

**Title 16, Division 14, Article 5, sections 1450 and 1456
Board of Registered Nursing**

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING
Continuing Education Courses, § 1456**

California Code of Regulations

NOTICE IS HEREBY GIVEN that the Board of Registered Nursing (Board) is proposing to amend California Code of Regulations (CCR), Title 16, Division 14, sections 1450 and 1456, as described in the Informative Digest.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. The Board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

Written comments, including those sent by mail, facsimile, or email to the addresses listed under Contact Person in this Notice, must be received by the Board at its office **by Monday, December 27, 2021**.

The Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. Apart from technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AUTHORITY AND REFERENCE:

Pursuant to the authority vested by Business and Professions Code (BPC) sections 2715 and 2811.5, and to implement, interpret or make specific BPC sections 2736.5 and 2811.5, the Board is considering changes to Article 5, Division 14 of Title 16 of the CCR as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

- **Amend Section 1450 – Definitions**

Existing law authorizes the Board to establish standards for continuing education (CE) for registered nurses (RN). Section 1450 currently provides definitions of basic terms used in this law such as “Continuing Education” and “Course.”

In this regulatory proposal, the Board proposes to amend section 1450 to add three new definitions, “Experimental medical procedure or treatment,” “Implicit bias,” and “Direct patient care.”

- **Amend Section 1456 – Continuing Education Courses.**

Existing law authorizes the Board to establish standards for continuing education (CE) for registered nurses (RN). Course content must be relevant to the practice of nursing and be related to the scientific knowledge or technical skills required for the practice of nursing or be related to direct or indirect patient or client care. 16 CCR 1456 adopts these requirements and offers examples of course content CE providers can permissibly offer.

In this regulatory proposal, the Board proposes to amend section 1456 to add that beginning January 1, 2022, CE courses contain curriculum that includes the understanding of implicit bias, unless the course is dedicated solely to research or other non-direct patient care components. 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 journals or studies, published in medical and scientific literature; and (2) the procedure or treatment is generally accepted as effective by the medical community. It would further provide that a medical procedure or treatment is experimental if it relates to a drug that the United States Food and Drug Administration approved, but the drug is used for a purpose other than that for which it was approved. A medical procedure or treatment would also be considered experimental if peer-reviewed scientific journals or studies show that the procedure or treatment is the subject of ongoing clinical trials.

ANTICIPATED BENEFITS OF THE PROPOSED REGULATION:

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, ensuring that it 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. These standards will also clarify to providers what content is appropriate for CE courses relating to experimental medical procedures or treatments.

Adding a requirement for coursework regarding implicit bias will raise awareness for RNs and foster better patient care.

DETERMINATION OF INCONSISTENCY/INCOMPATIBILITY WITH EXISTING REGULATION

During the process of developing these regulations and amendments, the Board conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. But interpretations and populations can differ. While 22 CCR 97700.17 includes administrative duties into “direct patient care” for the provisions of scholarships to registered nurses under the Health Professionals Education Foundation, 17 CCR 1029.70¹ does not include administrative duties for purposes of licensure of clinical laboratory personnel. The Board determined that for purposes of this regulation, and as is discussed more fully in the Initial Statement of Reasons, Direct Patient Care will not include first line supervision.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:

The Board will be able to ensure compliance with the new requirement for the inclusion of an understanding of implicit bias in all CE coursework as a part of its routine oversight of course providers.

The Board indicates approximately 50 CE providers opting to provide these courses in experimental treatments will be required to submit CE course applications to the Board for approval.

A Nursing Educational Consultant (NEC) will take approximately six hours to review and approve each application at costs of \$564 per institution. The Board’s total costs to review and approve 50 CE providers is estimated to be \$28,000.

Additionally, the Board will be required to ensure compliance with the proposed regulations. However, because the Board already regulates and provides oversight of these 50 CE providers, no additional workload or costs are anticipated at this time.

The Board notes there is no fee related to CE course applications. As a result, the proposed regulations do not result in additional revenue.

¹ “Direct patient care” means 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.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

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.

CE providers may only offer courses that meet the Board's requirements. They may be impacted if a CE provider develops a course that is not approved. Those CE providers that provide course content related to experimental procedures 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.

This regulation proposal will predominantly impact the following occupations: nursing, healthcare, education, accreditation and certification agencies. Jobs impacted other than nurses include: administrators, analysts, content experts, educators including program Directors and Deans, evaluators, instructors, physicians, researchers, scientists and technical experts.

Cost Impact on Representative Private Person or Business:

This regulation proposal impacts all nurses in California. BPC section 2811.5(a) requires RNs renewing their licenses to submit proof of completion of CE or other education deemed equivalent by the Board. CE providers who offer course content in experimental procedures and treatments and implicit bias in all coursework may pass along their costs to RNs who register for the training through tuition or course fees. Corporations represent 41% of the Board's CE providers and are more likely to fund this type of course content. Health facilities (17%), individuals (15%), associations (10%), universities/schools (9%), government agencies (5%), and partnerships (2%) represent the remaining 59% of the Board's CE providers.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The Board has determined this regulation will affect small businesses that provide course content related to experimental medical procedures or treatments and implicit bias requirements to California registered nurses. Small business CE providers 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. Any financial impact on these businesses will likely be offset by increased tuition or course fees.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS/ASSESSMENT

The Board has determined that this regulatory action will not create or eliminate jobs, will not create new business or eliminate existing businesses, and will not affect the expansion of businesses currently doing business within the State of California. Based on the number of courses affected by the amendments to section 1456, the Board does not anticipate that this regulatory action will create or eliminate jobs, create new businesses or eliminate existing businesses or affect the expansion of businesses currently doing business.

These regulations do benefit the health and welfare of California Residents by helping to ensure that licensees are properly trained and knowledgeable.

The proposed amendments will not affect worker safety and the environment because this regulation does not relate to worker safety and the environment.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would 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 than the proposed regulatory action or would be more cost-effective to the affected private persons and equally effective in implementing the statutory policy or other provision of the law.

Interested persons are invited to present statements relevant to the above determinations in writing during the written comment period or orally at a hearing, if scheduled.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information on which this proposal is based. This material is contained in the rulemaking file and may be obtained upon request from the person designated in the Notice under Contact

Person or by accessing the Board's website, www.rn.ca.gov.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below. You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

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Website Access: Materials regarding this proposal can be found at www.rn.ca.gov.