RESPIRATORY CARE BOARD
OF CALIFORNIA

Public protection is our highest priority.

Agenda Item: 6
Meeting Date: 10/14/24

Item: Consideration and Possible Action to Adopt Title 16, California Code of Regulations Section (CCR[1] 1399.365, Basic Respiratory Tasks and Services, Including Review of Any Comments Received During the 45-Day Comment Period and Regulation Hearing, and Consideration of Potential Modifications to Proposed Text

Item Summary: Staff are presenting the original proposed regulatory language, comments received during the 45-day public comment period and at the August 7 hearing with recommended responses, and proposed modified text for the Board's consideration to 1) edit and/or approve the recommended responses to comments and the proposed modified text and 2) edit and/or approve the proposed modified text.

Board Action: President calls the agenda item and it is presented by or as directed by the President. **This item should be divided into two points of interest and motions as follows:**

TOPIC 1: 45-DAY PUBLIC COMMENT PERIOD/ORIGINAL LANGUAGE

President requests a motion regarding public comments received:

MOTION

- "Move to accept or reject the proposed comments and direct Board staff to provide the responses to the comments as indicated in attachment 2 of this agenda item."

- Any other appropriate motion.

SECOND THE MOTION
President may request if there is a second to the motion, if not already made.

BOARD MEMBER DISCUSSION/EDITS (if applicable)

CALL FOR PUBLIC COMMENT
Public comment should be specific to the motion and the original text published for public comment between June 21 and August 7, 2024.

VOTE
Repeat motion and vote: 1) aye, in favor, 2) no, not in favor, or 3) abstain

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1 Unless otherwise noted, all references to the CCR hereafter are to Title 16.

TOPIC 2: PROPOSED MODIFIED TEXT

President requests a motion regarding the proposed modified text.

MOTION

- "Move to direct Board staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes any amendments discussed at this meeting. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt Section 1399.365 of the proposed regulations with the modified text."

- Any other appropriate motion.

SECOND THE MOTION
President may request if there is a second to the motion, if not already made.

BOARD MEMBER DISCUSSION/EDITS (if applicable)

CALL FOR PUBLIC COMMENT
Public comment should be specific to the motion and the modified text presented today.

VOTE
Repeat motion and vote: 1) aye, in favor, 2) no, not in favor, or 3) abstain

Background

The Respiratory Care Board (RCB) enforces the Respiratory Care Practice Act at Business and Professions Code (B&P) sections 3700-3779 and oversees approximately 24,000 licensed respiratory care practitioners and respiratory care practitioner applicants.

In January 2022, the RCB submitted its Sunset Report to the Assembly Business and Professions Committee and the Senate Business, Professions, and Economic Development Committee. In the report the RCB detailed a chain of events that began in 1996 when the Board of Vocational Nursing and Psychiatric Technicians (BVNPT) drafted and disseminated to multiple healthcare agencies and education programs a "policy" that provided Licensed Vocational Nurses (LVNs) were permitted to adjust ventilator settings. Such a policy is contrary to the Vocational Nursing Practice Act, which authorizes LVNs to perform tasks that require technical, manual skills. (B&P §2859). From the RCB's experience, adjusting ventilator settings exceeds the technical and manual skills limited to LVNs and goes

beyond basic respiratory tasks; it is a higher functioning task associated with higher adverse risks. Adjusting ventilator settings includes setting the mode of ventilation, tidal volume, respiratory rate, oxygen concentration, and positive end-expiratory pressure. Adjustment of one setting can throw off other settings. It requires regular assessment including the synthesis of data, of the patient's lung function, blood gases and overall response to ensure optimal oxygenation and ventilation while minimizing risks such as lung injury or infection. Results of changing a ventilator can be instant and dire if not performed correctly.

Since 1996, there have been many incidents reported to the RCB, of LVNs performing respiratory care outside the scope of the Vocational Nursing Practice Act resulting in patient harm and even death. The RCB contends that, while LVNs are invaluable to health care teams, some facilities in California have allowed LVNs to practice respiratory care to the detriment of patients (and LVNs). Since 1996, the RCB continued to push back and tried to rectify many issues through multiple avenues, though the problems persisted. Thus, the RCB requested the Sunset Committees' guidance and assistance.

SB 1436 (Chapter 624, Statutes of 2022) was the Sunset Committees' response. SB 1436 was signed by the Governor in 2022 which allows the RCB to codify and name basic respiratory tasks in an effort to reduce the unlicensed or unauthorized practice of respiratory care. In that bill, it laid out a pathway for exemption for LVNs employed by home health agencies, licensed by the California Department of Public Health, to practice beyond basic respiratory tasks.

In October 2022, immediately after the bill was signed, the RCB approved proposed regulatory language identifying basic respiratory tasks. Staff gave public notice of the proposed regulations and in December 2022, numerous comments were received in opposition. While it remains the RCB's position that unauthorized persons practicing respiratory care beyond these basic tasks, even now, is illegal and has a myriad of liability issues, the perception to these facilities was that the regulations were the catalyst to making unauthorized practice illegal. For emphasis, it is currently illegal for unauthorized or unlicensed persons to practice respiratory care at any level. The proposed regulations actually permit some very basic respiratory tasks to be performed by unlicensed and unauthorized personnel.

Because the proposed regulations were perceived to restrict patient care, a quell of panic ensued among some patients and facilities. However misguided that was, the RCB agreed to stay within the spirit of the intent of SB 1436, and at its March 2023 meeting, moved to pursue legislative language that would provide additional exemptions for home and community-based settings. Following the March 2023 meeting, additional needed exemptions were identified, so the legislative language was not ready to progress.

At the RCB's June 2023 meeting, the RCB agreed to withdraw the proposed regulations identifying basic respiratory tasks allowing an opportunity to secure a legislative exemption on behalf of several home and community-based facilities.

At the RCB's October 2023 meeting, staff presented, and the RCB approved, a legislative proposal that stays within the spirit of SB 1436 by allowing LVNs a pathway to practice beyond basic respiratory tasks with patient-specific training at several home and community-based settings (6 beds or less). Staff secured an author, and SB 1451 was introduced in February 2024.

At its March 2024 meeting, the RCB was aware of its obligation to move forward with defining basic respiratory care tasks and services via regulation as required to implement SB 1436. This proposed rulemaking defines, by enumerating tasks, what is and is not meant by "basic respiratory tasks and services." There are no expectations that the status or outcome of SB 1451 will interfere with implementing these regulations as these regulations and SB 1451 are two separate and unrelated issues.

However, the introduction of SB 1451 showed a good faith effort above and beyond, to address fears of home and community-based facilities and patients and provide time for those parties to understand the difference between implementing regulations that define basic respiratory tasks and legislation that provides a pathway for LVNs to legally practice more advanced respiratory care with specific training requirements and in specific settings, which does not currently exist. (As of September 20, 2024, SB 1451 is enrolled and awaiting the Governor's signature. The last day to sign or veto a bill is September 30, 2024.)

Section 2860 of the Vocational Nursing Practice Act was amended in SB 1436 *(statutes of 2022)* to provide that no authority exists for LVNs to provide respiratory care services and treatment with the exception of what the RCB defines as "basic respiratory tasks and services that do not require a respiratory assessment and only require manual, technical skills, or data collection" (B&P §3702.5(a)). Both the proposed regulations and the pending legislation (SB 1451), provide authority for LVNs to practice aspects respiratory care - they are not restricting services that may be provided.

At its March 2024 meeting, the RCB approved the proposed regulatory text for CCR section 1399.365 as presented, and directed staff to initiate the rulemaking process and take all steps necessary to complete the rulemaking process if no adverse comments were received during the 45-day comment period or at the public hearing.

The original regulation text that was presented at the RCB's March 2024 meeting was published on June 21, 2024 with a closing written comment period of August 6, 2024 and a hearing held for comment on August 7, 2024. The RCB received comments from five (5) commenters during the 45-day comment period for consideration.

Based upon further reflection in developing clearer recommendations, RCB Staff prepared and is presenting Modified Text for the RCB's consideration. If approved, staff will publish the modified text and a new 15-day comment period on the modified text will be opened. With the motions noted on the first two pages of this document, the RCB could approve the responses to the comments and ask staff to move forward with publishing the modified text to continue with the regulatory process.

RCB Mandate

The RCB's mandate is to protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care (B&P §3701). Further, protection of the public shall be the highest priority for the Respiratory Care Board of California in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount (B&P §3710.1).

