RESPIRATORY CARE BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing date has been scheduled.

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).

I. Background and Problem Being Addressed

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.

The RCB participated in a legislative "sunset review" hearing during the early months of 2022. In the RCB's 2022 Sunset Review Report, prepared in advance of the hearing, the RCB detailed a chain of events that began in 1996 when the Board of Vocational Nursing and Psychiatric Technicians (BVNPT) drafted and disseminated a policy providing that Licensed Vocational Nurses (LVNs) were permitted to adjust ventilator settings, a traditional respiratory care function. Since 1996, a number of incidents were reported to the RCB of LVNs performing respiratory care treatment for patients.

The Board summarized these events in its 2022 Sunset Review Report submitted to the Assembly Business and Professions Committee and the Senate Business, Professions, and Economic Development Committee, and SB 1436 (Chapter 624, Statutes of 2022) was enacted in response to the RCB Report.

SB 1436 added new text to the Vocational Nursing Practice Act, B&P Code sections 2840-2895.5, and the Respiratory Care Practice Act, which clarified, on one hand, that LVNs may not "provide respiratory care services and treatment," while also allowing the RCB, on the other hand, to define a set of "[b]asic respiratory tasks and services" that LVNs may perform. This proposed rulemaking expressly defines the tasks that comprise basic respiratory tasks and services that respiratory care practitioners (RCPs) and LVNs may perform.

There are no existing regulations related to this proposal.

II. Specific Purpose, Anticipated Benefit, and Rationale

This rulemaking proposes to add 16 CCR section 1399.365, Basic Respiratory Tasks and Services.

<u>Purpose</u>: The overall purpose of adding 16 CCR 1399.365 is to define, interpret or

identify basic respiratory tasks and services as provided in subdivision (a) of section 3702.5 of the B&P.

Anticipated Benefit: Increased consumer protection by ensuring only qualified personnel provide respiratory care beyond the services that only require manual, technical skills or data collection. In addition, all stakeholders (i.e., healthcare practitioners, facilities, employers, and patients) will have a clear understanding of which respiratory tasks and services may be performed by LVNs and which would require licensure as an RCP.

Rationale: The adoption of this section is necessary to effectuate subdivision (a) of B&P section 3702.5, and enable LVNs to perform basic respiratory care services pursuant to amended B&P section 2860. The respiratory tasks and services identified in this language were developed as a result of enforcement investigations into unlicensed and/or unauthorized practice and through consultation and discussion with experts, board members and staff from both the BVNPT and RCB. The proposed regulation identifies "basic" respiratory tasks and identifies activities that do not fall within the scope of those basic tasks.

Each broad type of task has been broken out into its own subdivision in the proposed regulation and is described individually in the following sections of this Initial Statement of Reasons.

a. Preamble

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

> 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:

Purpose: This preamble contextualizes the subdivisions that follow, establishing that the enumerated tasks follow from a specific directive for the RCB to create regulations defining basic respiratory tasks.

Anticipated Benefit: The preamble makes it easier for a reader to understand the context of the following subdivisions. By including a reference to B&P section 3702.5, the proposed preamble also directs readers to the statutory basis for the RCB's efforts to define basic respiratory tasks.

Rationale: The Board is expressly authorized to adopt regulations defining basic respiratory tasks via B&P section 3702.5. As noted, this preamble not only refers back to the statute conferring this authority, clarifying it for the reader, but also contains a definition of basic respiratory tasks taken from B&P section 3702.5. 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 shows the reader that the following subdivisions are examples of that definition. Finally, the Board is using the term "basic respiratory tasks" to include "tasks and services" to make the text more succinct and flow accordingly for the reader. Additionally, the preamble specifies that manipulation of a ventilator is not a basic task. In all cases, ventilator manipulation requires a respiratory assessment that is informed by formal respiratory care education and training, to ensure patient healthcare is not compromised. Tasks that require respiratory assessments are naturally excluded because they are excluded from the statutory definition for basic tasks pursuant to B&P section 3702.5. Additionally, B&P section 3702.5 distinguishes basic respiratory tasks from intermediate tasks on the basis that intermediate tasks "require formal respiratory education and training." Ventilator manipulation is such a task that requires formal education and training as an RCP to perform.

b. Subdivision (a)

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

> Data collection. Basic respiratory tasks do not include assessment and/or evaluation of chest auscultation.

