

**Dental Hygiene Board of California
California Department of Consumer Affairs**

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing has been scheduled.

Subject Matter of Proposed Amended Regulations: Reviews, Site Visits, Citation and Fines, and Probationary Status for Dental Hygiene Educational Programs

Section Affected: Section 1104.3 of Title 16 of the California Code of Regulations (CCR)

Specific Purpose of Each Adoption, Amendment, or Repeal:

1. Background/Statement of the Problem

The Dental Hygiene Board of California (Board) is charged with oversight of registered dental hygienists, registered dental hygienists in alternative practice, and registered dental hygienists in extended functions (collectively RDHs). The Board carries out its regulatory authority through enforcement of statutory provisions of the Dental Practice Act, Business and Professions Code (BPC) sections 1900 through 1967.4, and Title 16 of the CCR. The Board's core functions are issuing licenses to qualified applicants, investigating consumer complaints filed against licensees, disciplining licensees for sustained violations of the BPC and Title 16 of the CCR, regulating and approving RDH educational programs, and monitoring licensees placed on disciplinary probation by the Board.

Existing law provides the Board shall renew approval of an educational program for a registered dental hygienist, a registered dental hygienist in alternative practice, or a registered dental hygienist in extended functions (collectively DHEPs) provided the program continues to meet the Board's requirements.

Senate Bill 1482 (Hill, Chapter 858, Statutes of 2018) (SB 1482) added BPC section 1941.5 to the Code. BPC section 1941.5 authorizes the Board to conduct periodic surveys, evaluations, and announced and unannounced site visits on existing and new DHEPs. Section 1941.5 authorizes the Board to place an existing or new DHEP on probation with terms, issue a citation and fine, or withdraw approval of a DHEP if a DHEP does not comply with DHEP requirements and the Commission on Dental Accreditation of the American Dental Association (CODA) standards.

This proposal will implement section 1941.5 by: (1) requiring DHEPs to provide the Board access to program records and facilities to determine compliance with Board educational program requirements; (2) authorizing the Board to issue citations, fines and orders of abatement to DHEPs if the Board determines a DHEP is in violation of any law, regulation, or standard applicable to a DHEP; (3) requiring DHEPs to comply

with citations, fines, and orders of abatement; (4) providing for DHEPs to contest citations, fines, and orders of abatement; (5) providing the Board may place a DHEP on probation based on any violation of law, regulation, or standard applicable to a DHEP if the Board determines the violation, after review of evidence presented to the Board, warrants a probationary status; and (6) providing for DHEPs to appeal their probationary status.

The Board approved substantive amendments to the proposed language after review at the November 23, 2019, May 29, 2020, August 29, 2020, and November 20, 2021, Board meetings. The Board approved the amended language at its July 28, 2022, Board meeting and delegated authority to the Board's EO to make any technical, non-substantive changes, if necessary.

2. Anticipated Benefit(s) from this Regulatory Action:

The anticipated benefits of the proposed regulation are:

- First, requiring DHEPs to provide the Board access to program records and facilities will promote DHEPs' compliance and cooperation with Board reviews of educational program requirements. This promotes safety of the public because it incentivizes DHEPs to follow all laws, regulations, and standards applicable to a DHEP.
- Second, issuing citations, fines, and orders of abatement to DHEPs ensures they follow Board requirements. This promotes safety of the public as the Board will closely monitor DHEPs who are issued citations, fines, and orders of abatement to ensure DHEPs adhere to all laws, regulations, and standards applicable to a DHEP while caring for patients.
- Third, establishing a process by which DHEPs shall comply with citations, fines, and orders of abatement ensures DHEPs timely comply with Board requirements. This promotes safety of the public as the Board will closely monitor DHEPs issued citations, fines, and orders of abatement to ensure DHEPs adhere to all laws, regulations, and standards applicable to a DHEP while caring for patients.
- Fourth, establishing a process for DHEPs to contest and appeal citations, fines, and orders of abatement, affords a DHEP procedural due process. This promotes a fair, equal, and clear process for DHEPs to present appeals to the Board.
- Fifth, establishing a process for the Board to place DHEPs on probation, or withdrawing the Board's approval if compliance is not made within reasonable specified timelines, ensures DHEPs follow Board requirements. This promotes safety of the public as the Board will closely monitor DHEPs placed on probation to ensure DHEPs adhere to all laws, regulations, and standards applicable to a DHEP while caring for patients.

Factual Basis/Rationale

Section 1104.3

Subdivision (a)

Subdivision (a) requires DHEPs to provide access to the Board or its representatives during business hours to the program's premises and records (which would include, but are not limited to, course records, student records, faculty and staff records, and patient records) to review the DHEP for compliance with all laws, regulations, and standards applicable to a DHEP.

As the Board's highest priority is consumer protection, it is necessary DHEPs adhere to all laws, regulations, and standards. (Bus. & Prof. Code, § 1902.1.) These include the BPC, the CCR, CODA Standards, the Occupational Safety and Health Administration (OSHA), the Health and Safety Code (HSC), the Centers for Disease Control and Prevention (CDC), and the Health Insurance Portability and Accountability Act (HIPAA). Requiring DHEPs to provide access to the DHEP's premises enables the Board to review the DHEP's facilities (e.g., wet labs, clinic, equipment, and classrooms) required pursuant to 16 CCR section 1105(i) and 16 CCR section 1105.2(d)(3).