RCB Mission

To protect and serve consumers by licensing qualified respiratory care practitioners, enforcing the provisions of the Respiratory Care Practice Act, expanding the availability of respiratory care services, increasing public awareness of the profession, and supporting the development and education of respiratory care practitioners. (Strategic Plan 2023).

Legal References: Business and Professions Code

Vocational Nursing Practice Act

Section 2860

(a) This chapter confers **no authority** to practice medicine or surgery, **to provide respiratory care services and treatment,** or to undertake the prevention, treatment, or cure of disease, pain, injury, deformity, or mental or physical condition in violation of any provision of law.

(**b) Notwithstanding subdivision (a), a licensed vocational nurse who has received training and who demonstrates competency satisfactory to their employer may, when directed by a physician and surgeon, perform respiratory tasks and services expressly identified by the Respiratory Care Board of California pursuant to subdivision (a) of Section 3702.5.**

(Amended by Stats. 2022, Ch. 624, Sec. 1. (SB 1436) Effective January 1, 2023.)

Respiratory Care Practice Act

Section 3702.5

Except for the board, a state agency may not define or interpret the practice of respiratory care for those licensed pursuant to this chapter, or develop standardized procedures or protocols pursuant to this chapter, unless authorized by this chapter or specifically required by state or federal statute. The board may adopt regulations to further define, interpret, or identify all of the following:

(a) Basic respiratory tasks and services that do not require a respiratory assessment and only require manual, technical skills, or data collection.

(b) Intermediate respiratory tasks, services, and procedures that require formal respiratory education and training.

(c) Advanced respiratory tasks, services, and procedures that require supplemental education, training, or additional credentialing consistent with national standards, as applicable.

(Added by Stats. 2018, Ch. 180, Sec. 1. (SB 1003) Effective January 1, 2019.)

Attachments

1. Proposed Regulatory Language Title 16, CCR section 1399.365 Basic Respiratory Tasks and Services Published June 21, 2024.
2. Compilation of Comments Received During 45-Day Comment Period and Hearing Held August 7, 2024 with Staff's Recommended Responses for the RCB's consideration to approve.
3. Proposed Modified Text without double strikeout and underline.
4. Proposed Modified Text with double strikeout and underline for the RCB's consideration to approve.

California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 13.6. Respiratory Care Board
Article 6. Scope of Practice

PROPOSED LANGUAGE CONCERNING BASIC RESPIRATORY TASKS AND SERVICES

Legend—added text indicated by underline, deletion by ~~strikethrough~~.

Add section 1399.365 to read as follows:

1399.365 Basic Respiratory Tasks and Services

Pursuant to subdivision (a) of section 3702.5 of the Business and Professions code, basic respiratory tasks and services ("tasks"), described more specifically below, do not require a respiratory assessment, and only require manual, technical skills, or data collection. Basic respiratory tasks do not include manipulation of an invasive or non-invasive ventilator and do not include assessment or evaluation of chest auscultation. Basic respiratory tasks include:

(a) Data collection.

(b) Application and monitoring of the pulse oximeter.

(c) Medication administration by aerosol that does not require manipulation of an invasive or non-invasive mechanical ventilator. Basic respiratory tasks do not include pre-treatment assessment, use of medical gas mixtures other than oxygen, preoxygenation, endotracheal or nasal suctioning, or post-treatment assessment.

(d) Heat moisture exchanger (HME) and oxygen tank replacement for patients who are using non-invasive mechanical ventilation. Basic respiratory tasks do not include the initial setup, change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration.

(e) Hygiene care including replacement of tracheostomy ties and gauze and cleaning of the stoma sites. Basic respiratory tasks do not include tracheal suctioning, cuff inflation/deflation, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula.

(f) Use of a manual resuscitation device and other cardio-pulmonary resuscitation technical skills (basic life support level) in the event of an emergency.

(g) Documentation of care provided, which includes data retrieved from performing a breath count or transcribing data from an invasive or non-invasive ventilator interface.

NOTE: Authority cited: Sections 3702.5 and 3722, Business and Professions Code. Reference: Sections 2860, 3701, 3702, 3702.5, 3702.7, 3703, and 3765 Business and Professions Code.

Basic Respiratory Tasks and Services Regulations
Compilation of Comments Received During 45-Day Comment Period
and Hearing Held August 7, 2024

Objections or Recommendations/Responses

The Respiratory Care Board (RCB or Board) received 6 comments, objections, or recommendations on the proposed rulemaking, as discussed below.

COMMENTER A: NAOMI BUGAYONG
via: Hearing Held August 7, 2024

I am employed at UC Davis Health as an adult clinical educator as well I am the secretary for the CSRC which is the California Society for Respiratory Care. My opinions given are my personal opinions.

1) I really appreciate this proposal. I think that the enunciated 7 tasks within 1399.365 give the freedom for LVNs [licensed vocational nurses] to perform those seven tasks, I do appreciate that support, and I do appreciate the LVN community for their support for our patients and that the freedom of those seven tasks are ideal. And so, in my personal opinion, I do feel like the enunciated tasks within 1399.365 are appropriate.

Recommended Response: The RCB acknowledges this comment and appreciates the support, no text changes are deemed necessary in response to this comment.

2) Moving forward beyond that I would like to give my personal opinion that a return demonstrated competency would be ideal to protect patients and facilities and that I am dedicated to providing the resources for returned demonstrated competencies for colleagues who are LVNs providing patient care for California people that have families and lives and want to be well cared for and I think that's important- so I appreciate the Respiratory Care Board and I appreciate the LVN Community for always looking forward to keeping patients safe and I would love to begin the opportunity to participate in the future of these bills.

   Ms. Bugayong clarified that the comments that fall under this second comment are for future regulations unrelated to this regulatory package. She stated that the returned demonstrated competency should be for tasks beyond the seven tasks that are contained in this regulatory proposal, section 1399.365.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text because this comment is unrelated to this regulatory package as returned demonstrated competency is beyond the subject of basic respiratory tasks and services.

COMMENTER B: JULIE MCGILL
Long Beach City College
via: Email Dated June 30, 2024

I would like to notify the Respiratory Board of my concerns regarding the proposed statement regarding respiratory care. My concerns are several.

1) What would be the role of a student. It sounds to me like respiratory care would be a post-licensure skill. The students would not have the opportunity to perform the skill while in the direct observation of an instructor while during the VN [vocational nursing] program.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. Given the context of the entire comment, it is assumed that the student(s) in question are vocational nursing students. Senate Bill (SB) 1436 *(statutes of 2022)* amended the Vocational Nursing Practice Act at subdivision (a) of Business and Professions Code (B&P) section 2860 to state that the Vocational Nursing Practice Act provides “no authority” for LVNs to “provide respiratory care services and treatment” unless other conditions are satisfied.

Specifically, subdivision (b) of B&P section 2860, which is the subject of these regulations, states that LVNs who have received training and who demonstrate competency satisfactory to their employer may, when directed by a physician and surgeon, perform respiratory tasks and services expressly identified by the RCB pursuant to subdivision (a) of B&P section 3702.5. The specific tasks outlined in this proposed regulation package will be the only respiratory care tasks that LVNs may perform at any healthcare site, apart from other exemptions carried in SB 1451 *(statutes of 2024)*, which are pending and limited to specific home and community-based settings.

This regulatory proposal does not limit what is taught in an LVN classroom. However, pursuant to B&P sections 3741 and 3742, a student must be enrolled in an approved respiratory care training program to render respiratory care services during the period of any clinical training. Pursuant to B&P section 3742, the student shall be under the direct supervision of a licensed respiratory care practitioner (RCP). In order to practice an authorized basic respiratory task or service on a patient after becoming licensed as an LVN, the LVN must receive training and demonstrate competency satisfactory to their employer.

2) Also, I know that a lot of our LVN's become employed at Sub-acute facilities. This limitation may reduce employment options.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. The prompting of recent legislative and regulatory changes occurred because of the unlicensed and unauthorized practice of respiratory care occurring at some licensed facilities, including several subacute facilities, as detailed in the *RCB 2022 Sunset Oversight Review* report (item 2 of underlying data in the Initial Statement of Reasons (ISOR)), beginning at page 87. LVNs are not authorized to practice respiratory care at these sites beyond the tasks provided in this regulatory proposal if approved.

3) In addition, as facilities are already financially tight, they may just hire RN's [registered nurse] that can do the work of the RT [respiratory therapist] and LVN.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. These facilities are free to use an RN or an RCP to provide respiratory care services as it best meets the demand for their patients.

RNs have the appropriate educational and training foundation to acquire the respiratory skills necessary to perform respiratory care competently and safely. However, it should be noted that respiratory care is not a “skilled nursing service” and may not be counted toward the legally required patient-to-nurse ratio.

