1) Examples of how implicit bias affects perceptions and treatment decisions of licensees, leading to disparities in health outcomes.
 - (2) Strategies to address how unintended biases in decisionmaking may contribute to health care disparities by shaping behavior and producing differences in medical treatment along lines of race, ethnicity, gender identity, sexual orientation, age, socioeconomic status, or other characteristics.

Add Section 1456(b)

The Board proposes to adopt a new subdivision (b) to section 1456.

The first part of proposed subdivision (b) provides:

(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.

This new subdivision is necessary to impose specific guidelines governing what the Board considers appropriate CE content for experimental medical procedures and treatments. This, with the definition in section 1450, described above, will clarify to providers and licensees that such procedures and treatments must meet certain standards to qualify as permissible CE.

The proposal sets forth two requirements for CE content relating to experimental medical procedures and treatments.

First, the proposal would require the experimental medical procedure or treatment to be supported by at least two peer-reviewed publicly available journals or studies published in medical and scientific literature. Peer review has been defined as a process of subjecting an author’s scholarly work, research or ideas to the scrutiny of others who are experts in the same field. It functions to encourage authors to meet the accepted high standards of their discipline and to control the dissemination of research data to ensure that unwarranted claims, unacceptable interpretations or personal views are not published without prior expert review. Peer review helps ensure that papers published in scientific journals answer meaningful research questions and draw accurate conclusions based on professionally executed experimentation.

On September 11, 2011, the American Nurses Association (ANA) published a writing entitled *Nursing Peer Review: Principles and Practice*. According to the ANA:

“[t]he primary purpose of peer review is to help ensure the quality of nursing care through safe deliverance of standards of care and newly discovered evidence-based practices.... Peer review in nursing is the process by which practicing registered nurses systematically access, monitor, and make judgments about the quality of nursing care provided by peers as measured against professional standards of practice....”

By requiring two separate peer reviews, this regulatory requirement ensures that at least two authors have reviewed the procedure or treatment and have drawn accurate conclusions about the efficacy of the experimental medical procedure or treatment

before it is offered as the subject of CE. This prevents one erroneous study from being solely relied upon, but more than two may not be available for an emerging procedure or treatment.

Second, the proposal would require that the procedure or treatment is generally accepted as effective in the medical community before it can be the subject of CE courses. This requirement aims to ensure that there is a certain degree of medical consensus about the effectiveness of an experimental medical procedure or treatment before the Board will find it appropriate CE content. Without such a consensus, RNs could potentially learn about alternative treatments and procedures that could put patients at risk and cause harm to the public.

Underlying Data:

Technical, theoretical or empirical studies or reports relied upon:

- Senate Bill 799
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB799
- Assembly Bill 241
https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB241
- FDA Policy, Off-Label Drug Information, Regulation, Distribution, Evaluation, and Related Controversies by C. Lee Ventola, MS, Accepted for Publication June 29, 2009 -
<https://pdfs.semanticscholar.org/d091/3cf6c3e331d51ac04c716ccf528890aa1967.pdf>
- Understanding Unapproved Use of Approved Drugs "Off Label" –
<https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>
- Nursing Peer Review: Principles and Practice, September 2011 Vol. 6 No. 9, Author: Barb Haag-Heitman, PhD, RN, PHCNS-BC, and Vicki George, PhD, RN, FAAN - <https://www.americannursetoday.com/nursing-peer-review-principles-and-practice/>
- Office of Statewide Health Planning and Development Grant Guide For Fiscal Year 2020-21, page 11
<https://oshpd.ca.gov/wp-content/uploads/2020/10/AHLRP-Grant-Guide-FY-2020-21-Final-8-3-20.pdf>

- Steven M. Thompson Physician Corps Loan Repayment Program Grant Guide, Fiscal Year 2020-21, page 6.
<https://oshpd.ca.gov/wp-content/uploads/2020/12/STLRP-Grant-Guide-FY-2020-21.pdf>

Business Impact

The Board has made an initial determination that this proposed regulatory action will not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states.

The Board estimates that all CE courses for nurses will contain curriculum that includes the understanding of implicit bias unless the course is dedicated solely to research or other issues that does not include a direct patient care component. There will be some additional costs to CE providers for course curriculum changes.

Fifty (50) courses are estimated (those with a “Direct patient care” component) that possibly will acquaint nurses with experimental medical procedures or treatments that may need to meet the proposed standards. CE providers who wish to provide such course content in California may incur costs related to supporting efficacy requirements, course development and enlisting health care content experts to ensure the content is relevant to the practice of nursing. However, the Board currently only charges a fee for approving a CE provider and not for approving courses offered by the provider.

Economic Impact Assessment Results:

- The proposed amendments are unlikely to create or eliminate jobs within the State of California. Based on the number of courses affected by this proposal, the Board does not anticipate it will create or eliminate jobs.
- The proposed amendments are unlikely to create new business or eliminate existing businesses within the State of California. Based on the number of courses affected by this proposal, the Board does not anticipate it will create new businesses or eliminate existing businesses.
- The proposed amendments are unlikely to affect the expansion of businesses currently doing business within the State of California. Based on the number of courses affected by this proposal, the Board does not anticipate it will significantly affect the expansion of businesses.
- The proposed amendments will not affect the state’s environment because they are not related to any environmental issues.
- The proposed amendments will not affect worker safety because this regulation does not relate to worker safety.

Specific Technologies or Equipment

While this regulation does not mandate the use of specific technologies or equipment, RNs utilize computers and internet access in their daily duties. Many CE providers offer online courses and training.

Consideration of Alternatives

The Board has initially determined that no reasonable alternative to the regulatory proposal would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

Set forth below are the alternatives which were considered and the reasons each alternative was rejected or accepted:

1. Do not pursue a regulatory change. This alternative was rejected because the Board wants to rectify the undesirable consequences of the current regulations. Under current law, there is no restriction on CE course content related to the use of experimental procedures or treatments offered to RNs to satisfy the CE requirements for licensure. RNs could potentially learn about alternative treatments and procedures that could put patients at risk and cause harm to the public. This is not consistent with the Board's goal of consumer protection. This alternative would ignore the requirements of SB 799 of tightening the standards of continuing education. It would also ignore the requirements of AB 241.
2. Adopt the proposed regulatory amendments. This alternative was determined to be the most appropriate because it promotes the Board's goal of consumer protection. This alternative clarifies the standards for CE and advances the intent of SB 799 and AB 241.