For example, with regard to patient confidentiality: (1) HSC section 130203(a) requires every health care provider to establish and implement appropriate administrative, technical, and physical safeguards to protect the privacy of a patient's medical information and shall reasonably safeguard confidential medical information from any unauthorized or unlawful access; (2) HIPAA (Code of Federal Regulations, tit. 45, § 164.530(c)(1)) requires a covered entity to have appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information; and (3) CODA Standards 4-1 and 6-6 require confidentiality of information relating to the health status of each individual patient is strictly maintained. Therefore, allowing the Board access to the DHEP's facilities to inspect where patient records are maintained, the Board can determine if the DHEP is in compliance with the HSC, HIPAA, and CODA, thereby ensuring their confidential medical information is secure. Additionally, as patient confidentiality is a crucial element of patient care, the students of the program are taught the importance of protecting a patient's confidential medical information. The students then actively apply the knowledge during patient care within the program and beyond after licensure.

With regard to infection control: (1) 16 CCR section 1005 provides minimum standards of infection control as required for dental health-care facilities; (2) BPC section 5193 provides requirements regarding bloodborne pathogens (occupational exposure by the DHEP student, faculty, and staff to blood or other potentially infectious bodily fluids); and (3) the "Centers for Disease Control and Prevention, Guidelines for Infection Control in Dental Health-Care Settings – 2003" provides CDC infection control guidelines for dental health-care settings. Therefore, allowing the Board access to the DHEP's facilities to inspect infection control equipment, policies, and procedures, the Board can determine if the DHEP is in compliance with the CCR, BPC, and CDC

guidelines, thereby ensuring the facilities provide a safe and clean environment with which to treat patients. Additionally, as infection control is a crucial element of patient care to ensure patient safety, the students of the program are taught the importance of infection control. The students then actively apply the knowledge during patient care within the program and beyond after licensure.

Additionally, establishing access to the DHEP's records (e.g., student competencies to show completion of required clinical requirements and faculty biosketches to ensure adequate education and licensure to oversee students) ensures compliance with Board requirements pursuant to 16 CCR section 1105, 16 CCR section 1105.1, and 16 CCR section 1105.2.

Proposed subdivision (a) is consistent with requirements in other Board regulations (see e.g., Cal. Code Regs., tit. 16, §§ 1105.2(d)(3)(C), 1107(b)(3)-(4), and 1108(b)(3)-(4)).

Subdivision (b)

Subdivision (b) provides requirements for citations and final orders of abatement issued to DHEPs for violations of any law, regulation, or standard applicable to a DHEP. Subdivision (b) is necessary to establish a process to issue citations and orders of abatement that is clear, fair, and equitable.

Subdivision (b)(1)

Subdivision (b)(1) provides the EO or their designee may issue a citation to a DHEP containing an order to pay a fine not to exceed \$5,000 and an order of abatement against a DHEP in violation of any law, regulation, or standard applicable to a DHEP.

The Board determined a fine (up to \$5,000) is necessary to provide a deterrent against future violative conduct. (Bus. & Prof. Code, § 125.9, subd. (a)(3) [authorizing fines of up to \$5,000].) An order of abatement is a mandatory and prohibitory order requiring or prohibiting one or more acts in violation of the laws or regulations by the DHEP. This is necessary to ensure the DHEP corrects all violations which may place the public at risk of harm or to come into compliance with the law. A citation containing the order of abatement to the violation is necessary to clearly advise the DHEP regarding the specific violation(s). (Bus. & Prof. Code, § 125.9, subd. (b)(3).)

Subdivision (b)(1)(A)

Subdivision (b)(1)(A) provides a citation may be issued without the assessment of a fine when determined by the EO or their designee. (Bus. & Prof. Code, § 125.9, subd. (c)(1).) A fine may not be necessary provided the infraction is minor, easily corrected, and poses little to no patient harm. For example, omitting the DHEP's program's written mission statement from the program manual would be a minor, easily corrected violation which poses no patient harm. This violation, though cited, would not necessitate a fine.

Subdivision (b)(1)(B)

Subdivision (b)(1)(B) provides each citation issued pursuant to subdivision (b)(1) shall be in writing and shall describe with particularity the nature and facts of each violation specified in the citation. BPC section 125.9(b)(1) requires citations be in writing and to describe the nature of the violation, including specific reference to the provision of law determined to have been violated. Having the citation in writing is necessary to memorialize the citation and have a historical record of the violation. Memorializing the specific provision of law is necessary to provide the DHEP with a reference as to where the DHEP violated the law and provides guidance as to where corrections are required.

Subdivision (b)(2)

Subdivision (b)(2) provides if the Board or its authorized representative determines a DHEP is in violation of any law, regulation, or standard applicable to a DHEP, the DHEP shall correct the violation(s) within the amount of time specified in the order. BPC section 125.9(b)(2) requires citations shall contain an order of abatement fixing a reasonable time for abatement of the violation.