RTs or RCPs also have the statutory authority to provide “therapy, management, rehabilitation, diagnostic evaluation, and care for nonrespiratory-related diagnoses” as provided in subdivision (c) of B&P section 3701.

4) We are seeing that current RT, who thought this was already in process are not aware how to apply this to a teamwork approach with an LVN.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon because the comment is unclear. RCPs are educated and trained to work as a vital component of any disciplinary health care team for patients with respiratory ailments. RCPs are, however, subject to disciplinary action against their license for the aiding or abetting of any person to engage in the unlawful practice of respiratory care, pursuant to subdivision (i) of B&P section 3750.

COMMENTER C: **THERESA BECKER**
Interim Associate Dean of Nursing and Allied Health
Palo Verde College
via: E-Mail Dated August 1, 2024

1) I have a question that I hope you can answer. We have our Vocational Nursing students take a class in ventilator management. At the completion of this course, they are certified in ventilator management. They have competencies such as tracheostomy care and suctioning the instructor. Will this allow these students to provide those kinds of treatments to patients? I look forward to your response.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text because the comment appears to be an inquiry that provided no objection or recommendation. The RCB provided a written response to the inquiry on DATE as follows:

> Thank you for your inquiry. SB 1436 *(statutes of 2022)* amended the Vocational Nursing Act to codify that the Vocational Nursing Practice Act provided “no authority” for LVNs to “provide respiratory care services and treatment” with limited exceptions as identified through regulation.

Vocational Nursing Practice Act, Business and Professions Code

2860.

(a) This chapter confers no authority to practice medicine or surgery, to provide respiratory care services and treatment, or to undertake the prevention, treatment, or cure of disease, pain, injury, deformity, or mental or physical condition in violation of any provision of law.

(b) Notwithstanding subdivision (a), a licensed vocational nurse who has received training and who demonstrates competency satisfactory to their employer may, when directed by a physician and surgeon, perform respiratory tasks and services expressly identified by the Respiratory Care Board of California pursuant to subdivision (a) of Section 3702.5.

You note that LVN students are "certified" in ventilator management. "Certified" implies official recognition, possessing certain qualifications, or meeting certain standards. Given that the health care industry is highly regulated, implying a person is certified to perform a health care task also implies a legislative or regulatory process has been established to authorize such certification. Please be advised that no such government authority exists to permit anyone to "certify" a person to legally perform "ventilatory management." The only authority that exists to provide respiratory care resides within the Respiratory Care Practice Act (including exemptions for other health care personnel such as RNs or physicians to perform respiratory care).

You also mention the respiratory care tasks of tracheostomy care and suctioning the [LVN] instructor and ask if this will "allow these students to provide those kinds of treatments to patients." The proposed regulations for "Basic Respiratory Tasks and Services," to which the RCB believes are being referenced in this comment, if passed will allow LVNs to perform hygiene care including replacement of tracheostomy ties and gauze and cleaning of the stoma sites. However, it will not allow LVNs to perform tracheal suctioning, cuff inflation/deflation, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula because those tasks are not basic respiratory tasks and services.

This regulatory proposal does not limit what is taught in an LVN classroom. However, pursuant to sections 3741 and 3742 of the Business and Professions Code, a student must be enrolled in an approved respiratory care training program to render respiratory care services during the period of any clinical training. Pursuant to 3742, the student shall be under the direct supervision of a licensed RCP. Therefore, a student may not provide these respiratory services to patients. However, once the student obtains their LVN license, they can perform the hygiene care including replacement of tracheostomy ties and gauze and cleaning of the stoma sites upon demonstrated competency satisfactory to their employer and when directed by a physician and surgeon pursuant to subdivision (b) of Section 2860 of the Business and Professions Code and the Vocational Nursing Practice Act.

I trust this responds to your inquiry. If you have any further questions, please reach out to us at rcbinfo@dca.ca.gov.

COMMENTERS D: MARY ADORNO
Legislative Specialist
California Association for Health Services at Home (CAHSAH)

DEAN CHALIOS
President and CEO
California Association for Health Services at Home (CAHSAH)

Via: Email Dated August 5, 2024 with Letter Dated July 31, 2024 Attached

The California Association for Health Services at Home (CAHSAH) representing licensed, and Medicare certified home health agencies, hospices, and home care agencies appreciates the opportunity to comment on the proposed regulations for the scope of practice of licensed vocational nurses who provide respiratory care.

1) We are especially focused on ensuring continuity of care for patients who are ventilator-dependent and receive care from LVNs in the home and school setting.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. Effective January 1, 2023, SB 1436 *(statutes of 2022*, underlying data Item 1 in the ISOR*)* made it legal for patients in home care settings to receive respiratory care from LVNs employed by a home health agency licensed by the State Department of Public Health as follows:

Respiratory Care Practice Act, Business and Professions Code

3765.
This act does not prohibit any of the following activities:
…
(i) The performance, by a vocational nurse licensed by the Board of Vocational Nursing and Psychiatric Technicians of the State of California who is employed by a home health agency licensed by the State Department of Public Health, of respiratory tasks and services identified by the board, if the licensed vocational nurse complies with the following:

(1) Before January 1, 2025, the licensed vocational nurse has completed patient-specific training satisfactory to their employer.

(2) On or after January 1, 2025, the licensed vocational nurse has completed patient-specific training by the employer in accordance with guidelines that shall be promulgated by the board no later than January 1, 2025, in collaboration with the Board of Vocational Nursing and Psychiatric Technicians of the State of California.
…

SB 1451 (*statutes of 2024)* proposes to change the dates in subdivision (i) above from January 1, 2025 to January 1, 2028, to align with other changes needed with training due to the new exemptions sought for other home and community-based settings that are also carried in SB 1451. Subdivision (i)(1) allows LVNs who are employed by a licensed home health agency to continue to practice respiratory care if the LVN has completed patient-specific training to the satisfaction of the employer. While the RCB has not yet identified those “respiratory tasks and services,” at this time, the law leans in favor of giving home health agencies enough authority to continue performing the same tasks and services that most have done for years with patient-specific training. It is the RCB’s position that the RCB must specify those “respiratory tasks and

services" before it can pursue any form of disciplinary or administrative action against an LVN employed by a home health agency or an LVN employed by a home health agency, with the exception of cases where gross negligence, gross incompetence, or inadequate training, as determined by a reasonable person, causes patient harm or death. It is incumbent upon home health agencies to consult with their legal counsel to determine any liability issues.

As it pertains to LVNs who accompany patients to school, there is currently no legal authorization for an LVN to provide respiratory care if they are not employed by a home health agency. These proposed regulations will allow specific respiratory tasks to be performed if, and when, they become effective. In addition, SB 1451 *(statutes of 2024)* would also provide a legal exemption for LVNs to perform tasks beyond basic respiratory care tasks and services, who accompany patients to school, but it will not be in effect until 2028, if the legislation passes.

However, given the legislative and regulatory transition that is currently underway, the RCB has no plans to impose disciplinary measures or administrative sanctions contrary to the intended and final legislative and regulatory plan, with the exception of cases where gross negligence, gross incompetence, or inadequate training, as determined by a reasonable person, causes patient harm or death. It is incumbent upon LVNs and facilities to consult with their legal counsel to determine any liability issues. The RCB expects the legislative and regulatory transition to be complete by January 1, 2028.

2) We also want to ensure that LVNs are not unjustly forced to leave their current jobs.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. It is the RCB's position that LVNs have never been legally authorized to practice respiratory care, and which is what prompted the RCB to seek a legal remedy through the California Legislature to amend the Vocational Nursing Practice Act to codify existing law. As noted in the Recommended Response to Comment B-1, SB 1436 *(statutes of 2022)* amended the Vocational Nursing Practice Act at B&P 2860(a) to state that LVNs have "no authority" to "provide respiratory care services and treatment." Subdivision (b) was also added to B&P 2860, providing that an LVN who has received training and who demonstrates competency satisfactory to their employer may, when directed by a physician and surgeon, perform respiratory tasks and services expressly identified by the RCB pursuant to B&P section 3702.5(a). This regulatory proposal, if approved, would set forth those basic respiratory tasks and services LVNs can perform.

3) CAHSAH has been very active in several stakeholder meetings that were held by the Licensed Vocational Nursing and Psychiatric Technicians Board (BVNPT) and the Respiratory Care Board, (RTB) [sic] on the practice of LVNs performing respiratory care. During those stakeholder meetings many families of ventilator-dependent patients spoke out in support of continuity of care by the LVNs who are currently caring for their family members and urged the Respiratory Care Board to consider the detrimental impact that could occur if LVNs were not permitted to continue their scope of practice.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. These regulations would not be the catalyst to disrupting the continuity of care. These regulations actually provide a legal pathway for LVNs to provide basic respiratory care tasks and services.

