TITLE 16. DIVISION 13.6. RESPIRATORY CARE BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: August 7, 2024

Subject Matter of Proposed Regulations: Basic Respiratory Tasks and Services

Sections Affected: 1399.365 of Division 13.6, Title 16 of the California Code of Regulations (CCR)[1]

Background and Statement of the Problem:

The Respiratory Care Board of California (RCB or Board) oversees approximately 24,000 licensed respiratory care practitioners (RCPs) and RCP applicants. RCPs regularly perform critical lifesaving and life support procedures prescribed by physicians and surgeons that directly affect major organs of the body. It is the RCB's duty to enforce and administer the Respiratory Care Practice Act at Business and Professions Code (B&P) sections 3700-3779 (Act). The RCB is authorized to establish necessary rules and regulations for the enforcement of the Act and the laws subject to its jurisdiction (B&P Code §§ 3701, 3722).

The problem the RCB is addressing with the adoption of this regulation is a scope of practice issue concerning Licensed Vocational Nurses (LVNs), licensed by the California Board of Vocational Nursing and Psychiatric Technicians (BVNPT), performing respiratory care outside the scope of the Vocational Nursing Practice Act. A chain of events began in 1996 when the BVNPT drafted and disseminated to multiple health care agencies and education programs a "policy" permitting LVNs to adjust ventilator settings. Since then, 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.

The Board addressed this scope of practice issue and tried to rectify related concerns through multiple avenues, though the problems persisted. In 2022, the RCB underwent its legislative sunset review and provided a summary of this scope of practice issue in its *2022 Sunset Oversight Review* report submitted to the Assembly Business and Professions Committee and the Senate Business, Professions, and Economic Development Committee requesting their guidance and assistance.

The Legislative Sunset Review Oversight Committee proposed Senate Bill (SB) 1436 (Chapter 624, Statutes of 2022) that, among other actions, amended B&P section 2860

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

of the Vocational Nursing Practice Act to reflect that LVNs may not provide respiratory care services and treatment, except 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 Board pursuant to subdivision (a) of Section 3702.5 of the B&P. Subdivision (a) of Section 3702.5 of the B&P provides in part that the Board may adopt regulations to further define, interpret, or identify basic respiratory tasks and services that do not require a respiratory assessment and only require manual, technical skills, or data collection. Governor Newsom signed SB 1436 on September 27, 2022.

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." CCR Division 13.6 provides Article 6 "Scope of Practice" as the appropriate placement for this new regulation. This proposal would adopt a new section 1399.365 to further define, interpret, or identify basic respiratory tasks and services as provided in subdivision (a) of section 3702.5 of the B&P. Specifically, this proposed regulation would adopt the following:

- Add section 1399.365 – Basic Respiratory Tasks and Services
- Add preamble section 1399.365 – Basic Respiratory Tasks and Services
- Add subsections 1399.365(a)-(g) enumerating Basic Respiratory Tasks and Services
- Add note to proposed section 1399.365 – Basic Respiratory Tasks and Services

To address other portions of SB 1436, the RCB will begin holding meetings in 2024 to address tasks and services related to home care that will ultimately lead to additional rulemaking.

Anticipated Benefits from This Regulatory Action:

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.

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. Providing such

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.

Specific Purpose of, and Rationale for, Each Adoption:

1. **A preamble will be added to proposed 16 CCR 1399.365 as follows:**

   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:

Purpose: This preamble contextualizes the subdivisions that follow, establishing that the enumerated tasks result from a specific directive for the Board to create regulations further defining, interpreting, and identifying basic respiratory tasks.

Rationale: This 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. This preamble also contains a definition of basic respiratory tasks taken from B&P section 3702.5(a). This may at first appear repetitive, but it is strategic for clarity purposes, so a reader will have the statutory text of B&P section 3705(a) before them without have to search for it elsewhere. In the context of the subdivisions that come after, the definition provided of tasks that "do not require a respiratory assessment, and only require manual, technical skills, or data collection" helps a reader understand not only what the definition is, but it shows the reader that the following subdivisions are examples of that definition. Further, the term "tasks" is used to mean "tasks and services" to make the text more succinct and flow accordingly for the reader.

The preamble 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.

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 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.

2. **Subdivision (a) is added to this proposed rulemaking as follows:**

   Data collection.