Subdivision (b)(2) is consistent with reporting timelines in other regulations. (See e.g., Cal. Code Regs., tit. 16, §§ 1105.3, 1107(b), and 1108(b)(1).) Subdivision (b)(2) also requires the DHEP to furnish the Board written proof of compliance with the order and to permit a site visit by the Board's authorized representative to confirm compliance. As the Board's highest priority is protection of the public, subdivision (b)(2) is necessary to ensure facilities and records are compliant with all laws, regulations, and standards and reporting requirements found in subdivision (b)(2) are also consistent with other regulations. (See e.g., Cal. Code Regs., tit. 16, §§ 1104(b)(1), 1105(e), 1107(a)(4) and (a)(5), and 1108(a) and (a)(5).)

Subdivision (b)(3)

Subdivision (b)(3) provides factors the Board considers in the issuance of any citation or fine to a DHEP. The Board determined the following factors are relevant to the severity of citation or fine issued to a DHEP.

The first factor is the nature and severity of the violation. The Board must consider the nature and severity of the violation because this is the offense against which the DHEP's remediation efforts will be evaluated. For example, not properly sterilizing dental hygiene instruments to be used in a patient's mouth will jeopardize the patient's health by causing the spread of infections (e.g., Hepatitis B, HIV, etc.), which could ultimately lead to death. This violation would be considered severe and requires a maximum penalty (e.g., citations, fines, orders of abatement, probation and/or revocation of approval). However, omitting the DHEP's written mission statement from a program manual would be a minor violation and requires only a citation.

The second factor is the length of time that has passed since the date of the violation. Upon discovery of a violation, the length of time passed from the date of the violation to

the date of discovery is relevant to determining the type of punishment the Board imposes. For example, if the Board discovers an infection control violation by a DHEP within one week of the violation, the DHEP may be issued a citation and order of abatement. However, if the Board discovers an infection control violation which perpetuated for over one year, the DHEP would be subject to further, more restrictive discipline (citations, fines, orders of abatement, and/or probation).

The third factor is the consequences of the violation, including the potential to harm, or actual patient harm. The potential or actual harm is relevant to the blameworthiness of the conduct and the danger to the public posed by the conduct. For example, if the Board cited two DHEPs with an infection control violation, and the first DHEP failed to have signs clearly demarking “clean” versus “dirty” areas in the sterilization room, while the second DHEP failed to properly maintain their autoclaves (machine to sterilize instruments used in the mouth of patients), the second DHEP would be subject to further, more restrictive discipline (fines and/or probation) due to the severe nature of the violation and risk to the public’s health.

The fourth factor is the history of previous violations of a similar nature. A history of previous violations of a similar nature bears on the DHEP’s ability and willingness to make amends from prior violations and willingness to conform to the laws, regulations, and standards in the future as required by the DHBC. For example, if DHEP A was cited for infection control violations regarding instrument sterilization in 2017 and DHEP A has continued the same, inappropriate processes in 2021, DHEP A may now be subject to further, more restrictive discipline (increased fines and/or probation).

The fifth factor is evidence the violation was willful. If the Board finds evidence the violation was willful (i.e., intentional), the consequences for the violation would warrant increased severity of consequences. For example, if DHEP A is aware their instrument sterilization processes are inappropriate and poses a health risk to their patients, yet continues those same processes, DHEP A may now be subject to further, more severe, and restrictive discipline (increased fines, probation, or revocation of approval).

The sixth factor the Board would consider is the gravity (i.e., extreme or alarming importance; seriousness) of the violation. The Board considers the seriousness of harm to the public bears on the consequences for the violation. For example, if a DHEP knowingly utilized faulty autoclaves and continued to use those same autoclaves over the span of five years, the use of those faulty autoclaves could expose patients to pathogens (bacteria, viruses, or other microorganisms that can cause disease) due to improper sterilization of instruments utilized in the patient’s mouths. This differs from the factor of severity in that this scenario jeopardizes the health of all the patients serviced by the DHEP’s clinic over those five years, numbering into the thousands of patients affected. The DHEP would be subject to more severe, and restrictive discipline (increased fines, probation, or revocation of approval).

The seventh factor is the extent to which the cited DHEP has remediated the deficiencies. For example, if a DHEP was cited for not securing patient treatment records, and the DHEP demonstrated it had taken steps to remediate the issue

(immediately locking the file room door until a new, locked cabinet could be ordered, and provided sales receipts and pictures of a new locked cabinet after delivery to the DHEP), this would tend to show the DHEP was cognizant of the severity of the violation and ensuring it did not recur. This may warrant less severe discipline because the potential harm has been averted. However, some discipline (e.g., fine or probation) may still be warranted as a deterrent to the DHEP committing such situations in the future.

These factors are consistent with citation and fine criteria in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1140.)

Subdivision (b)(4)

Subdivision (b)(4) provides requirements regarding compliance with citations and order of abatements. Subdivision (b)(4) is necessary for the Board to provide a clear, fair, and equitable process in evaluating compliance with citations and orders of abatement.