As noted in the Recommended Response to Comment D-2, it is the RCB's position that LVNs have never been legally authorized to practice respiratory care, which is what prompted the RCB to seek a legal remedy through the California Legislature to amend the Vocational Nursing Practice Act to codify existing law. SB 1436 *(statutes of 2022)* amended the Vocational Nursing Practice Act at B&P 2860(a) to state that LVNs have "no authority" to "provide respiratory care services and treatment." This same bill, effective January 1, 2023, also gave home health agencies even greater leeway to allow LVNs employed by them to perform respiratory care beyond basic tasks provided patient-specific training is provided by the employer as described in the Recommended Response to Comment D-1.

4) As your Board prepares to address the tasks that fall within basic respiratory care performed by an LVN, we ask that you consider all the facts presented by the during the [sic] BVNPT during the state's legislative committee hearing that were conducted when SB 1436 was enacted.

Recommended Response: The RCB acknowledges this comment but declines to make any amendments to the proposed regulatory text because these regulations were drafted after careful consideration of all the comments and facts that were presented at numerous meetings and hearings, as well as those that resulted in the Joint Resolution (item 3 of underlying data in ISOR) established in 2019 (discussed in greater detail in the Recommended Response to Comment D-5).

5) First and foremost, the BVNPT issued guidance to licensees permitting LVNs to adjust ventilator settings. BVNPT cited CCR 2518.5 for the basis of allowing LVNs to manage ventilator patients. CCR 2518.5 specifies LVNs can use and practice basic assessment, participate in planning, execute interventions in accordance with the care plan or treatment plan, and contribute to evaluation of individualized interventions related to the care plan or treatment plan. An LVN may also administer medications.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. As detailed in the *RCB 2022 Sunset Oversight Review* report, at page 87, in 1996, the BVNPT drafted and disseminated to multiple healthcare agencies and education programs a "policy" that provided LVNs are permitted to adjust ventilator settings.

However, it is the position of the RCB that the guidance issued by the BVNPT allowing LVNs to adjust ventilator settings is an underground regulation carrying no legal authority because such a reading of California Code of Regulations (CCR[1]) Title 16, Section 2518.5 exceeds the scope of that regulation. Adjusting ventilator settings is a complex respiratory task. It includes setting the mode of ventilation, tidal volume, respiratory rate, oxygen concentration and positive end-expiratory pressure. Adjustment of one setting can throw off other settings. It requires regular assessment including the synthesis of data, of the patient's lung function, blood gases and overall response to ensure optimal oxygenation and ventilation while minimizing risks such as lung injury or infection. Results of changing a ventilator can be instant and dire if not performed correctly. The language of CCR Section 2518.5 provides in part, "The licensed vocational nurse performs services requiring *technical and manual skills*" (emphasis added). As noted in the ISOR at page 3, in the RCB's experience, ventilator manipulation requires a respiratory assessment that is informed by formal respiratory care education and training to ensure patient

[1] Unless otherwise noted, all references to the CCR hereafter are to Title 16.

health care is not compromised. Such a task exceeds the technical and manual skills limited to LVNs.

Further, the BVNPT's guidance that LVN's are permitted to adjust ventilator settings does not align with current statutory law. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act states that LVNs have no authority to "provide respiratory care services and treatment." Further, section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except the RCB may define or interpret the practice of respiratory care. Adjustment of ventilator settings falls within what constitutes the practice of respiratory care as set forth in B&P section 3702 because it is a direct pulmonary care service that requires assessment, including the synthesis of data and evaluation, and as such within the RCB's express authority to define and interpret.

6) The following are specific text edits for the Board's current proposed regulations [Comments D-6 to D-9]:

   1399.365 Basic Respiratory Tasks and Services Pursuant to subdivision (a) of section 3702.5 of the Business and Professions code, basic respiratory tasks and services ~~("tasks"), described more specifically below, do not require a respiratory assessment, and only require manual, technical skills, or data collection. Basic respiratory tasks do not include manipulation of an invasive or non-invasive ventilator and do not include assessment or evaluation of chest auscultation. Basic respiratory tasks~~ include:
   (a) Data collection.
   (b) Application and monitoring of the pulse oximeter.

Recommended Response: The RCB accepts in part and rejects in part this comment.

In light of this comment, generally, and upon further RCB staff review, the RCB proposes amending the text of CCR section 1399.365 to delete the term "task" as a shorthand for "basic respiratory tasks and services," and deleting the statutory language found in B&P section 3702.5(a), stating that basic respiratory tasks and services "only require manual, technical skills, or data collection." By removing this language, the RCB aims to increase readability and be more succinct.

The RCB rejects the comment regarding other text deletion to the preamble, although for the reasons discussed in the Recommended Response to Comment D-10, the RCB proposes rearranging the content found in the preamble to increase clarity and readability. As stated in the Initial Statement of Reasons (ISOR) at pages 3-4, the preamble makes it easier for a reader to understand the context of the following subdivisions. B&P section 3702.5 expressly authorizes the Board to adopt regulations further defining, interpreting, and identifying basic respiratory tasks. By including a reference to B&P section 3702.5(a), the proposed preamble directs readers to the statutory basis for clarifying what constitutes basic respiratory tasks. By including from the definition of basic respiratory tasks taken from B&P section 3702.5(a) that basic respiratory tasks "do not require a respiratory assessment" helps a reader understand not only what the definition is, but it shows the reader that the following subdivisions are examples of that definition.

The proposed regulatory text specifies that manipulation of an invasive or non-invasive ventilator is not a basic respiratory task. Basic respiratory tasks do not include manipulation of a ventilator in any form because, in the Board's experience, ventilator manipulation

requires a respiratory assessment that is informed by formal respiratory care education and training to ensure patient health care is not compromised, which is beyond the scope of basic respiratory tasks.

Further, assessment and evaluation of chest auscultation is not a basic respiratory task because, in the Board's experience and in the common practice of the field, it requires pulmonary and cardiopulmonary education and training specific to numerous respiratory conditions and contraindications to which requires a comprehensive analysis to achieve the best intended patient outcomes. Pursuant to B&P section 3740, to become licensed as an RCP, an applicant must complete an education program that is accredited by the nationally recognized Commission on Accreditation for Respiratory Care (CoARC).

There are both associate degree and baccalaureate degree programs in California. However, even the RCP associate degree programs take a minimum of three years to complete with full-time attendance and the programs are weighted heavily with courses specific to respiratory care. While other health care disciplines will include a high-level review of respiratory care in their education programs, respiratory care students delve into the intricacies of the practice that also requires advanced math and science.

Respiratory care is considered a health care specialty that takes thousands of hours of education to be prepared to pass the national competency exam and begin practicing at the minimum competency level.

7) (c) Medication administration by aerosol, ~~that does not require manipulation of an invasive or non-invasive mechanical ventilator. Basic respiratory tasks do not include~~ pre-treatment assessment, use of medical gas mixtures ~~other than oxygen~~, preoxygenation, *oral suctioning*, endotracheal or nasal suctioning, or post-treatment assessment *when there is a specific written medical order by an authorized practitioner.*

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. As stated in the ISOR at page 5, adoption of this regulatory language maximizes resources of the health care teams to perform duties at their skill levels without interruption to health care delivery or reducing the quality of care delivered. It is necessary to enumerate regulatory standards about the administration of medication via aerosol because, in the Board's experience and in the common practice of the field, the actual task of delivering aerosol medication to a patient that does not require ventilator manipulation consists of waving aerosol medication around the patient's mouth and nose area and takes an average of 20 minutes to give. As such, this task is one that, in the language of B&P section 3702.5(a), only requires manual skills to accomplish and does not require formal education. This frees physicians, RNs, and RCPs to perform intermediate and advance level of respiratory care for all patients, maximizing resources.

Following from this, it is appropriate to exclude administration requiring the manipulation of an invasive or non-invasive mechanical ventilator because there are many more possible adverse outcomes that require advanced skills to mediate problems; thus, ensuring patients are receiving expected quality of care. There are a host of considerations when delivering medication via aerosol to a ventilator patient such as blockages in the ventilator circuit, ventilator settings, endotracheal tube size, heat and moisture exchange, gas density, obstruction in major airways, aerosol particle size, and delivery methods, to name just a few. With each delivery of an aerosol medication, the ventilator patient is at greater risk for possible

adverse outcomes, thereby making it necessary to have the most qualified health care provider delivering the medication.