Purpose: Subdivision (a) clarifies that collecting data on a patient is a basic respiratory task.

Rationale: As a general matter, "data collection" is explicitly part of the statutory description of basic respiratory tasks in B&P section 3702.5(a). This proposed subdivision reinforces that inclusion. Specifically identifying data collection as a basic respiratory task makes clear that LVNs are authorized to collect data, which will enhance the timely delivery of health care monitoring and attention.

3. **Subdivision (b) is added to this proposed rulemaking as follows:**

   Application and monitoring of the pulse oximeter.

Purpose: Subdivision (b) clarifies application and monitoring of a pulse oximeter is intended specifically by the Board to be a basic respiratory task.

Rationale: In the Board's experience and in the common practice of the field, application and monitoring of a pulse oximeter is a basic respiratory task because its use and application do not require extensive education or training. The pulse oximeter is a commonly used device employed for respiratory and non-respiratory patients as a means of measuring the oxygen level (oxygen saturation) of the blood that can alert health care teams to problems. This subdivision clarifies that LVNs are permitted to use pulse oximeters in the care of all patients, not just specific respiratory care patients, which will promote the timely delivery of health care monitoring.

4. **Subdivision (c) is added to this proposed rulemaking as follows:**

   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.

Purpose: Subdivision (c) clarifies when administration of medication by aerosol is and is not a basic respiratory task. This subdivision also covers assessments and specific tasks related to aerosol medication administration the Board intends to explicitly exclude from basic respiratory tasks.

Rationale: Adoption of this subdivision 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 and RCPs to perform intermediate and advance level of 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.

5. **Subdivision (d) is added to this proposed rulemaking as follows:**

   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.

Purpose: Subdivision (d) describes the tasks associated with HME and oxygen tank replacement for certain patients and clarifies which associated tasks are not to be considered basic respiratory tasks.

Rationale: 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.

6. **Subdivision (e) is added to this proposed rulemaking as follows:**

   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.

Purpose: Subdivision (e) describes the tasks associated with hygiene care the Board believes are appropriately defined as basic respiratory tasks. Proposed subdivision (e) also contains text specifically excluding certain associated tasks.

Rationale: 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.

7. **Subdivision (f) is added to this proposed rulemaking as follows:**

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

Purpose: Subdivision (f) specifies when the use of resuscitation devices and skills are to be considered basic respiratory tasks.

Rationale: The performance of respiratory care services in an emergency is statutorily permitted, as reflected in B&P sections 3703(a) and 3765(d) and (e). Accordingly, the use of a manual resuscitation device and cardiopulmonary resuscitation are already permitted in emergency circumstances, and this proposed regulatory subdivision (f) is consistent with the statutes governing emergencies. Nonetheless, it is not always clear when healthcare practitioners other than RCPs may perform respiratory care functions, even in emergency situations. By expressly identifying, "use of manual resuscitation devices and other cardio-pulmonary resuscitation technical skills (basic life support level) in the event of an emergency," as a basic respiratory task, the proposed regulation will make clear that all medical personnel are permitted to employ manual respiratory life-saving devices, skills, or both in an emergency to recover a patient in respiratory or cardiac arrest. Emergency events require urgent attention, and it is necessary to immediately employ life saving measures such as these to sustain life until a patient can be stabilized. Moreover, education and training in the use of manual resuscitation devices, like a breathing bag and basic cardio-pulmonary resuscitation, are widely available even for people who are not licensed healthcare providers, and these tasks do not require formal respiratory education or training to master.

8. **Subdivision (g) is added to this proposed rulemaking as follows:**

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

Purpose: Proposed subdivision (g) describes which tasks related to documentation of care are basic respiratory tasks.

Rationale: The category of "documentation of care provided" is included as a basic respiratory task because this is a health care standard that requires neither respiratory assessment nor specialized respiratory education or training. This helps ensure there are no barriers for other health care personnel to document the respiratory tasks and services provided, allowing for the best overall care of each patient. Including this category as a basic respiratory task communicates to the public the documentation of care provided.

Further, including "data retrieved from performing a breath count" and "transcribing data from an invasive or non-invasive ventilator interface" is appropriate because these are respiratory tasks that do not require an assessment or evaluation and are important

data to include in patients' medical records to monitor patients' conditions. These tasks do not require anything beyond data collection and do not require formal respiratory education or training, putting them within the types of tasks defined as basic respiratory tasks and services in B&P section 3702.5(a).