Subdivision (b)(4)(A)

Subdivision (b)(4)(A) provides if a cited DHEP who has been issued an order of abatement is unable to complete the correction within the time set forth in the citation because of conditions beyond the DHEP's control after the exercise of reasonable diligence, the DHEP cited may request an extension of time, in writing, from the EO or their designee in which to complete the correction.

The Board is aware there are situations that may occur out of the DHEP's control, and therefore require additional time to come into compliance. For example, if a DHEP is short one nitrous oxide-oxygen unit because of a national supply chain issue, this would be outside the DHEPs control and favor an extension of time to comply.

Additionally, subdivision (b)(4)(A) provides the request for an extension shall be in writing and be made within the time set forth for abatement. The Board requires the request in writing to memorialize the difficulty encountered by the DHEP to correct the violation, to provide a plan to accomplish correction of the violation, and for a historical record of the DHEP's acknowledgement of culpability to correct the violation within the requested timeframe.

Subdivision (b)(4)(B) and (C)

Subdivision (b)(4)(B) provides when a citation or order of abatement is not contested or if the order is appealed and the DHEP cited does not prevail, failure to abate the violation within the time allowed or pay the fine imposed, if any, shall constitute a violation and a failure to comply with the citation or order of abatement.

Subdivision (b)(4)(C) provides if the DHEP fails to timely comply with an order of abatement or pay a fine imposed, it may result in disciplinary action being taken by the Board, in addition to other remedies. The Board determined a DHEP's failure to correct violations and/or pay a fine issued by the Board within the allotted time demonstrates

the DHEP's lack of accountability and warrants further discipline. For example, DHEP A refuses to conduct spore testing on their autoclaves. Failing to conduct spore testing to ensure sterility of instruments places the public at risk for infections due to possibly improperly sterilized instruments. The Board would then determine if further action against DHEP A (e.g., probation or revocation of approval) is warranted.

Subdivision (b)(5)

Subdivision (b)(5) provides requirements regarding contesting citations. Subdivision (b)(5) is necessary because it allows the DHEP the ability to request further information or present further evidence of compliance. This promotes a fair, equal, and clear process for DHEPs to present appeals to the Board.

Subdivision (b)(5)(A)

Subdivision (b)(5)(A) provides the citation shall inform the cited DHEP if they desire a hearing to contest the finding of a violation, the hearing shall be requested by written notice to the Board within 30 calendar days of the date of issuance of the citation.

BPC section 125.9(b)(4) requires a citation or fine issued pursuant to a citation inform the licensee that if the licensee desires a hearing to contest the finding of a violation, the hearing shall be requested by written notice to the board, bureau, or commission within 30 days of the date of issuance of the citation or assessment. This requirement is also consistent with contestation requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142.)

Additionally, subdivision (b)(5)(A) provides hearings shall be held pursuant to the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. BPC section 125.9(b)(4) requires hearings be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

Subdivision (b)(5)(B)

Subdivision (b)(5)(B) provides in addition to, or as an alternative to, requesting a hearing as provided in subdivision (b)(5)(A), the cited DHEP may, within 14 calendar days after service of the citation, submit a written request to the Board for an informal conference with the EO.

This subdivision is necessary because DHEPs may have questions regarding violations or citations and informal conferences provide the DHEP the ability to request further information or present further evidence of compliance. Additionally, in the Board's experience, 14 calendar days provides the DHEP sufficient time to request an informal conference with the EO. Having the request in writing is necessary to memorialize and have a historical record of the DHEP's acknowledgement of culpability to correct the violation within the requested timeframe.

Subdivision (b)(5)(B) is consistent with informal conference requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (b).)

Subdivision (b)(5)(C)

Subdivision (b)(5)(C) provides the EO or their designee shall, within 30 calendar days from receipt of the written request for an informal conference pursuant to subdivision (b)(5)(A), hold an informal conference with the DHEP cited and/or their legal counsel or authorized representative, if any, unless continued for good cause (e.g., delays due to federal or state holidays, states of emergencies, etc.). DHEPs may have questions regarding violations or citations and this provision allows the DHEP the ability to request further information or present further evidence of compliance. Furthermore, in the Board's experience, 30 calendar days provides the DHEP sufficient time to gather pertinent information applicable to their contestation.

Subdivision (b)(5)(C) is consistent with informal conference requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (c).)

Subdivision (b)(5)(D)

Subdivision (b)(5)(D) provides the EO or their designee may affirm, modify, or dismiss the citation at the conclusion of the informal conference. Depending on the submission of the evidence provided by the DHEP to contest the violation, the EO, acting as an agent of the Board, has the ability to modify or dismiss the citation should the DHEP show just cause for modification or dismissal, or affirm the violation if facts and evidence do not support modification or dismissal of the violation.

Delegating the authority from the Board to the EO or designee to handle the informal conference is necessary because the Board meets approximately quarterly, and having such matters handled in a shorter time is more efficient. Further, there may be information shared in an informal conference that would not be appropriate to share in an open Board meeting, such as issues regarding confidential health information.