Further, excluded from this category of basic respiratory tasks are pre-treatment assessments, the use of medical gas mixtures other than oxygen, preoxygenation, endotracheal or nasal suctioning, and post-treatment assessment. These tasks have been excluded because they are often performed when providing medication by aerosol, especially for patients on ventilators. These tasks require assessment, evaluation, or both based on complete respiratory education and training and the Board believes it is important to make the distinction to ensure patient health care is not compromised.

8) (d) Heat moisture exchanger (HME) and oxygen tank replacement, ~~for patients who are using non-invasive mechanical ventilation. Basic respiratory tasks do not include the initial setup,~~ change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration *when there is a specific written medical order by an authorized practitioner*.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. As stated in the ISOR at page 6, it is necessary to specify that HME and oxygen tank replacement are basic respiratory tasks because, in the Board's experience and in the common practice of the field, these tasks are not invasive–that is they do not involve a puncture or incision of the skin, insertion of an instrument or foreign material into the body, and do not require extensive education and training. However, it is necessary to specify that these tasks are only basic respiratory tasks if they relate to patients who are using non-invasive mechanical ventilation because there are many more common contraindications with patients using invasive mechanical ventilation that requires advanced skills to mediate adverse reactions, thereby ensuring patients are receiving expected quality of care.

Further, it is necessary to specify that related tasks that are not basic respiratory tasks include "the initial setup, change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration" because these tasks require assessment, evaluation, or both based on complete respiratory education and training, and making the distinction helps ensure patient health care is not compromised.

9) (e) Hygiene care including replacement of tracheostomy ties and gauze and cleaning of the stoma sites, ~~Basic respiratory tasks do not include~~ tracheal suctioning, cuff inflation/deflation, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula.

   (f) Use of a manual resuscitation device and other cardio-pulmonary resuscitation technical skills (basic life support level) in the event of an emergency.

   (g) Documentation of care provided, which includes data retrieved from performing a breath count or transcribing data from an invasive or non-invasive ventilator interface.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. As stated in the ISOR at page 6, the rationale for specifying hygiene care that includes replacement of tracheostomy tie and gauze, and the cleaning of stoma sites are basic respiratory tasks because, in the Board's

experience and in the common practice of the field, these tasks are not invasive and do not require in-depth respiratory education or training. On the other hand, tracheal suctioning, cuff inflation/deflation, the use or removal of an external speaking valve or removal and replacement of the tracheostomy tube or inner cannula are not basic respiratory tasks because these tasks may require assessment, evaluation, or both based on complete respiratory education and training. Further, there are numerous contraindications that can occur requiring extensive respiratory care education and training to properly mediate adverse reactions. Each licensed RCP must pass both written and clinical simulation exams that both test the competency in all these tasks. Making the distinction helps ensure patient health care is not compromised.

10) All the above recommended text edits made to the proposed regulations remove wording that states “does not include.” The regulations should focus on outlining what is allowed not what is not allowable. This will ensure the reader is not confused because they missed reading the word “not.”

Recommended Response: The RCB rejects in part and accepts in part this comment.

The RCB rejects this comment with respect to removing from the proposed regulatory text the words “does not include” or what is not allowed as a basic respiratory care task or service. The RCB finds it imperative to identify the tasks associated with respiratory services that are not considered manual and technical tasks so that there is no confusion. As stated in the ISOR at page 2 to 3, the Board’s highest priority is protection of the public in exercising its licensing, regulatory, and disciplinary functions. The Board is mandated to protect the public from the unauthorized and unqualified practice of respiratory care and from unprofessional conduct by persons licensed to practice respiratory care. To continue performing these functions in support of its mandate, the Board must ensure only qualified personnel are providing respiratory care beyond tasks and services that only require manual, technical skills, or data collection. In addition, all stakeholders (i.e., health care practitioners, facilities, employers, and patients) benefit by having a clear and precise understanding of which respiratory tasks and services may be performed by LVNs clarity will overall enhance the timely delivery of health care monitoring and attention by maximizing resources of the health care teams to perform duties and functions at their skill levels without interruption to health care delivery or planning or reducing the quality of care delivered.

In light of this comment, generally, and upon further RCB staff review, the RCB proposes amending the text of CCR section 1399.365 by reorganizing the content of the preamble into two separate subdivisions. One subdivision sets forth what is included as basic respiratory tasks and services followed by a list of such tasks, and one subdivision sets forth what is not included as basic respiratory tasks and services followed by a list of such tasks. By reframing the subdivisions, the RCB aims to promote further clarity and readability.

11) We are recommending the inclusion of several tasks that were not presented as allowable basic respiratory tasks; hence, you will see the removal of the word “not allowed.” These changes were made to align with the current scope of practice that the BVNPT issued guidance upon to its licensees. The Respiratory Care Board must ensure that it does not alter the continued scope of practice which an LVN learns to perform during their basic pre-licensure training, both in the classroom setting and in clinical rotations.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. These regulations were drafted

after careful consideration of public input and after several meetings between the BVNPT and the RCB. It is the position of the RCB that the guidance issued by the BVNPT does not align with current law, including subdivision (a) of section 2860 of the Vocational Nursing Practice Act, which states that LVNs have no authority to “provide respiratory care services and treatment.” Further, section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except the RCB may define or interpret the practice of respiratory care.

These regulations do not alter the education or classroom training of LVNs. Rather, these regulations interpret and clarify subdivision (a) of Section 3702.5 of the Respiratory Care Practice Act as referenced in subdivision (b) of Section 2860 of the Vocational Nursing Practice Act by identifying the basic respiratory care tasks and services that LVNs are legally authorized to perform.

12) Respiratory assessment is a technical skill to assist with data collection. Specifically, chest auscultation, endotracheal or nasal suctioning, removal and replacement of inner cannula, and removal of external speaking valves are all within the LVN scope of practice and part of the basic respiratory assessment performed by LVNs. Patient assessment is essential to ensuring that the patient’s conditions are not changing or worsening. Assessment does not entail an LVN changing the directed treatment without consultation and direction from the physician or RN supervising the LVN. It does entail basic tasks like suctioning to keep a patient safe and comfortable.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. Subdivision (a) of B&P section 2860 provides that the Vocational Nursing Practice Act provides “no authority” for LVNs to “provide respiratory care services and treatment…” Evaluation or assessment of chest auscultation, endotracheal or nasal suctioning, removal and replacement of inner cannula and removal of external speaking valves are all the practice of respiratory care. Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except the RCB may define or interpret the practice of respiratory care.

However, to increase clarity, the RCB proposes to amend the text of CCR section 1399.365 to include a definition of “assessment,” as detailed in the Recommended Response to Comment F-1.

13) California Business and Professions Code Section 2859 specifies “The practice of vocational nursing within the meaning of this chapter is the performance of services requiring those technical, manual skills acquired by means of a course in an approved school of vocational nursing, or its equivalent, practiced under the direction of a licensed physician and surgeon, or registered nurse, as defined in Section 2725.”

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. It appears the commenter is inferring that if an LVN school teaches a skill, that skill is within the LVN scope of practice. On the contrary, the RCB contends the LVN scope of practice is not solely set by B&P section 2859, and when LVN education programs teach skills that are inconsistent with the law, the law prevails, and the curriculum of the school should be reconsidered.

As noted previously, subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to “provide respiratory care services and treatment.” B&P

section 2860(a) also provides that LVNs have no authority to practice medicine or surgery. Within a physician's and surgeon's practice there are many tasks that may appear as "manual, technical tasks" without the proper education and training of a physician or surgeon. For example, if an LVN school taught students how to perform a minor surgery, perhaps the removal of a small lipoma, doing so would not make minor surgeries part of the LVN scope of practice. Removal of a lipoma is done by 1) washing the area, 2) injecting a local anesthetic, 3) making a small cut in the skin, 4) removing the lipoma, and 5) placing one or two stitches. Those without a medical background could learn how to do this and some may categorize this as manual, technical tasks. However, a lay person risks an improper diagnosis as well as damage to surrounding structures (e.g. nerves, muscles, blood vessels). The same is true for the practice of respiratory care. This is what prompted the California Legislature to establish in law Section 3702.5 of the Respiratory Care Practice Act, which expressly authorizes the RCB, and no other state agency, to define or interpret the practice of respiratory care. Because the Board currently has no existing regulations further defining, interpreting, or identifying "basic respiratory tasks and services," the Board proposes this rulemaking to implement SB 1436 in part by identifying, through enumerating tasks, what is and is not meant by "basic respiratory tasks and services."

