



Item: Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, Section 1399.365, Basic Respiratory Tasks and Services

Item Summary: Staff are presenting proposed regulatory language and the initial statement of reasons for the Board's consideration to edit and/or approve the regulatory text and to proceed with the rulemaking process accordingly.

- Board Action:**
1. President calls the agenda item and it is presented by or as directed by the President.
 2. President requests motion on Proposed Regulatory Language:
 - move for the Board to approve the proposed regulatory text for section 1399.365 as presented, direct staff to submit the text to the Director of the Department of Consumer Affairs and to the Business, Consumer Services, and Housing Agency for review, and if no adverse comments are received, authorize the Executive Officer to take all steps necessary to initiate the rulemaking process, make any non-substantive changes to the package, and set the matter for a hearing. If no adverse comments are received during the 45-day comment period or during the public hearing if requested, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at section 1399.365 of Title 16, California Code of Regulations as noticed.
 - any other appropriate motion.
 3. President may request if there is a second to the motion, if not already made.
 4. Board member discussion/edits (if applicable).
 5. Inquire for public comment / further Board discussion as applicable.
 6. 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. Since 1996, there have been many incidents reported to the RCB, where LVNs are performing respiratory care outside the scope of the Vocational Nursing Practice Act (the law only authorizes LVNs to perform tasks that require manual, technical skills or data collection). Many cases of patient harm and death as a result, have also been reported. 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 CA Dept. of Public Health, to practice beyond basic respiratory tasks.

In October 2022, right after the bill was signed, the RCB approved regulatory language identifying basic respiratory tasks. Staff gave public notice of the proposed regulations and in December, 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 permitted some very basic 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 meeting additional needed exemptions were identified and the legislative language was not ready to progress.

At the RCB's June 2023 meeting, the RCB agreed to withdraw the 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.

The RCB is obligated 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 again interfere with implementing these regulations as these regulations and SB 1451 are two separate and unrelated issues. However, the introduction of SB 1451 shows a good faith effort-above and beyond- to address fears of home and community-based facilities and patients while providing time for those parties to understand the difference in implementing regulations that define basic respiratory tasks and legislation that provides a pathway for LVNs to legally practice respiratory care with specific training requirements and in specific settings, that does not currently exist. In other words, the implementation of these regulations allow LVNs to provide basic respiratory tasks but has zero impact on LVNs practicing advanced respiratory tasks. It is currently illegal for LVNs to perform any advanced respiratory task and will remain illegal unless a legislative pathway is established (as provided in SB 1451).

RCB Mandate

The RCB's mandate is to protect consumers by ensuring only qualified licensees practice in the Board's regulated field (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)

Attachments

Proposed Regulatory Language Title 16, California Code of Regulations CCR section 1399.365 Basic Respiratory Tasks and Services

Initial Statement of Reasons (ISOR)

**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, 3702, 3702.5 and 3702.7, Business and Professions Code.

RESPIRATORY CARE BOARD OF CALIFORNIA

INITIAL STATEMENT OF REASONS

Hearing Date: May 3, 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).

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 Respiratory Care Board (RCB) underwent its legislative sunset review during the early months of 2022. In the RCB's 2022 Sunset Review Report, the RCB details 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. 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 which only authorizes LVNs to perform tasks that require manual, technical skills or data collection. 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 Respiratory Care Board continued to push back and tried to rectify many issues through multiple avenues, though the problems persisted.

As a last resort, the Board provided a summary of the chain of events that had occurred since 1996 in its 2022 Sunset Review Report submitted to the Assembly Business and Professions Committee and the Senate Business, Professions, and Economic Development Committee in January 2022 requesting their guidance and assistance.

SB 1436 (Chapter 624, Statutes of 2022) was the Sunset Review Oversight Committees' response to provide resolution. The Board is now moving forward with addressing basic respiratory care tasks and services via regulation and to address other portions of SB 1436, the RCB will begin to hold meetings in 2024 to address tasks and services related to home care that will ultimately lead to another rulemaking package.

Existing regulations: There are no existing regulations related to this proposal. 16 CCR provides Article 6 Scope of Practice as the appropriate placement for this new regulation.

Problem being addressed: SB 1436 (Chapter 624, Statutes of 2022) signed by Governor Newsom on September 27, 2022, added new language to the Vocational Nursing Practice Act and the Respiratory Care Practice Act allowing the Board to, among other things, develop definitions for “basic respiratory tasks.” This proposed rulemaking defines, by enumerating tasks, what is and is not meant by “basic respiratory tasks.”

II. Specific Purpose, Anticipated Benefit, and Rationale

General Purpose of this Rulemaking

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

Purpose: As a general matter, the 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 are providing respiratory care beyond services that only require manual, technical skills or data collection. In addition, all stakeholders will have a clear and precise understanding of which respiratory tasks and services may be performed by LVNs.