Additionally, subdivision (b)(5)(D) provides for a written decision stating the reasons for the decision, which shall be mailed to the cited DHEP and their legal counsel, if any, within 14 calendar days from the date of the informal conference. This decision is deemed to be a final order with regard to the informal conference procedure. The Board provides the decision will be in writing to provide a historical record of the decision. Furthermore, in the Board's experience, 14 calendar days provides the EO sufficient time to provide a written record of the decision. Stating the timeline by which a decision shall be rendered provides certainty to a cited DHEP, who may otherwise need to be preparing for a formal hearing.

Subdivision (b)(5)(D) is consistent with informal conference requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (d).)

Subdivision (b)(5)(D)(i)

Subdivision (b)(5)(D)(i) provides if the citation, including any administrative fine levied or order of abatement pursuant to subdivision (b)(1) is dismissed, the request for a hearing shall be deemed withdrawn. If the citation is dismissed, there is no need for further action against the DHEP.

Subdivision (b)(5)(D)(i) is consistent with contestation requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (d)(1).)

Subdivision (b)(5)(D)(ii)

Subdivision (b)(5)(D)(ii) provides if the citation, including any administrative fine levied or order of abatement is affirmed, the cited DHEP may, in its discretion, withdraw the request for a hearing or proceed with the administrative hearing process as set forth in subdivision (b)(5)(A). The Board determined if the order is affirmed after the informal conference, the DHEP should be able to withdraw the request for a hearing or proceed with the administrative hearing process, depending on the wishes of the individual DHEP. This avoids the need for a hearing process if the DHEP does not need or wish to pursue it.

Additionally, subdivision (b)(5)(D)(ii) provides an informal conference shall not be held on affirmed citations. The Board determined once the citation is affirmed by the EO, further challenges shall be conducted by the Board under the administrative hearing process as set forth in subdivision (b)(5)(A), as the Board's primary function is to enforce all provisions applicable to RDHs and DHEPs. (Bus. & Prof. Code, § 125.9, subd. (a)(7).) This provision is necessary to prevent a duplicative cycle of informal conference requests on which an EO determination has already been made.

Subdivision (b)(5)(D)(ii) is consistent with contestation requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (d)(2).)

Subdivision (b)(5)(D)(iii)

Subdivision (b)(5)(D)(iii) provides if the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If the order is modified, the original citation is nullified. As subdivision (b)(5)(D)(iii) requires the issuance of a new citation, BPC section 125.9(b)(1) requires citations be in writing and describe with particularity the nature of the violation, including reference to the provision of law violated.

Additionally, subdivision (b)(5)(D)(iii) provides if a cited DHEP wishes to contest a modified citation, the cited DHEP shall, within 30 calendar days after issuance of the modified citation, contest it by submitting a written request for an administrative hearing. BPC section 125.9(b)(4) requires if a citation or fine assessment is issued pursuant to a citation, the citation shall inform the licensee that if the licensee desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the

board, bureau, or commission within 30 days of the date of issuance of the citation or assessment.

Furthermore, subdivision (b)(5)(D)(iii) provides an informal conference shall not be held on modified citations. As in subdivision (b)(5)(D)(ii), the Board determined once the citation is affirmed by the EO, further contestations shall be conducted under the administrative hearing process as set forth in subdivision (b)(5)(A), as the Board's primary function is to enforce all provisions applicable to RDHs and DHEPs. (Bus. & Prof. Code, § 125.9, subd. (a)(7).) This provision is necessary to prevent a duplicative cycle of informal conference requests on which an EO determination has already been made.

Subdivision (b)(5)(D)(iii) is consistent with contestation requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (d)(3).)

Subdivision (c)

Subdivision (c) provides the requirements a DHEP on probationary status must comply with once placed on probation. Subdivision (c) is necessary to provide the requirements applicable to DHEPs placed on probation and provide a clear, fair, and equitable process.

Subdivision (c)(1)

Subdivision (c) provides after one or more violations by a DHEP are discovered and brought before the Board, the Board may place a DHEP on probation pursuant to BPC section 1941.5.

As not all violations are equal in severity, the Board's decision to place a DHEP on probation depends on several factors. Therefore, the Board determined to utilize criteria set forth in subdivision (c)(2) to assist in the determination. Setting the factors out in regulation is necessary to show the due process considerations to which the Board will abide.

Subdivision (c)(2)

Subdivision (c)(2) provides factors the Board considers to place a DHEP on probation. The Board determined the factors referenced in subdivision (b)(3) are relevant to the severity of violation applicable to place a DHEP on probation. The Board incorporates by reference its discussion relating to subdivision (b)(3) above.

Subdivision (c)(3)

After one or more violations by a DHEP are discovered and brought before the Board, the Board may decide to place a DHEP on probation. Subdivision (c)(3) requires DHEPs placed on probation to disclose their probationary status in writing to its students within fifteen (15) business days of being placed on probation. The DHEP shall

also advise each potential student applicant to the DHEP of their probationary status before offering to enroll the applicant.