14) Furthermore, as indicated by the BVNPT "The licensed vocational nurse performs services requiring technical and manual skills which include the following: (a) Uses and practices basic assessment (data collection), participates in planning, executes interventions in accordance with the care plan or treatment plan, and contributes to evaluation of individualized interventions related to the care plan or treatment plan. (b) Provides direct patient/client care by which the licensee: (1) Performs basic nursing services as defined in subdivision (a); (2) Administers medications; (3) Applies communication skills for the purpose of patient/client care and education; and (4) Contributes to the development and implementation of a teaching plan related to self-care for the patient/client."

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. The commenter appears to be citing to CCR Section 2518.5: Scope of Vocational Nursing Practice.

CCR Section 2518.5 defining the scope of the vocational nursing practice is not the subject of these regulations. This regulatory action proposes to interpret and make specific subdivision (a) of Section 3702.5 of the Respiratory Care Practice Act. As stated in the ISOR on page 2, this regulatory proposal benefits the health and welfare of California residents by further defining, interpreting, and identifying basic respiratory tasks and services that may be safely performed by LVNs or other properly trained health care personnel consistent with the underlying statutory requirements. This will help ensure the most up-to-date standards and practices are met and will help protect patients in need of respiratory care.

15) The BVNPT has indicated that "endotracheal or nasal suctioning is a manual, technical skill, and part of the LVN prelicensure training, and practiced in the LVN clinical rotation. The proposed text lists pre-treatment assessment and post treatment assessment but does not clarify the specific treatment this is in reference to. Basic respiratory assessment is a manual, technical skill and part of the LVN prelicensure training, and practiced in the LVN clinical rotation."

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. The guidance issued by the

BVNPT does not align with existing law. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act states that LVNs have no authority to “provide respiratory care services and treatment.” Further, section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care. Pre- and post-treatments assessments require synthesis of data or evaluation, far beyond data collection, and are therefore not considered a basic respiratory care task or service. Endotracheal and nasal suctioning when improperly done can lead to bleeding disorders, severe bronchospasm, laryngeal stridor, severe hemodynamic instability, hemoptysis, severe coagulopathies. Even when properly performed complications may arise including blood pressure instability, mucosal trauma, or hypoxemia. It is imperative that the care provider have a wholly rounded education to provide a real-time assessment and synthesis of data while performing the task as well as have the education and training to immediately respond to complications that may arise. Each licensed RCP must pass both written and clinical simulation exams that test the competency in all these tasks. Making the distinction helps ensure patient health care is not compromised.

16) Because the BVNPT has indicated that it is within an LVN’s scope to perform respiratory assessment, we believe an LVN with the appropriate training and education can perform the following interventions: replacement of HME and oxygen tank as well as setup, change out and replace breathing circuits. These tasks fall within manual/technical skills.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to “provide respiratory care services and treatment.” Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care. Heat moisture exchanger (HME) and oxygen tank replacement for patients who are using non-invasive mechanical ventilation are considered basic respiratory tasks. As noted in the ISOR at page 6, the initial setup, change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration are respiratory tasks and services that require assessment, evaluation, or both based on complete respiratory education and training, and, thus, are not considered basic respiratory tasks or services.

17) Additionally, an LVN should be able to adjust oxygen liter flow, or oxygen concentration on ventilated and non-ventilated patient when there is a specific MD order. These tasks are essential interventions that have been provided by LVNs for many years to thousands of ventilator-dependent patients under the Medi-Cal program.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to “provide respiratory care services and treatment.” Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care. Adjusting ventilator settings is a respiratory task that requires assessment, including the synthesis of data and evaluation. The RCB thanks the commenter for bringing to the RCB’s attention that Medi-Cal may be reimbursing LVNs improperly. Upon implementation, the RCB will reach out to the Department of Health Care Services to ensure reimbursement is being made in accordance with established laws and regulations.

18) The BVNPT has indicated that removal, cleaning, and replacement of an inner cannula, tracheal suctioning and removal of an external speaking valve is within an LVNs scope of practice. Considering that determination by the BVNPT, we also believe that cuff/inflation and deflation should be included as well.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. The guidance issued by the BVNPT does not align with existing law. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to “provide respiratory care services and treatment.” Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care. Removal and replacement of an inner cannula, tracheal suctioning, removal of an external speaking valve and cuff inflation/deflation are respiratory tasks and services that require assessment, including the synthesis of data and evaluation, and, thus, are not considered basic respiratory tasks or services. Further, there are numerous contraindications that can occur requiring extensive respiratory care education and training to properly mediate adverse reactions. Each licensed RCP must pass both written and clinical simulation exams that both test the competency in all these tasks. Making the distinction helps ensure patient health care is not compromised.

19) Lastly, we would like to ensure the board understands and considers the fiscal impact of these proposed regulations. Costs will be incurred to recruit staff, change policies and procedures, and orient staff on any new necessary protocols to ensure compliance. Those costs can vary for the small employer to the large employer. If LVNs are displaced from their current roles, the resulting impact will be catastrophic costs to the State and to families as many of these individuals will be forced into institutional care because there are not enough LVNs or Respiratory Care Therapists.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to “provide respiratory care services and treatment.” Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care.

These regulations do not remove authority for LVNs to practice respiratory care. These regulations clarify those basic respiratory care tasks and services LVNs can legally perform.

Moreover, effective January 1, 2023, SB 1436 *(statutes of 2022)* made it legal for patients in home care settings to receive respiratory care from LVNs employed by a home health agency licensed by the State Department of Public Health (B&P section 3765).

It is the RCB’s position that the RCB must specify those “respiratory tasks and services” referred to in B&P section 3765(i) before it can pursue any form of disciplinary or administrative action against an LVN employed by a home health agency or an LVN employed by a home health agency, with the exception of cases where gross negligence, gross incompetence, or inadequate training, as determined by a reasonable person causes patient harm or death. While it is incumbent upon each home health agency to discuss liability issues with their legal counsel, legislative authority exists for LVNs employed by a home health agency to continue to practice respiratory care with appropriate patient-specific training.

COMMENTER E: ELAINE YAMAGUCHI
Executive Officer
Board of Vocational Nursing and Psychiatric Technicians
via: E-Mail Dated August 5, 2024 with Two Letters Attached Dated August 2, 2024 and December 13, 2022

Letter Dated August 2, 2024

1) The Board of Vocational Nursing and Psychiatric Technicians (BVNPT) submits the attached comment that incorporates a letter including attachments. Since the text that has been noticed is the same as previously noticed in 2022, the BVNPT hereby resubmits the same document filed in December 2022, and raises the same points of concern.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. The text of this proposed regulation is not identical to text that was publicly noticed in 2022.

2) BVNPT wants to express our appreciation for the opportunity to address concerns raised in establishing standards regarding these important services and hope that this Board appreciates the BVNPT's commitment to achieving an outcome which best serves the public. Consistent with the Board's previous position on this issue, I wanted to reiterate an important concern. The Licensed Vocational Nurse (LVN) scope of practice has always been the same in any setting and consistent with the pre-licensure training and scope of practice recognized by this Board pursuant to Business and Professions Code section 2859. All licensees currently have the same opportunity for training and Continuing Education courses acknowledged by the BVNPT. We absolutely support the need for consistent, expert training in this vital patient care area, but we are against specifying standards that are inconsistent with the training received at BVNPT approved schools.

Recommended Response: The RCB acknowledges the supporting comments and appreciates the support in achieving an outcome that best serves the public. The RCB reviewed and rejects the opposing comments and declines to make any amendments to the proposed regulatory text based thereon. These regulations enumerate specific basic respiratory tasks and services LVNs are permitted to practice in any location. Moreover, any legislation such as SB 1451 (*statutes of 2024*) that specifies a specific type of facility where LVNs may practice respiratory care beyond basic respiratory tasks and services, overrides the BVNPT's position or policy as a legal matter.

COMMENTER F: ELAINE YAMAGUCHI
Executive Officer
Board of Vocational Nursing and Psychiatric Technicians

Letter Dated December 13, 2022

The Board of Vocational Nursing and Psychiatric Technicians (BVNPT) met on Friday, December 9, 2022, to discuss the Respiratory Care Board's (RCB's) proposed regulatory action concerning Basic Respiratory Tasks and Services. The BVNPT voted unanimously to file an official comment recommending amendments to the RCB's proposed Title 16 Division 13.6, Article 6, Section 1399.365 that reflect the current Licensed Vocational Nurses' (LVN) prelicensure training and scope of practice. Specifically, the BVNPT respectfully requests the following amendments, which are highlighted in yellow. Suggested added text is indicated by double underline. Deleted text by ~~double strikethrough~~.

