

Item: Update and Discussion Regarding Proposed Regulations Related to Home and Community-Based Respiratory Tasks and Services and Training Requirements

Item Summary

Staff are presenting <u>conceptual</u> regulatory language for stakeholder input. Once language is drafted, it will be presented to the Respiratory Care Board (RCB) at a future meeting for approval to begin the official regulatory process. This regulatory language, once final, will impact home and community-based settings by exempting LVNs, under specified conditions, to perform respiratory care tasks.

Stakeholder Comments

<u>All stakeholders are encouraged to provide input and feedback</u>. Please provide your comments at the meeting when this agenda item is called for public comment or send written comments to: **rcbinfo@dca.ca.gov.** If you would like to be included in any future round table meetings, please also provide your contact information to the RCB at this email. Your input will be beneficial in drafting proposed regulatory language that will be presented to the RCB, at a future meeting, for approval to begin the regulatory process.

Background

In response to longstanding disputes and concerns over patient safety, Senate Bill (SB) 1436 (Statutes of 2022) was enacted in January 2023, introducing three key provisions:

- Codification of the Vocational Nursing (VN) Practice Act, explicitly stating that LVNs have no authority to perform respiratory care services or treatments (Business and Professions (B&P) Code §2860(a)).
- Limited exemption for LVNs with specified training and demonstrated competency, may perform basic respiratory tasks identified by the RCB that do not require assessment, only manual or technical skills, or data collection (B&P Code §§2860(b) and 3702.5(a)).
- Expanded exemption for LVNs employed by home health agencies, permitting them to perform respiratory tasks beyond the basic tasks as identified by the RCB, provided they have completed patient-specific training.

Following the signing of SB 1436 in October 2022, the RCB approved regulatory language defining basic respiratory tasks, addressing only the first two provisions (not the third). However, these proposed regulations were misinterpreted as restricting patient care, causing widespread concern among home and community-based patients and facilities. In response, the RCB reaffirmed its commitment to the intent of SB 1436 and, in March 2023, pursued legislative language for additional exemptions in home and community-based settings, which were later incorporated into SB 1451 (Statutes of 2024).

[Regulations related to the first two provisions were withdrawn, re-noticed, and will be presented at the RCB's March 13, 2025, meeting for final consideration under agenda item 9a, "Basic Respiratory Tasks and Services."]

Key Elements of SB 1451 (Statues of 2024)

The conceptual language presented herein, addresses the third key provision of SB 1436 and the additional exemptions introduced by SB 1451 amending B&P Code §3765:

- Extended the exemption for LVNs in home health agencies to perform respiratory tasks, beyond basic tasks, provided they have completed patient-specific training to the satisfaction of their employer. This exemption was extended from 2025 to 2028. After 2028, patient-specific training must align with RCB-provided training guidelines, which these regulations aim to address.
- Expanded LVN exemptions to allow performance of respiratory care services beyond basic tasks as identified by the RCB in home and community-based settings identified below, provided that the LVN satisfies the following:
 - Completes patient-specific training satisfactory to their employer.
 - Holds a valid certification of competency, for each respiratory task to be performed, issued by the California Association of Medical Product Suppliers or the California Society for Respiratory Care, (effective January 1, 2028) (*Home health agencies may fulfill training requirements under either subdivision (i), which does not require this certification, OR subdivision (j) of Section 3765 of the B&P*)

Eligible Practice Settings:

- Congregate living health facilities (six beds or fewer) licensed by the California Department of Public Health (CDPH).
- Intermediate care facilities (six beds or fewer) licensed by the CDPH.
- Adult day health care centers licensed by the CDPH.
- LVNs employed by a home health agency, licensed by the CDPH, or individual nurse providers working in a residential home
- Pediatric day health and respite care facilities licensed by the State Department of Public Health.
- Small family homes (six beds or fewer) licensed by the State Department of Social Services.
- Private duty nurses assisting with daily transportation, activities outside the patient's residence or family respite for home- and community-based patients.

Discussion

The conceptual language presented herein is intended to facilitate discussion on regulatory amendments addressing legislative changes in SB 1436 and SB 1451. These proposed amendments define the scope of respiratory tasks and services that LVNs may perform in noted home and community-based settings, and establish training guidelines for LVNs, as follows:

§ 1399.360. Unlicensed Personnel Services; Home Care.

• Amend language in this section to increase clarity by deleting possibly confusing language in response to comments received from the Basic Respiratory Tasks and Services regulation package.