These requirements are necessary because students are consumers of educational programs. If the DHEP on probation fails to timely correct the violation(s), the Board may revoke approval of the DHEP. If the DHEP's approval is revoked, the students would be graduating from a non-approved DHEP and would not be able to obtain California licensure as BPC section 1917(a) requires the completion of a DHEP approved by the Board for licensure. Further, the basis for the probation may implicate health and safety issues that could potentially put the students themselves in harm's way, and it is important to disclose that potential harm so that the students can make informed choices to protect themselves.

Additionally, the formal notice shall include, but not be limited to, a notice that the DHEP was placed on probation by the Board, the date of the beginning of the probation, as well as a copy of the Board's order issuing probation to the DHEP which includes the terms of the probation. As the Board's highest priority is protection of the public (Bus. & Prof. Code, § 1902.1), the Board determined full disclosure of the Board's order is necessary to inform the public as to potential health and safety issues that could potentially put the public in harm's way, and it is important to disclose that potential harm so that the public can make informed choices to protect themselves.

Furthermore, subdivision (c)(3) requires DHEPs to provide the Board with written proof of compliance with the subdivision as a condition for removal from probationary status. Subdivision (c)(3) is necessary to ensure students and potential students are notified of the probationary status because if the DHEP's approval is revoked, the students would be graduating from a non-approved DHEP and would not be able to obtain California licensure pursuant to BPC section 1917(a). In addition, DHEP reporting requirements in subdivision (c)(3) are also consistent with other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1104.)

Subdivision (c)(4)

Subdivision (c)(4) requires a DHEP on probationary status to correct the violation(s) within the amount of time specified in the order.

It is necessary for a probationary DHEP to correct the violation within a set timeframe to avoid perpetuation of the violation. Additionally, it is necessary to ensure facilities and records comply with proposed subdivision (a). Subdivision (c)(4) is also consistent with reporting timeline stipulations in other regulations. (See e.g., Cal. Code Regs., tit. 16, §§ 1105.3, 1107(b), and 1108(b)(1).)

Additionally, subdivision (c)(4) requires DHEPs to furnish the Board written proof of compliance with the order and permit a site visit by the Board's authorized representative to confirm compliance. It is necessary for the Board to receive documented proof of compliance and consent with a site visit to ensure facilities and records comply with proposed subdivision (a).

DHEP review and reporting requirements in subdivision (b) are also consistent with other regulations. (See e.g., Cal. Code Regs., tit. 16, §§ 1104(b)(1), 1105(e), 1107(a)(4) and (a)(5), and 1108(a) and (a)(5).)

Subdivision (c)(4)(A)

Subdivision (c)(4)(A) provides if the DHEP on probation demonstrates it has corrected the violation(s) and meets all requirements for approval set forth in 16 CCR 1104, the DHEP will be removed from probationary status. Demonstration of compliance may be accomplished by submission of written documentation of proof, photographic submissions, and/or site visit(s) by a Board-authorized representative. This is necessary because once a DHEP meets all requirements enforced by the Board, the DHEP will be in compliance with BPC section 1941.5 and its approval shall be restored.

Additionally, probationer DHEPs are regularly visited as part of the Board's public protection mandate and if the DHEP demonstrates compliance, then the probation monitor can recommend to the Board their removal from probationary status. Finally, 16 CCR 1104(b)(5) states continuation of approval of all DHEPs shall be contingent upon compliance with the requirements described in Article 3, and therefore probationer DHEPs may be removed from probationary status and be returned to a full-approved status.

Subdivision (c)(4)(B)

Subdivision (c)(4)(B) provides if the DHEP fails to demonstrate (by the aforementioned process) to the Board by the end of its probationary period, the DHEP has corrected all violation(s) and met the requirements for approval set forth in 16 CCR 1104, the Board will revoke approval of the DHEP.

16 CCR 1104(b)(5) states continuation of approval of all DHEPs shall be contingent upon compliance with the requirements described in Article 3 (applicable to educational programs). If the DHEP does not correct all violations and meet the requirements for approval set forth in 16 CCR 1104, the Board may choose to withdraw approval of the DHEP.

The process for the Board to withdraw approval would include staff bringing the matter before the Board at a noticed public meeting. Staff would provide all documentation presented to and received from the DHEP to include: 1) site visit reports and photographic evidence (if any) from the site visit; 2) responses and compliance documentation to the site visit reports; and 3) report from staff as to the current status of deficiencies and violations discovered at the DHEP. The Board would then determine upon review of evidence provided whether to revoke the approval of the DHEP.

Violations of Article 3 have the potential to cause harm to the public. For example, 16 CCR 1105.2(d)(3)(A) requires DHEPs to provide infection control equipment according to the requirements of 16 CCR 1005. If a DHEP fails to follow infection control protocols pursuant to 16 CCR 1005 [e.g., subdivision (b)(12) requires critical instruments to be

discarded (local anesthesia needles) or sterilized (instruments such as scalers to clean teeth)], the public could potentially be exposed to contamination from other patients and may be placed at risk for infections or disease (e.g., Hepatitis B or HIV from contaminated needles or instruments).

Subdivision (c)(5), Appeals Process for a DHEP on Probationary Status

Subdivision (c)(5) provides the requirements for a DHEP to appeal their probationary status. Subdivision (c)(5) is necessary to make the process to file an appeal a clear, fair, and equitable process.