Rationale: The adoption of this section is necessary to effectuate subdivision (a) of section 3702.5 of the Business and Professions Code (B&P). 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, legal counsel, board members and staff from both the Board of Vocational Nursing and Psychiatric Technicians and the Respiratory Care Board of California. It was determined that it was necessary to not only identify the specific “basic” task, but to also include tasks that are not basic, but closely associated with the specific task. Given the long history of debate on what constitutes respiratory care and the continued misconceptions from persons outside the respiratory care field, the Board believed it was imperative that “basic respiratory tasks and services” be made exceptionally clear.

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 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 follow from a specific directive for the Board 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 Board’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. The Board acknowledges this may at first appear repetitive, but it is strategic for clarity purposes. 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 “tasks” to mean “tasks and services” to make the text more succinct and flow accordingly for the reader.

The Board has determined that 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, it should be noted that even the 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.]

By carefully outlining what is and is not 'data collection,' the Board will ensure high care standards are maintained in the profession and that patients and the public will be appropriately protected.

b. Subdivision (a)

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

Data collection.

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 task will ensure that symptoms requiring respiratory education, training and assessment are not missed or misinterpreted. This will benefit the public by ensuring only qualified health care givers are providing assessment and evaluations of 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) per SB 1346. This proposed subdivision reinforces that inclusion and further implements the statute by outlining what is excluded from 'data collection.'

c. Subdivision (b)

Subdivision (b) is added to this proposed rulemaking 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 all patients, not just specific respiratory care patients. This will benefit consumers and practitioners in the timely delivery of health care monitoring.

Rationale: The Board has determined, 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 extensive education and training.

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 assessments and specific tasks related to aerosol medication administration the Board intends to explicitly exclude from basic respiratory care tasks.

Anticipated Benefit: The Board believes 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: The Board has determined it is appropriate 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, only requires manual skills to accomplish and does not require formal education. This frees physicians and respiratory therapists to perform intermediate and advance level of care for all patients, maximizing resources.

Following from this, the Board determined it was 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 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, 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. All of these tasks require assessment and/or evaluation based on complete respiratory education and training and the Board believes it is important to make the distinction to ensure 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 tasks associated with heat moisture exchanger and oxygen tank replacement for certain patients and clarifies which associated tasks are not to be considered basic respiratory tasks.

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

Rationale: The Board believes it is necessary to specify that heat moisture exchanger and oxygen tank replacement are basic respiratory services 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 or insertion of an instrument or foreign material into the body and do not require extensive education and training.

However, the Board also believes 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, 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 assessment and/or evaluation based on complete respiratory education and training and the Board believes it is important to make the distinction to ensure patient healthcare is not compromised.

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 the tasks associated with hygiene care the Board believes are appropriately defined as basic respiratory tasks. Proposed subdivision 5 also contains text specifically excluding certain associated tasks.

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 the healthcare teams by maximizing resources of the healthcare teams to perform duties functions at their skill levels without interruption to health care delivery or reducing the quality of care delivered.

Rationale: The Board is specifying hygiene care, 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, the Board has determined that 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 require assessment and/or evaluation based on complete respiratory education and training and/or 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 of these tasks. The Board believes it is important to make the distinction to ensure patient healthcare is not compromised.

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 to be considered basic respiratory tasks.

Anticipated Benefit: By allowing the use of manual resuscitation devices and other cardio-pulmonary resuscitation technical skills in the event of an emergency, the Board is clarifying that all medical personnel should employ this respiratory life-saving device and/or skills to recover a patient in respiratory and/or cardiac arrest.

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

Rationale: The Board is specifying that the use of a manual resuscitation device and use of cardiopulmonary resuscitation are basic respiratory tasks in the circumstance of an emergency because these events require immediate attention. When a respiratory and/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.

h. Subdivision (g)

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 and are not basic respiratory tasks.

Anticipated Benefit: Adding this subdivision benefits health care providers by clarifying there are no barriers from documenting respiratory care provided. This subdivision also benefits consumers by ensuring there are no barriers for health care personnel to accurately document patients' care and status as provided by each health care provider, allowing for the best overall care of each patient.

Rationale: The Board has included the category of documentation in its definition of basic respiratory tasks because this is a health care standard which requires no respiratory assessment and requires no specialized respiratory education or training. The Board also wants to ensure there are no barriers for other healthcare personnel to document respiratory tasks and services provided. 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 and/or evaluation and are important data to include in patients' medical records to monitor patients' 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 3701, 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) SB 1436 (Roth), Chapter 624, Statutes of 2022.
- 2) Board's 2022 Sunset Review Report

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.
- 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 this proposal will ensure LVNs are only performing those basic respiratory tasks and services for which they are educated, trained, and competency tested to perform. Thereby ensuring 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.

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.

VIII. 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.