§ 1399.361. Home and Community-Based Respiratory Tasks and Services- LVN Exemption.

- This section defines the respiratory tasks permitted in home and community-based settings.
- This language addresses "respiratory tasks and services identified by the RCB under §3765(i) and "respiratory care services" under §3765(j).

§ 1399.362. Home and Community-Based Patient-Specific LVN Training Guidelines.

- This section establishes patient-specific training guidelines for employers to use when training LVNs to provide respiratory care in home and community-based settings.
- Addresses "patient-specific training" under B&P §3765(i) and (j).
- Note: Per B&P § 3765(i) these guidelines must be developed in collaboration with the Board of Vocational Nursing and Psychiatric Technicians of the State of California (BVNPT).

§ 1399.363. Demonstrated Competency Certification.

- Establishes criteria for issuing and maintaining valid competency certification for LVNs performing respiratory tasks in noted home and community-based settings.
- Certification shall be provided by the California Association of Medical Product Suppliers (CAMPS), the California Society for Respiratory Care (CSRC), or both.
- Note: Discussions with CAMPS and CSRC regarding implementation have not yet taken place at the time of this writing.
- This section addresses "current and valid certification of competency" as required by B&P § 3765(j)(1)(C).

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 RCB 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 (B&P §§ 3700-3779), 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

VN 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.)

Section 3765

This act does not prohibit any of the following activities:

(a)

(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, 2028, the licensed vocational nurse has completed patientspecific training satisfactory to their employer.

(2) On or after January 1, 2028, 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, 2028, in collaboration with the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(j) The performance of respiratory care services identified by the board by a licensed vocational nurse who satisfies the requirements in paragraph (1) in the settings listed in paragraph (2).

(1) (A) The licensed vocational nurse is licensed pursuant to Chapter 6.5 (commencing with Section 2840).

(B) The licensed vocational nurse has completed patient-specific training satisfactory to their employer.

(C) The licensed vocational nurse holds a current and valid certification of competency for each respiratory task to be performed from the California Association of Medical Product Suppliers, the California Society for Respiratory Care, or another organization identified by the board.

(2) A licensed vocational nurse may perform the respiratory care services identified by the board pursuant to this subdivision in the following settings:

(A) At a congregate living health facility licensed by the State Department of Public Health that is designated as six beds or fewer.

(B) At an intermediate care facility licensed by the State Department of Public Health that is designated as six beds or fewer.

(C) At an adult day health care center licensed by the State Department of Public Health.

(D) As an employee of a home health agency licensed by the State Department of Public Health or an individual nurse provider working in a residential home.

(E) At a pediatric day health and respite care facility licensed by the State Department of Public Health.

(F) At a small family home licensed by the State Department of Social Services that is designated as six beds or fewer.

(G) As a private duty nurse as part of daily transportation and activities outside a patient's residence or family respite for home- and community-based patients.

(3) This subdivision is operative on January 1, 2028.

...

(Amended by Stats. 2024, Ch. 481, Sec. 13. (SB 1451) Effective January 1, 2025.)

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

CONCEPTUAL REGULATORY LANGUAGE CONCERNING HOME AND COMMUNITY-BASED RESPIRATORY TASKS AND SERVICES

AMEND SECTION 1399.360

§ 1399.360. Unlicensed Personnel Services; Home Care.

(a) Unlicensed personnel (UP) may perform limited and basic respiratory care or respiratory care related services identified in subdivisions (b) and (c) in the home setting, for for the purposes of patient transfer to the home setting, or at the facility of a Licensed Home Care Employer, provided the following conditions are met:

(1) The UP is providing services through his or her their employment with a Licensed Home Care Employer (LHCE);

(2) The UP has been provided initial training, and at least annually, ongoing in-service education, and periodic competency testing specific to each service and equipment-type by either a California licensed respiratory care practitioner (RCP) or other qualified licensed personnel, in accordance with his or her their scope of practice, and documentation of such training, education and testing is maintained by the LHCE for a period of four years, and

(3) The LHCE ensures that the patient, the patient's family, or the patient's caregiver(s) are advised prior to or at the time equipment or supplies are delivered, that a RCP or other qualified licensed personnel, in accordance with his or her their scope of practice, shall provide follow up checks, by telephone or in-person as appropriate, at the request of the patient or the patient's family, caregiver, or physician, or any person who has had contact with the patient, or as otherwise directed by a plan of care, and such services are provided accordingly. (***)

ADD SECTION 1399.361

1399.361. Home and Community-Based Respiratory Tasks and Services- LVN Exemption

(a) For purposes of subdivision (j) of section 3765 of the B&P, a licensed vocational nurse (LVN) may perform respiratory care tasks and services as follows, in the settings identified in subdivision (c), provided conditions in subdivision (b) are met:

(1) ... [see attached list]

(b) An LVN may perform those respiratory care tasks and services as provided in subdivision (a), in settings identified in subdivision (c), provided all of the following conditions are met:

(1) The LVN is performing the respiratory care task and service based on a valid and lawful order or prescription issued by a California licensed physician and surgeon.