Subdivision (c)(5)(A)

Subdivision (c)(5)(A) provides any DHEP placed on probation may request, in writing, to appeal their probationary status by following the requirements in either subdivision (c)(5)(A)(i) or subdivision (c)(5)(A)(ii).

Requiring the request in writing is necessary to memorialize and have a historical record of the DHEP's request for appeal of their probationary status within the requested timeframe.

Subdivision (c)(5)(A) is consistent with informal conference requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (b).)

Subdivision (c)(5)(A)(i)

Subdivision (c)(5)(A)(i) provides the Executive Officer shall notify the DHEP of the final decision of the Executive Officer within ten days of the informal conference.

In the Board's experience, ten (10) days provides the EO sufficient time to provide a record of the decision. Stating the timeline by which a decision shall be rendered provides certainty to a cited DHEP, who may otherwise need to be preparing for a formal hearing.

Additionally, based on the outcome of the informal conference, the DHEP may request a hearing to contest the Executive Officer's final decision. A DHEP shall request a hearing by written notice to the Board within 30 calendar days of the date of the letter of the Executive Officer's final decision after the informal conference. Hearings shall be held pursuant to the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. Like subdivision (b)(5)(D)(ii), the Board determined once the EO makes a final decision after an informal conference, further challenges to the order shall be conducted under the administrative hearing process as set forth in subdivision (b)(5)(A), as the Board's primary function is to enforce all provisions applicable to RDHs and DHEPs. (Bus. & Prof. Code, § 125.9, subd. (a)(7).)

Subdivision (c)(5)(A)(ii)

Subdivision (c)(5)(A)(ii) provides the DHEP may request a hearing to appeal their probationary status pursuant to the provisions of Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. Such notification shall be made to the Board before the date of the informal conference.

The Board determined a DHEP may utilize the administrative hearing process as set forth in subdivision (b)(5)(A), as an option to appeal the DHEP's probationary status. A DHEP may have a preference for adjudication before an administrative law judge and the Board wishes to acknowledge that preference. Additionally, the Board's primary function is to enforce all provisions applicable to RDHs and DHEPs. (Bus. & Prof. Code, § 125.9, subd. (a)(7).)

Subdivision (c)(5)(A)(ii) is consistent with contestation requirements in other regulations. (See e.g., Cal. Code Regs., tit. 16, § 1142, subd. (d)(3).)

Underlying Data:

- Senate Bill 1482 (Hill, Chapter 858, Statutes of 2018).
- Minutes: DHBC Legislative and Regulatory Subcommittee Meeting, November 22, 2019.
- Meeting Materials: DHBC Legislative and Regulatory Subcommittee Meeting, November 22, 2019.
- Minutes: DHBC Full Board Meeting, November 23, 2019.
- DHBC Fee Resolution, November 23, 2019.
- Minutes: DHBC Full Board WebEx Teleconference, May 29, 2020.
- Meeting Materials: DHBC Full Board WebEx Teleconference, May 29, 2020.
- Minutes: DHBC Full Board WebEx Teleconference, August 29, 2020.
- Meeting Materials: DHBC Full Board WebEx Teleconference, August 29, 2020.
- Minutes: DHBC Full Board WebEx Teleconference, November 20, 2021.
- Meeting Materials: DHBC Full Board WebEx Teleconference, November 20, 2021.
- Minutes: DHBC Full Board Meeting, July 23, 2022.
- Meeting Materials: DHBC Full Board Meeting, July 23, 2022.

Business Impact:

If non-compliant and fined by the Board, this regulation may have an economic impact on businesses of up to five thousand dollars (\$5,000) because it is in violation of laws, regulations, or standards applicable to a DHEP, depending on the severity of the violation. This initial determination is based on the following facts:

The proposed regulatory language defines parameters for the Board to conduct periodic surveys, evaluations, and announced and unannounced site visits to existing and new DHEPs. This ensures continued compliance with all laws, regulations, and standards

applicable to a DHEP, and defines consequences, including probation with terms, issuance of a citation and fine, or withdrawal of approval if the Board finds the DHEP noncompliant. Any DHEP cited and fined will most likely be fined the maximum \$5,000 by the Board to deter future violations. The amount collected would be used as cost recovery to offset enforcement-related costs.

An institution may opt to appeal any citation and fine issued, but these costs are unknown at this time. As noted above, fines would only be assessed on non-compliant DHEPs, that is, DHEPs found in violation of law. These fines, while a deterrent to non-compliance, are not considered a statewide adverse economic impact, because a fine can be avoided completely by compliance with law. DHEPs in compliance with law would have zero business cost impacts from this regulatory action.

Economic Impact Assessment:

The Board has determined this regulatory action would not impact jobs within the State of California as the proposed language in the regulation only defines parameters for the Board to conduct periodic surveys, evaluations, and announced and unannounced site visits to existing and new DHEPs to ensure continued with all laws, regulations, and standards applicable to a DHEP and define consequences, including probation with terms, issuance of a citation and fine, or withdrawn approval if the DHEP is found noncompliant.