9. **A Note is proposed to be added to proposed 16 CCR Section 1399.365 as follows:**

   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.

Purpose: The Note contains information showing the Board's authority to engage in this rulemaking and references to the specific statutes being implemented or clarified by the regulation.

Rationale: The Board's authority for this regulation derives from two places. First, the Board's specific authority related to further defining, interpreting, or identifying basic respiratory tasks comes from subdivision (a) of section 3702.5 of the B&P, which states: "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." Second, the Board's general rulemaking authority is described at B&P section 3722.

The Reference note in this proposed rulemaking refers to B&P sections 2860, 3701, 3702, 3702.5, 3702.7, 3703, and 3765.

This rulemaking implements B&P section 2860, as that section clarifies the boundaries of the scope of practice of vocational nursing. This rulemaking further defines, interprets, and identifies which respiratory care tasks are allowable. This rulemaking implements Section 3701 by adopting regulation to protect the public from the unauthorized and unqualified practice of respiratory care. This rulemaking implements B&P section 3702 because it further defines the scope of the practice of respiratory care by elucidating what constitutes basic respiratory tasks. This rulemaking implements B&P section 3702.5(a) by further defining, interpreting, and identifying basic respiratory tasks as explicitly allowed by B&P section 3702.5. B&P section 3702.7 establishes that respiratory care practice includes mechanical and physiological ventilatory support, administration of medical gases and pharmacological agents in certain circumstances, extracorporeal life support, and other tasks. This regulation implements B&P section 3702.7 by establishing further rules regarding ventilatory support, administration of medical gases and pharmacological agents, and tasks associated with extracorporeal life support. B&P sections 3703(a) and 3765(d) and (e) address performing respiratory care in an emergency. This regulation implements B&P sections 3703 and 3765 by reinforcing that respiratory care is permissible in an emergency.

Underlying Data:

1) SB 1436 (Roth), Chapter 624, Statutes of 2022
2) Board's *2022 Sunset Oversight Review* report
3) Respiratory Care Board of California and Board of Vocational Nursing and Psychiatric Technicians Joint Statement – April 2019

Business Impact:

The Board has made an initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The Board investigates between one and five facilities each year based on complaints of unlicensed or unauthorized practice stemming directly from LVNs violating the Act, some unknowingly, at the behest of their employer. This proposed regulation aims to reduce these complaints, and at the same time, increase complaints for other facilities that have not yet been reported. Businesses in compliance with existing law will have no impact. Those not in compliance may need to adjust their procedures.

Economic Impact Assessment:

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs within the State of California because the regulation does not make any changes or provide for any new provisions that would affect the creation or elimination of jobs. The regulation is aimed primarily at reenforcing existing law by providing specific detail of what constitutes basic respiratory tasks and services that may be performed by LVNs.

- It will not create new business or eliminate existing businesses within the State of California because the regulation does not make any changes or provide for any new provisions that would result in the creation or elimination of new businesses. The regulation is aimed at ensuring existing businesses employing health care personnel understand which respiratory care tasks and services may be performed by LVNs.

- It will not result in expansion of any businesses currently doing business within the State of California because the regulation does not make any changes or provide for new provisions that would directly affect the expansion of any businesses. The regulation is not expected to create new jobs nor expand businesses.

- This regulatory proposal will benefit the health and welfare of California residents because this proposal will ensure LVNs are only performing those basic respiratory tasks and services for which they are trained and demonstrate competency satisfactory to their employer, and when directed by a physician or

surgeon, to perform. This ensures patients requiring respiratory care beyond basic tasks and services are receiving such care from qualified health care personnel.

- This regulatory proposal does not affect worker safety because it only makes the respiratory care practice more specific by identifying basic respiratory tasks and services. The regulatory proposal does not involve worker safety.

- This regulatory proposal does not affect the state's environmental safety because it only makes the respiratory care practice more specific by identifying basic respiratory tasks and services. The regulatory proposal does not involve environmental issues.

Specific Technologies or Equipment:

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

Consideration of Alternatives:

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

Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business:

No such alternatives have been proposed; however, the Board welcomes comments from the public.