(2) A California licensed physician and surgeon, registered nurse, or respiratory care practitioner with direct oversight responsibility for the LVN, assesses and verifies [to be defined] all of the following:

(A) The LVN holds a valid license issued by the California Board of Vocational Nursing and Psychiatric Technicians.

(B) The LVN received the proper training and demonstrated competency as required by either:

i. Subdivisions (1) or (2) of subdivision (i) of section 3765 of the B&P for LVNs employed by a home health agency or

ii. Subdivisions (1)(B) and (1)(C) of subdivision (j) of section 3765 of the B&P for any LVN employed in the settings identified in subdivision (b).

(C) The LVN demonstrated competence to perform each respiratory task and service specific to each patient in accordance with the guidelines in section 1399.362 of the CCR.

(D) The LVN shall provide in writing, in accordance with subdivision (d) of section 1399.362 their understanding of their responsibilities, including when to report a patient's status change, what constitutes an emergency, and the steps to take in case of an emergency.

(3) The training records for the LVN shall document in detail the assessments and determinations made as described in subdivision (2) above including the name(s) of health care personnel providing direct oversight responsibility of the LVN, patient's name and date(s) of the assessment and determination.

(A) Training records must be maintained for a period of four years by the supervising medical professional, the employing organization, or, in cases of independent contracting, the entity or individual responsible for overseeing the LVN.

(c) This section is applicable to respiratory care tasks and services provided by LVNs in the following settings:

(1) A private residential home.

(2) A congregate living health facility licensed by the State Department of Public Health that is designated as six beds or fewer.

(3) An intermediate care facility licensed by the State Department of Public Health that is designated as six beds or fewer.

(4) An adult day health care center licensed by the State Department of Public Health.

(5) A pediatric day health and respite care facility licensed by the State Department of Public Health.

(6) A small family home licensed by the State Department of Social Services that is designated as six beds or fewer.

(7) As part of transportation and activities or family respite for patients living in any home or community-based setting.

Note: Authority cited: Sections xxx, Business and Profession Code. Reference: Sections 3717, xxx, Business and Professions Code. Section 1399.377 of the CCR

ADD SECTION 1399.362. (Collaboration with BVNPT needed)

1399.362. Employer-Provided Home and Community-Based Patient-Specific LVN Training Guidelines

(a) For purposes of subdivisions (i)(2) and (j)(1)(B) of section 3765 of the B&P, employerprovided home and community-based patient-specific LVN training shall include the following:

(1) Subject matter education (with examples including skills training, simulation training, return demonstration trials (not on a patient), and competency assessments).

(2) The employer shall provide each licensed vocational nurse (LVN) in their employment with patient-specific training within guidelines identified in this section as it pertains to each respiratory care task and service performed.

(3) For each respiratory task and service to be provided, the employer shall provide an assessment of the LVN performing all of the following:

(A) Demonstrated knowledge of the subject.

(B) Demonstrated knowledge of how and when to respond to equipment failures.

(C) Demonstrated knowledge of how and when to respond to contraindications, precautions and/or possible complications, and hazards and complications.

(D) Demonstrated knowledge of how and when to contact a supervising RCP, RN, or MD or patient's family.

(E) Demonstrated knowledge of how and when to contact 911 or other emergency services.

(F) Demonstrated ability to provide clear communication in English language.

(G) Return demonstration to the supervising licensed physician, registered nurse or respiratory care practitioner by the LVN, of each respiratory task and service performed on a patient with daily review of subdivisions (A)-(F) for a minimum of xx hours or xx working shift, whichever is less.

(4) The supervising licensed physician, registered nurse or respiratory care practitioner shall complete post training evaluations that confirm the readiness of the LVN to provide each respiratory care task and service for each patient that will be cared for by the LVN.

(5) The employer shall perform annual patient-specific competency checks for each respiratory task and service and for each patient under the care of each LVN.