1) **Amendment 1**

1399.365 Basic Respiratory Tasks and Services

Pursuant to subdivision (a) of section 3702.5 of the B&P, basic respiratory tasks and services ("basic respiratory tasks") ~~do not require a respiratory assessment, and only~~ require manual, technical skills, or data collection. Basic respiratory tasks do not include manipulation of an invasive or non-invasive ventilator. Basic respiratory tasks include:

Rationale for suggested change: Basic respiratory assessment is within the scope of the licensed vocational nurse (LVN). The LVN learns how to perform this task during the fundamentals section of their LVN prelicensure program and it is performed throughout the remainder of the program when assessing assigned patients. Basic respiratory assessment is a technical skill to assist with data collection. The term "data collection" is commonly used when assessing a patient, collecting data from any type of assessment or from patient verbally. The term is also within BVNPT's existing regulations:

2518.5. Scope of Vocational Nursing Practice.
The licensed vocational nurse performs services requiring technical and manual skills which include the following:
(a) Uses and practices basic assessment (data collection), participates in planning, executes interventions in accordance with the care plan or treatment plan, and contributes to evaluation of individualized interventions related to the care plan or treatment plan.
(b) Provides direct patient/client care by which the licensee:
(1) Performs basic nursing services as defined in subdivision (a);
(2) Administers medications;
(3) Applies communication skills for the purpose of patient/client care and education; and
(4) Contributes to the development and implementation of a teaching plan related to self-care for the patient/client.

Recommended Response: The RCB accepts this comment. The RCB modified the proposed regulatory text to define assessment as used in this proposed regulatory action to clearly delineate that assessment goes beyond gathering data, specifically as follows:

"For purposes of this section, 'assessment' is defined as making an analysis or judgment and making recommendations concerning the management, diagnosis, treatment or care of a patient or as a means to perform any task in regard to the care of a patient. Assessment as used in this section is beyond documenting observations, and gathering and reporting data to a licensed RCP, RN, or physician."

2) Amendment 2

(a) Basic respiratory assessment and data collection ~~Basic respiratory tasks do not include assessment and/or evaluation of chest auscultation~~.

Rationale for suggested change: Chest auscultation is within the LVN scope of practice and is part of the basic respiratory assessment. This is a part of their LVN prelicensure training and practiced in the LVN clinical rotations.

Frequency. Is the sound high or low pitched?
Intensity. How loud is the sound?
Duration. How long does the sound last?
Number. Is the sound repeated?
Quality. How would you describe the sound?
Auscultation is a valuable diagnostic tool because it is safe and noninvasive. It can also be done at a moment's notice, since most healthcare providers have their stethoscopes close at hand.

Recommended Response: The RCB accepts in part and rejects in part this comment.

The RCB accepts this comment with respect to acknowledging that some tasks involving chest auscultation are basic respiratory tasks and services, including reporting on or gathering data from chest auscultation. To increase clarity of which tasks related to chest auscultation are and are not basic respiratory tasks, the RCB proposes amending the regulatory text to include in the list of basic respiratory task and service, "Observe and gather data from chest auscultation, palpation and percussion." Further, the RCB proposes amending the regulatory text to include in the list of what is not basic respiratory task and service, "Assessment or evaluation of observation and gathered data from chest auscultation, palpation and percussion."

The RCB rejects this comment to the extent it suggests that tasks and services involving chest auscultation beyond observing, reporting on, or gathering data fall within basic respiratory tasks. In December 2006, the BVNPT president responded and provided that LVNs "should most certainly have the ability to decide, for example, whether or not to listen to breath sounds in a patient previously diagnosed with pneumonia and then report it to the R.N. or physician directing the LVN." As detailed in the *RCB 2022 Sunset Oversight Review* report, beginning at page 88, in response to this specific claim, the RCB sought a legal opinion from its liaison at the Office of the Attorney General. Mara Faust, DAG, who provided the following:

> "'Basic assessment or data collection' does not anticipate the independent assessment of breath sounds and is therefore outside [the] scope of practice of an LVN. Clearly respiratory care therapist[s] can interpret breath sounds in the scope of their practice under Business and

> Professions Code section 3702....” “While a respiratory care therapist and a physician can assess a patient’s respiratory status and alter the ventilator setting, in my opinion, an LVN who does so acts outside their scope of practice.”

As stated in the ISOR at pages 3-4, and discussed in the Recommended Response to Comment D-6, assessment or evaluation of chest auscultation is not a basic respiratory task because, in the Board’s experience and in the common practice of the field, it requires pulmonary and cardiopulmonary education and training specific to numerous respiratory conditions and contraindications to which requires a comprehensive analysis to achieve the best intended patient outcomes. Pursuant to B&P section 3740 to become licensed as an RCP, an applicant must complete an education program that is accredited by the nationally recognized CoARC. There are both associate degree and baccalaureate degree programs in California. However, even the RCP associate degree programs take a minimum of three years to complete with full-time attendance and the programs are weighted heavily with courses specific to respiratory care. While other health care disciplines will include a high-level review of respiratory care in their education programs, respiratory care students delve into the intricacies of the practice that also requires advanced math and science. Respiratory care is considered a health care specialty that takes thousands of hours of education to be prepared to pass the national competency exam and begin practicing at the minimum competency level.

Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to “provide respiratory care services and treatment.” Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care.

3) Amendment 3

> (c) Medication administration by aerosol that does not require manipulation of an invasive or non-invasive mechanical ventilator. Basic respiratory tasks do not include pre-treatment assessment, use of medical gas mixtures other than oxygen, preoxygenation, ~~endotracheal or nasal suctioning~~,or post-treatment assessment.
>
> Rationale for suggested change: Endotracheal or nasal suctioning is a manual, technical skill and part of the LVN prelicensure training, and practiced in the LVN clinical rotation.
>
> The proposed text lists pre-treatment assessment and post treatment assessment but does not clarify the specific treatment this is in reference to. Basic respiratory assessment is a manual, technical skill and part of the LVN prelicensure training, and practiced in the LVN clinical rotation. Staff should work with RCB to develop a mutually acceptable definition of pre and post treatment assessment. These definitions may need to list specific treatments

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. The guidance issued by the BVNPT does not align with existing law. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act states that LVNs have no authority to “provide respiratory care services and treatment.” Further, section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care. Pre- and post-treatments assessments require synthesis of data or evaluation, far beyond data collection, and are therefore not considered a basic respiratory care task or service. Endotracheal and nasal suctioning when improperly done can lead to bleeding disorders,

severe bronchospasm, laryngeal stridor, severe hemodynamic instability, hemoptysis, severe coagulopathies. Even when properly performed, complications may arise including blood pressure instability, mucosal trauma or hypoxemia. It is imperative that the care provider have a wholly rounded education to provide a real-time assessment and synthesis of data while performing the task as well as have the education and training to immediately respond to complications that may arise. Each licensed RCP must pass both written and clinical simulation exams that test the competency in all these tasks. Making the distinction helps ensure patient health care is not compromised.

4) Amendment 4

> (d) Heat moisture exchanger (HME) and oxygen tank replacement for patients who are using non-invasive mechanical ventilation. Basic respiratory tasks do not include the initial setup, change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration on ventilated patients.
>
> Rationale for suggested change: "On ventilated patients" was added to clarify the task of oxygen therapy and to make it clear this statement is only referring to mechanical ventilation.

Recommended Response: The RCB rejects this comment. However, to increase clarity, the RCB proposes amending the regulatory text to state that initial setup, change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration are not basic respiratory tasks. These tasks require assessment, evaluation, or both based on complete respiratory education and training. Making the distinction helps ensure patient health care is not compromised.

5) Amendment 5

> (e) Hygiene care, including replacement of tracheostomy ties and gauze, removal, cleaning, and replacement of inner cannula, ~~and~~ cleaning of the stoma sites, tracheal suctioning, and removal of an external speaking valves. Basic respiratory tasks do not include ~~tracheal suctioning~~, cuff inflation/deflation~~, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula.~~
>
> Rationale for suggested change: Removal and replacement of inner cannula is a manual, technical skill and part of the LVN prelicensure training, and practiced in the LVN clinical rotation.

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon. As noted in the ISOR at page 6, in the Board's experience and in the common practice of the field, tracheal suctioning, cuff inflation/deflation, the use or removal of an external, speaking valve or removal and replacement of the tracheostomy tube or inner cannula are not basic respiratory tasks because these tasks may require assessment, evaluation, or both based on complete respiratory education and training. Further, there are numerous contraindications that can occur requiring extensive respiratory care education and training to properly mediate adverse reactions. Each licensed RCP must pass both written and clinical simulation exams that both test the competency in all these tasks. Making the distinction helps ensure patient health care is not compromised.

Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to "provide respiratory care services and treatment." Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care.

6) Amendment 6

> g) Documentation of care provided, which includes documentation of data retrieved from performing a breath count~~.~~, chest auscultation, or transcribing data from an invasive or non-invasive ventilator interface.
>
> Rationale for suggested change: Chest auscultation is a manual, technical skill and part of the LVN prelicensure training, and practiced in the LVN clinical rotation.

Recommended Response: The RCB accepts this comment. The RCB modified the proposed regulatory text to include "Observe and gather data from chest auscultation, palpation and percussion" as basic respiratory care tasks and services, which is also discussed in Recommended Response to Comment F-2.

7) These six amendments will bring the RCB's proposed regulations into conformity with the Vocational Nursing Practice Act and enable our licensees to continue providing essential patient care. Coupled with other provisions in SB 1436 *(Roth, Chapter 624 of the Statutes of 2022)*, these suggested amendments will allow both Boards to regulate and enforce safe and trained nursing care. [Attachments include: 1) *Memo from the Board of Vocational Nursing and Psychiatric Technicians (BVNPT) office to BVNPT members, December 9. 2022*; and 2) BVNPT Suggested Amendments to RCB Proposed Text.]

Recommended Response: The RCB rejects this comment and declines to make any amendments to the proposed regulatory text based thereon, except with respect to Comments F-1, F-2, F-4, and F-6. Since 1996, the RCB has contended that LVNs have never been legally authorized to practice respiratory care beyond manual, technical tasks. The misinterpretation and misinformation is what prompted the RCB to seek a legal remedy through the California Legislature to amend the Vocational Nursing Practice Act to codify existing law. SB 1436 *(statutes of 2022)* amended the Vocational Nursing Practice Act to state that LVNs have "no authority" to "provide respiratory care services and treatment:"

These regulations were drafted after careful consideration of public input and after several meetings between the BVNPT and the RCB. The guidance issued by the BVNPT permitting LVNs to adjust ventilator settings does not align with existing law. Subdivision (a) of section 2860 of the Vocational Nursing Practice Act provides that LVNs have no authority to "provide respiratory care services and treatment." Section 3702.5 of the Respiratory Care Practice Act provides that no other state agency except for the RCB may define or interpret the practice of respiratory care.

These regulations do not prohibit LVNs from practicing respiratory care. These regulations clarify those basic respiratory care tasks and services LVNs can legally perform. These regulations interpret and make specific subdivision (a) of Section 3702.5 of the Respiratory Care Practice Act as referenced in subdivision (b) of Section 2860 of the Vocational Nursing Practice Act.

NOT AN OFFICIAL PART OF THE RULEMAKING PACKAGE
SUGGESTED PROPOSED MODIFIED TEXT WITHOUT DOUBLE UNDERLINE AND STRIKEOUT

1399.365. Basic Respiratory Tasks and Services.

(a) For purposes of this section, “assessment” means making an analysis or judgment and making recommendations concerning the management, diagnosis, treatment, or care of a patient or as a means to perform any task in regard to the care of a patient. Assessment as used in this section is beyond documenting observations, and gathering and reporting data to a licensed respiratory care practitioner, registered nurse, or physician.

(b) For purposes of subdivision (a) of section 3702.5 of the B&P, basic respiratory tasks and services do not require a respiratory assessment and include the following:

(1) Patient data collection.
(2) Application and monitoring of a pulse oximeter.
(3) Medication administration by aerosol that does not require manipulation of an invasive or non-invasive mechanical ventilator.
(4) Heat moisture exchanger (HME) and oxygen tank replacement for patients who are using non-invasive mechanical ventilation.
(5) Hygiene care including replacement of tracheostomy ties and gauze and cleaning of the stoma sites.
(6) Use of a manual resuscitation device and other cardio-pulmonary resuscitation technical skills (basic life support level) in the event of an emergency.
(7) Documentation of care provided, which includes data retrieved from performing a breath count or transcribing data from an invasive or non-invasive ventilator interface.
(8) Observing and gathering data from chest auscultation, palpation, and percussion.

(c) For purposes of subdivision (a) of section 3702.5 of the B&P, basic respiratory tasks and services do not include the following:

(1) Manipulation of an invasive or non-invasive ventilator.
(2) Assessment or evaluation of observed and gathered data from chest auscultation, palpation, and percussion.
(3) Pre-treatment or post-treatment assessment.
(4) Use of medical gas mixtures other than oxygen.
(5) Preoxygenation, or endotracheal or nasal suctioning.
(6) Initial setup, change out, or replacement of a breathing circuit or adjustment of oxygen liter flow or oxygen concentration.
(7) Tracheal suctioning, cuff inflation/deflation, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula.

NOTE: Authority cited: Sections 3702.5 and 3722, Business and Professions Code. Reference: Sections 2860, 3701, 3702, 3702.5, 3702.7, 3703, and 3765 Business and Professions Code.

California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 13.6. Respiratory Care Board
Article 6. Scope of Practice

PROPOSED MODIFIED LANGUAGE

BASIC RESPIRATORY TASKS AND SERVICES

Legend:

Changes addressed in Notice of Proposed Regulatory Action (45-day comment period):
- Deleted text is indicated by ~~strikethrough~~
- Added text is indicated with an underline

Modified Text (15-day comment period):
- Deleted text is indicated by ~~double strikethrough~~
- Added text is indicated by double underline

Adopt Proposed Section 1399.365 as follows:

1399.365. Basic Respiratory Tasks and Services.

(a) For purposes of this section, “assessment” means making an analysis or judgment and making recommendations concerning the management, diagnosis, treatment, or care of a patient or as a means to perform any task in regard to the care of a patient. Assessment as used in this section is beyond documenting observations, and gathering and reporting data to a licensed respiratory care practitioner, registered nurse, or physician.

(b) For purposes of~~Pursuant to~~ subdivision (a) of section 3702.5 of the B&P~~Business and Professions code~~, basic respiratory tasks and services ~~(“tasks”), described more specifically below,~~ do not require a respiratory assessment~~,~~ and ~~only require manual, technical skills, or data collection. Basic respiratory tasks do not include manipulation of an invasive or non-invasive ventilator and do not include assessment or evaluation of chest auscultation. Basic respiratory tasks~~ include the following:

(~~a~~1) Patient ~~D~~data collection.

(~~b~~2) Application and monitoring of ~~the~~a pulse oximeter.

(~~c~~3) Medication administration by aerosol that does not require manipulation of an invasive or non-invasive mechanical ventilator.~~Basic respiratory tasks do not include pre-treatment assessment, use of medical gas mixtures other than oxygen, preoxygenation, endotracheal or nasal suctioning, or post-treatment assessment.~~

(~~d~~4) Heat moisture exchanger (HME) and oxygen tank replacement for patients who are using non-invasive mechanical ventilation.~~Basic respiratory tasks do not include the initial setup, change out, or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration.~~

(~~e~~5) Hygiene care including replacement of tracheostomy ties and gauze and cleaning of the stoma sites. ~~Basic respiratory tasks do not include tracheal suctioning, cuff inflation/deflation, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula.~~

(~~f~~6) Use of a manual resuscitation device and other cardio-pulmonary resuscitation technical skills (basic life support level) in the event of an emergency.

(~~g~~7) Documentation of care provided, which includes data retrieved from performing a breath count or transcribing data from an invasive or non-invasive ventilator interface.

(8) Observing and gathering data from chest auscultation, palpation, and percussion.

(c) For purposes of subdivision (a) of section 3702.5 of the B&P, basic respiratory tasks and services do not include the following:

(1) Manipulation of an invasive or non-invasive ventilator.

(2) Assessment or evaluation of observed and gathered data from chest auscultation, palpation, and percussion.

(3) Pre-treatment or post-treatment assessment.

(4) Use of medical gas mixtures other than oxygen.

(5) Preoxygenation, or endotracheal or nasal suctioning.

(6) Initial setup, change out, or replacement of a breathing circuit or adjustment of oxygen liter flow or oxygen concentration.

(7) Tracheal suctioning, cuff inflation/deflation, use or removal of an external speaking valve, or removal and replacement of the tracheostomy tube or inner cannula.

NOTE: Authority cited: Sections 3702.5 and 3722, Business and Professions Code. Reference: Sections 2860, 3701, 3702, 3702.5, 3702.7, 3703, and 3765 Business and Professions Code.