Purpose: Subdivision (a) clarifies the Board's intended limitations on data collection as a basic respiratory task.

Anticipated Benefit: The Board believes excluding assessment and evaluation of chest auscultation from the definition of basic respiratory data collection will ensure that symptoms requiring specialized respiratory education, training, and assessment are not missed or misinterpreted. This will benefit the public by ensuring only qualified health care providers assess and evaluate chest auscultation.

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 further implements the statute by outlining that assessment and evaluation of chest auscultation is not a basic respiratory data collection task because, in the RCB's experience and in the common practice of the field, these functions require formal pulmonary and cardiopulmonary education and training specific to numerous respiratory conditions and contraindications, and a comprehensive analysis to achieve the best intended patient outcomes.

RCPs are specially trained to perform these functions. 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. There are both associate degree and baccalaureate degree programs in California, and even the Associate Degree programs take a minimum of three years to complete with full-time attendance, and the programs are weighted with courses specific

to respiratory care. While other health care disciplines may include a high-level review of respiratory care in their education programs, respiratory care students delve into the intricacies of the practice, and receive specialty training in chest auscultation assessment and evaluation. B&P section 3702.5 distinguishes basic respiratory tasks from intermediate tasks on the basis that intermediate tasks “require formal respiratory education and training.” Chest auscultation assessment and evaluation is a respiratory care task that requires such formal training and, consequently, is properly not considered a basic task. Additionally, basic tasks are defined in B&P section 3702.5 to not include respiratory assessments.

By specifically excluding assessment and evaluation of chest auscultation from the type of basic patient data that may be collected, the proposed regulation conforms to the statute, ensures high care standards are maintained in the profession and that patients and the public will be appropriately protected.

c. Subdivision (b)

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 care task.

Anticipated Benefit: This subdivision clarifies that LVNs are permitted to use pulse oximeters in the care of respiratory care patients. This will benefit consumers and practitioners in the timely delivery of health care monitoring.

Rationale: In the Board’s experience and in the common practice of the field, the application and monitoring of a pulse oximeter is a basic respiratory task because 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 which can alert health care teams to problems. Its use and application do not require formal or supplemental respiratory education and training, which differentiates it from other non-basic respiratory care tasks and services specified in B&P section 3702.5.

d. Subdivision (c)

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 care task. This subdivision also covers patient assessments and other specific tasks related to aerosol medication administration that would be explicitly excluded from basic respiratory care tasks.

Anticipated Benefit: This subdivision will benefit both the public and the healthcare teams by maximizing resources of the healthcare teams to perform duties at their skill levels without interruption to health care delivery or reducing the quality of care delivered.

Rationale: In the Board's experience and in the common practice of the field, the task of delivering aerosol medication to a patient that does not require ventilator manipulation consists of the simple job of waving aerosol medication around the patient's mouth and nose area and takes an average of 20 minutes to administer. As such, this task is one that, pursuant to B&P section 3702.5, subdivision (a), only requires manual skills to accomplish and does not require formal education. Specifically identifying this as a basic care task that LVNs may perform will free physicians and respiratory therapists to perform intermediate and advance level of respiratory care for all patients, maximizing the resources of multi-disciplinary healthcare teams.