(b) "Patient-specific training" as used in this section means training of an LVN, by a California licensed physician, registered nurse, or respiratory therapist, who provides care to each patient they are assigned and assumes responsibility to determine whether the LVN is competent to provide care for each patient.

(c) Patient-Specific training shall be based on the version of guidelines published at the time the patient-specific training is provided by any of the following:

- (1) The American Association for Respiratory Care.
- (2) The California Thoracic Society.
- (3) The American College of Surgeons.
- (4) The American College of Chest Physicians.
- (5) Society for Critical Care Medicine.

(6) Latest versions of textbooks used by Commission on Accreditation for Respiratory Care (CoARC) approved respiratory care programs.

Note: Authority cited: Sections xxx, Business and Profession Code. Reference: Sections 3717, xxx, Business and Professions Code. Section 1399.377 of the CCR.

ADD SECTION 1399.363

1399.363. Demonstrated Limited-Competency Certification

(a) Pursuant to subdivision (1)(C) of subdivision (j) of section 3765 of the B&P, the California Society for Respiratory Care (CSRC) and the California Association of Medical Product Suppliers (CAMPS) may provide learning experiences for respiratory tasks and services and issue corresponding certificates of demonstrated limited-competency to licensed vocational nurses (LVN) in accordance with this section.

(b) Learning experiences include education and training and LVN return demonstration provided and observed by instructors holding a Board-issued respiratory care practitioner license in good standing.

(1) Education and training may be delivered in any format, including the following examples: in-person classroom education, online education, skills lab demonstration, and situational analysis/case studies.

(2) Education and training shall be based on guidelines published by organizations listed in subdivision (c) of section 1399.362, where applicable.

(3) Return demonstration must be completed in an in-person format, where the RCP is able to observe and perform a limited-competency assessment for each respiratory care task and service.

(c) "Limited competency" as used in this section, means the completion of education and return demonstration limited to stable or stable and chronic patients, and the most easily corrected troubleshooting techniques. Limited competency does not include an emphasis on the full range of respiratory complications and hazards. Limited competency does not include a response to all respiratory complications and hazards, but rather emphasizes responding to patient activity that warrants contacting a physician, registered nurse, respiratory care practitioner or emergency personnel.

(d) A "limited-competency assessment" as used in this section means an evaluation, performed by the licensed RCP, of the knowledge and critical thinking skills of an LVN to safely perform respiratory tasks and services to the level of limited competency.

(1) If the limited-competency assessment includes the use of equipment or supplies, the assessment must then also include the evaluation of the LVN's ability and knowledge, trouble-shooting techniques, any special considerations and emergency protocol associated with the device or procedure in the use and/or application of equipment or any portion thereof, within the framework as provided in subdivision (c).

(2) When the limited-competency assessment requires evaluation of the LVN's ability and knowledge in the use or application of equipment or any portion thereof, the actual or comparable functioning device must be used.

(e) Upon successful completion of the limited-competency assessment, a certificate of completion shall be issued for a period of one-year and shall include all of the following:

(1) The title of the certificate shall read "Limited-Competency Certificate."

(2) The date the certificate was issued.

(3) The statement "This certificate is valid for one year from the date issued."

(4) The LVN's full name (verified by picture identification, including a California Driver's License, passport, or other government-approved issued identification).

(5) The LVN's California vocational nurse license number.

(6) The name and license number of the RCP(s) and their organization, who conducted the limited-competency assessment.

(7) The list of respiratory tasks and services with corresponding date(s) the LVN successfully passed the limited-competency assessment (within a 30-day period from when the certificate is issued).

(8) The following statement: "Patient-Specific Training by the employer shall be completed as provided in section 1399.362 of division 13.6 of title 16 of the California Code of Regulations."

(f) For each Limited-Competency Certificate issued, the CSRC and CAMPS shall retain related [define which records] records for a period of four years from the date the Limited-Competency Certificate is issued.