The Board has determined this regulatory action would not impact new businesses within the State of California as the proposed language in the regulation would only define parameters for Board to conduct periodic surveys, evaluations, and announced and unannounced site visits to DHEPs to ensure continued compliance with all laws, regulations, and standards applicable to a DHEP and define consequences, including probation with terms, issuance of a citation and fine, or withdrawn approval if the Board finds the DHEP noncompliant.

This regulatory proposal will positively impact worker safety as the proposed language in the regulation would ensure DHEPs adhere to all laws, regulations, and standards applicable to a DHEP, including worker safety (OSHA).

This regulatory proposal will positively impact the health and welfare of California residents as the proposed language in the regulation would ensure DHEPs to adhere to all laws, regulations, and standards applicable to a DHEP, including patient safety (HIPAA, HSC, CDC).

This regulatory proposal will not affect the state's environment because this proposed regulation does not involve environmental issues.

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:¹

The Board currently has 29 approved DHEPs operating in the state. Under the proposed regulations, the Board anticipates conducting (on average) four site visit inspections per year.

A typical DHEP site visit inspection takes approximately 12 hours (8 hours of on-site inspection time plus 4 hours to write the report) to complete. The work is conducted by an Associate Governmental Program Analyst (AGPA) and a Subject Matter Expert (SME) at a cost of up to approximately \$3,073 per inspection. The total costs to perform four annual inspections is estimated to be \$12,292 and up to \$122,920 over a ten-year period.

In the event a DHEP is placed on probation, the Board's AGPA and SME will conduct a follow-up inspection to ensure the institution has taken action(s) to ensure compliance. The follow-up inspection typically takes 8 hours to complete (AGPA – 8 hours, SME 4 – hours) at a cost of approximately \$1,929 per year and up to \$19,290 over a ten-year period.

Total site visit inspections workload and costs are estimated as follows:

Cite and Fine Estimated Workload Costs			
Initial Compliance Inspection	Costs/Yr	4 Initial/Yr	10-Yr Total
Inspection (*AGPA 12 hours @ \$136 per hour)	\$1,632	\$6,528	\$65,280
Travel (1 day) - (airline, hotel, car rental, & per diem @ \$241 per day)	\$241	\$964	\$9,640
Subject Matter Expert (SME) - (8 hours @ \$150 per hour)	\$1,200	\$4,800	\$48,000
Total Initial Costs:	\$3,073	\$12,292	\$122,920
Follow-Up Inspection (Probationers Only)	Costs/Yr	Costs/Yr	10-Yr Total
Follow-Up Inspection (8 hours @ \$136 per hour)	\$1,088	\$1,088	\$10,880
Travel (1 day) - (airline, hotel, car rental, & per diem @ \$241 per day)	\$241	\$241	\$2,410
Subject Matter Expert (SME) - (4 hours @ \$150 per hour)	\$600	\$600	\$6,000
Total Follow-Up Costs:	\$1,929	\$1,929	\$19,290
Total Costs:	\$5,002	\$14,221	\$142,210

*Associate Governmental Program Analyst (approximately \$136 per hour - includes **enforcement-related (\$30) and DCA pro rata (\$21) costs)

**Enforcement Costs (\$548,000)/Licensee Population (18,545) = \$30 per licensee

If cited and fined, a DHEP will most likely be fined the maximum amount of \$5,000 by the Board as cost recovery to partially offset enforcement-related costs. Therefore, the Board anticipates citation and fine revenues of \$5,000 per year and up to \$50,000 over a ten-year period.

In the event an institution opts to appeal the citation, the Board will incur additional workload and costs, including Attorney General and Office of Administrative Hearing fees of approximately \$12,412 per case as follows:

¹ The Board places this item in the initial statement of reasons because charts may not be used in the notice based on accessibility reasons.

Citations Appeals (costs)					
Job Class/Job Task	Events*	Hours Per	Total Hours	Costs Per Unit	Total Costs
*AGPA - Processes Appeal	1	1	1	\$106	\$106
*AGPA - Scheduling	1	1	1	\$106	\$106
AG & OAH	1	-	-	\$12,200	\$12,200
Totals:				\$12,412	\$12,412

*Associate Governmental Program Analyst (approximately \$106 per hour - includes DCA pro rata (\$21) costs)

**Attorney General/Office of Admin Hearings (projected average costs)

The regulations do not result in costs or savings in federal funds to the state.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

The Board has initially determined that no reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner which 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:

- 1) Not adopt the regulation: This alternative was rejected by the Board as BPC sections 1906 and 1941.5 authorize the Board to establish regulations to place an existing or new DHEP on probation with terms, issue a citation and fine, or withdraw its approval if compliance is not made with laws, regulations, and standards within reasonable specified timelines.
- 2) Adopt the regulation: The Board determined this alternative is the most feasible because it establishes a regulation for the Board to conduct periodic surveys, evaluations, and announced and unannounced site visits to existing and new DHEPs to ensure continued compliance with all laws, regulations, and standards applicable to a DHEP and define consequences, including probation with terms, issuance of a citation and fine, or withdrawn approval if the DHEP is found noncompliant.