The proposed regulation would exclude administration requiring the manipulation of an invasive or non-invasive mechanical ventilator because this is the type of respiratory care function that requires formal respiratory education and training, and there are many more possible adverse outcomes that require advanced skills to mediate problems, thereby 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. With each delivery of an aerosol medication, the ventilator patient is at greater risk for possible adverse outcomes thereby making it necessary to have a formally-trained respiratory 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. Respiratory assessments are naturally excluded because they are excluded from the statutory definition for basic tasks. The remaining tasks have been excluded because they are often performed when providing medication by aerosol, especially for patients on ventilators. All of these tasks, however, require a respiratory assessment or evaluation informed by formal respiratory care education and training to ensure that patient healthcare is not compromised.

e. Subdivision (d)

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 basic respiratory tasks associated with heat moisture exchanger and oxygen tank replacement for certain patients and clarifies which associated tasks are not considered basic respiratory tasks.

Anticipated Benefit: By defining tasks related to heat moisture exchanger and oxygen tank replacement, both the public and multi-disciplinary healthcare teams will benefit from maximizing resources of the healthcare teams to perform functions at their skill levels without interruption to health care delivery or reducing the quality of care delivered.

Rationale: In the Board's experience and in the common practice of the field, the replacement of heat moisture exchangers and oxygen tanks for non-invasive, mechanically ventilated patients is not an invasive task, inasmuch as replacement does not involve a puncture or incision of the skin or insertion of an instrument or foreign material into the body, and it does not require formal respiratory education and training to execute. It also requires only manual or technical skill to perform, and does not require the exercise of professional respiratory care judgment.

Basic tasks are limited to patients treated with non-invasive mechanical ventilation due to the low healthcare risks associated with that form of ventilation treatment. Treatment via invasive mechanical ventilation, on the other hand, involves many more common contraindications that require formal respiratory education and training to mediate adverse reactions, thereby ensuring patients are receiving expected quality of care.

Further, the Board believes 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 a respiratory assessment or evaluation, informed by formal respiratory care education and training, to ensure patient healthcare is not compromised. Also, tasks that require respiratory assessments are naturally excluded because they are excluded from the statutory definition for basic tasks in B&P section 3702.5.

f. Subdivision (e)

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: Proposed subdivision (e) describes tasks generally associated with management of the trachea. Hygiene care relating to procedures like tracheostomies are appropriately defined as basic respiratory tasks that need not be performed by an RCP. Proposed subdivision (e) also contains text that excludes certain associated tasks that require formal respiratory education and training to perform.

Anticipated Benefit: By defining what is and is not a basic respiratory task related to hygiene care, the Board believes this will benefit both the public and multi-disciplinary healthcare teams by maximizing resources of the healthcare teams to perform functions at their skill levels without interruption to health care delivery or reducing the quality of care delivered.

Rationale: Hygiene care, including replacement of tracheostomy ties and gauze, and the cleaning of stoma sites, are basic respiratory care tasks because, in the Board's experience and in the common practice of the field, these tasks are not invasive and do not require formal respiratory education or training to perform. They are necessary healthcare tasks associated with the treatment and care of respiratory care patients, but they require only manual or technical skill and do not require the exercise of professional RCP judgment.

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 they require a respiratory assessment or evaluation, informed by formal respiratory care education and training, to ensure patient healthcare is not compromised. Tasks that require respiratory assessments are naturally excluded because they are excluded from the statutory definition for basic tasks pursuant to B&P section 3702.5. Moreover, there are numerous contraindications that can occur for these advanced therapies that require extensive respiratory care education and training to properly mediate adverse reactions. Indeed, licensed RCPs must pass both written and clinical simulation exams that test for competency in these tasks.

g. Subdivision (f)

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 considered basic respiratory tasks.

Anticipated Benefit: The performance of respiratory care services in an emergency is permitted by B&P sections 3703, subdivision (a) and 3765, subdivision (e). Nonetheless, it is not always clear when other healthcare practitioners may perform

respiratory care functions, even in emergency situations. By expressly identifying the use of manual resuscitation devices and other cardio-pulmonary resuscitation technical skills in the event of an emergency, the proposed regulation will make clear that non-RCPs (particularly LVNs) may freely employ respiratory life-saving devices and skills to recover a patient in respiratory or cardiac arrest.