Note: Authority cited: Sections xxx, Business and Profession Code. Reference: Sections 3717, xxx, Business and Professions Code. Section 1399.377 of the CCR

Attachment

Respiratory Care Tasks and Services Currently Provided in Home Care- Jan. 24, 2023

RESPIRATORY CARE TASKS AND SERVICES CURRENTLY PROVIDED IN HOME CARE January 24, 2023

1. Ventilator set-up and change-out and configuration

Includes:

- Connecting a patient to a ventilator who may breathe independently at other times of the day
- Transferring a patient from a stationary ventilator to a travel ventilator
- Change out to a back-up ventilator as necessary
- The ongoing build and configuration of the ventilatory circuit (after cleaning, replacement, ventilator change-out or an emergency)
- The connection and disconnection of a ventilatory circuit as needed
- Changing to an alternative preprogrammed and physician ordered ventilator setting upon a physician's order/approval

Does not include:

- Programming a ventilator per prescription for initial use by a home care health provider.
- Initiating or changing any ventilator setting
- The initial build and configuration of the ventilator circuit

2. Ventilator Alarms: Set, test, respond to, reset, or silence

Includes:

- Testing ventilator alarms before connecting a patient to the ventilator
- Responding to alarms
- Silencing alarm once caregiver resolves or in the process of resolving the reason for the alarm

Does not include:

 Setting alarms (LVNs are not permitted to access locked ventilator menu where alarms are set)

3. Non-invasive ventilation mask and straps

Includes:

• Placing ventilation mask on patient for use of a ventilator including straps and placement is secure

Does not include:

• Fitting a new mask for initial use of a ventilator

4. Ventilator oxygen concentrations

Includes:

• Initiating or changing oxygen concentrations through a ventilator (with a physician's order), without changing the programming of the ventilator itself

5. Aerosol treatments (nebulizer and meter dosed inhaler)

Includes:

- Configuration and application of trach mask, face mask and inline ventilatory circuit for the purpose of administering nebulized medications
- The connection and disconnection of an aerosol circuit as needed
- Pre-treatment assessment
- Preoxygenation as ordered by a physician
- Use of medical gas mixtures
- Endotracheal and nasal suctioning
- Post-treatment assessment
- Pushing a ventilator button (if applicable) to provide nebulizer treatments

6. Troubleshooting artificial airway problems

Includes:

• Troubleshooting artificial airway problems checking that trach tube is in place and is clear and correcting problems or blockages

Does not include:

• Making decisions about the type or style of tracheostomy tube or performing any type of intubation

7. Ventilator weaning

Includes:

• Performing physician ordered "sprints" off the ventilator for increasing periods of time

Does not include:

• Management of ventilator weaning

8. Oxygen and Humidification

Includes:

- Initial set-up, change out or replacement of the breathing circuit or adjustment of oxygen liter flow or oxygen concentration for oxygen tanks, heat moisture exchanger or other humidification device
- Filling, refilling, and cleaning the heater humidifier water chamber used with ventilators

9. Tracheal care

Includes:

- Replacement of tracheostomy tie
- Replacement of tracheostomy gauze
- Cleaning of the stoma site
- Tracheal suctioning (surface and deep suctioning)
- Cuff inflation/deflation
- Placement or removal of external speaking valve or trach cap
- Removal or replacement of tracheostomy tube, inner canula and outer cannula
- Placing / removing a Heat Moisture Exchanger (HME) from a tracheostomy tube

Does not include:

- Assessment for the use of a speaking valve or trach cap
- Deep nasal or endotracheal suctioning

10. Assessment of and response to a patient's respiratory status

Includes:

- Observing patients for signs and symptoms of respiratory distress
- Taking action in response to respiratory distress that the LVN has been trained in
- Administering life support protocols for which he/she has been trained
- Use of an ambu-bag

Does not include:

• Performing any task for which an LVN does not feel competent or has not received training

11. Respiratory treatments and therapies and other devices

Includes:

The initiation, instruction, and assistance, set up, operation, connection, disconnecting and troubleshooting, as applicable for the following:

- Intrapulmonary Percussive Ventilator (IPV) Treatments / Percussive vest treatments
- Manual chest percussive therapy
- Cough assist machines
- Pushing a ventilator button (if applicable) to engage cough assist function
- Heater/humidifiers used in line with a ventilator.
- Airvo/Optiflow Direct tracheostomy interface (high flow oxygen/humidifier device)
- Air compressor (cool mist/heater/humidifier)
- Metered Dose Inhaler (independent device and those connected to vent/trach tube)
- Medication delivery via the ventilator
- Medication delivery via patented Podhaler system for TOBI brand tobramycin
- Treatments delivered via a Continuous Positive Airway Pressure (CPAP) device
- CPAP/BiLevel Positive Airway Pressure (BiPAP) devices
- All types of pulse oximeter devices
- Apnea monitor
- Device power supply

12. Documentation

Includes:

• Documenting all care provided and observations of patients' status and response

13. Education and Instruction

Includes:

- Providing instruction on the proper operation or application of those respiratory devices, procedures, or therapy for which the LVN has received training
- Providing advice or instruction on safety hazards