This will benefit the public by ensuring that multi-disciplinary healthcare delivery teams, including LVN members, may deploy such services to sustain life.

Rationale: The use of a manual resuscitation device and cardiopulmonary resuscitation are already permitted in emergency circumstances and, consequently, this regulatory provision is consistent with the statutes governing emergencies. Nonetheless, the proposed regulation would expressly include these services as basic respiratory tasks in the circumstance of an emergency because, by listing them here, LVNs and other members of multi-disciplinary healthcare teams can have confidence that an LVNs performance of these functions in an emergency is permissible. When a respiratory or cardiac arrest occurs, 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 is widely available even for people who are not licensed healthcare providers, and these tasks do not require formal respiratory education and training to master.

h. Subdivision (g)

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

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

Purpose: Proposed subdivision (g) explains which documentation of respiratory care would be considered a basic respiratory task, and it specifically calls out two types of documentation that occur regularly in the course of providing respiratory care.

Anticipated Benefit: Adding this subdivision benefits health care providers particularly in multi-disciplinary healthcare teams by clarifying there are no barriers to documenting respiratory care provided to a patient. This subdivision also benefits consumers by ensuring there are no barriers for health care personnel to accurately document patients' respiratory care and status.

Rationale: Documentation of the provision of respiratory care in medical records requires no respiratory assessment or formal respiratory education or training. Consequently, this aspect of respiratory care is properly considered a basic task or service.

Two common documentation tasks include recording data “retrieved from performing a breath count” and “transcribing data from an invasive or non-invasive ventilator interface.” These respiratory tasks do not require a respiratory assessment but they are important data to include in patients’ medical records to monitor their respiratory health conditions. These tasks also 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).

h. Note to Proposed 16 CCR Section 1399.365

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, 3702, 3702.5 and 3702.7, 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 defining basic respiratory tasks comes from B&P section 3702.5 and subdivision (a), 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.” The Board’s general rulemaking authority is described at B&P section 3722.

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

This rulemaking implements section 2860, as that section clarifies the boundaries of the scope of practice defined in its chapter. This rulemaking further defines which practices are allowable as well. This rulemaking implements section 3702 because it is further defining the scope of the practice of respiratory care by establishing rules about basic respiratory tasks. This rulemaking implements section 3702.5 by defining basic respiratory tasks as explicitly allowed by section 3702.5. Finally, 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 section 3702.7 by establishing further rules regarding ventilatory support, administration of medical gases and pharmacological agents, and tasks associated with extracorporeal life support.

III. Underlying Data

1) RCB’s 2022 Sunset Review Report

2) Respiratory Care Board of California and Board of Vocational Nursing and Psychiatric Technicians Joint Statement – April 2019 (Revised July 2019)

IV. 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 Respiratory Care Practice 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.

V. 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 regulations do not make any changes or provide for any new provisions that would affect the creation or elimination of jobs. The regulations are 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 regulations are aimed at ensuring existing businesses employing health care personnel understand which respiratory care services may be performed by LVNs and which require other licensed healthcare professionals.

- 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 regulations are not expected to create new jobs nor expand businesses.

- This regulatory proposal will benefit the health and welfare of California residents because it will ensure LVNs are only performing those basic respiratory tasks and services for which they are trained and competency tested to perform. Patients requiring more advanced levels of respiratory care beyond basic tasks and services will receive such care from qualified health care personnel.

- This regulatory proposal does not affect worker safety because it has nothing to do with worker safety. It defines which respiratory care tasks may be performed

by different healthcare professionals.

- This regulatory proposal does not affect the state's environment because it does not involve environmental issues.

VI. Specific Technologies or Equipment

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

VII. 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.