F695

(Rev. 208; Issued:10-21-22; Effective: 10-21-22; Implementation:10-24-22)

§483.25(i) Respiratory care, including tracheostomy care and tracheal suctioning. The facility must ensure that a resident who needs respiratory care, including tracheostomy care and tracheal suctioning, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, and 483.65 of this subpart.

INTENT §483.25 (i)
The intent of this provision is that each resident receives necessary respiratory care and services that is in accordance with professional standards of practice, the resident's care plan, and the resident's choice.

DEFINITIONS §483.25 (i)
"Automatic self-adjusting positive airway pressure(APAP)". APAP is a non-invasive ventilation machine that automatically adjusts the air pressure according to the patient's requirement at a particular time.

"Bi-level positive airway pressure(BiPAP)". BiPAP is a non-invasive ventilation machine that is capable of generating two adjustable pressure levels - Inspiratory Positive Airway Pressure (IPAP) - high amount of pressure, applied when the patient inhales and a low Expiratory Positive Airway Pressure (EPAP) during exhalation.

"Continuous positive airway pressure(CPAP)". CPAP is a non-invasive ventilation machine that involves the administration of air usually through the nose by an external device at a predetermined level of pressure.

"Hypoxia"means decreased perfusion of oxygen to the tissues.

"Hypoxemia"means decreased oxygen level in arterial blood.

"Intermittent positive pressure breathing (IPPB)"is a technique used to provide short term or intermittent mechanical ventilation for the purpose of augmenting lung expansion, delivering
aerosol medication, or assisting ventilation and can include pressure- and time-limited as well as pressure, time, and flow-cycled ventilation, and may be delivered to artificial airways and non-intubated patients.

"Mechanical Ventilation"may be defined as a life support system designed to replace or support normal ventilatory lung function.[1]

"Noninvasive ventilation (NIV)"refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). [1]

"Obstructive Sleep Apnea (OSA"refers to apnea syndromes due primarily to collapse of the upper airway during sleep.

"Oxygen therapy"is the administration of oxygen at concentrations greater than that in ambient air (20.9%) with the intent of treating or preventing the symptoms and manifestations of hypoxia.

"Respiratory Therapy Service"are-services that are provided by a qualified professional (respiratory therapists, respiratory nurse) for the assessment, treatment, and monitoring of residents with deficiencies or abnormalities of pulmonary function (See §483.65, Specialized Rehabilitative Services).

"Tracheotomy or Tracheostomy"is an opening surgically created through the neck into the trachea (windpipe) to allow direct access to the breathing tube and is commonly done in an operating room under general anesthesia. A tube is usually placed through this opening to provide an airway and to remove secretions from the lungs. Breathing is done through the tracheostomy tube rather than through the nose and mouth. The term "tracheotomy" refers to the incision into the trachea (windpipe) that forms a temporary or permanent opening, which is called a "tracheostomy," however the terms are sometimes used interchangeably.

"Ventilator Assisted Individual (VAI)"requires mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or maintain life. [2]

GUIDANCE §483.25(i)

Changes in the respiratory system related to aging may lead to the development of and/or difficulty/challenges in treating diseases in the respiratory system, and may impact treatments/interventions. The Minimum Data Set (MDS) has identified the most frequent respiratory diseases/syndromes that a resident may have been admitted with or required after admission to a nursing home, including but not limited to pneumonia, asthma, chronic obstructive pulmonary disease (COPD), chronic lung disease (chronic bronchitis and restrictive lung diseases such as asbestosis), respiratory failure, shortness of breath (dyspnea) with exertion, or when sitting at rest, lying flat, or during an illness such as influenza. In addition, residents have been admitted with or previously had *acute* respiratory distress syndrome (*ARDS*), lung cancer, obstructive sleep apnea or a history of tuberculosis.

Various modalities/treatments for respiratory care identified on the MDS include respiratory treatments/therapy, oxygen therapy, the use of BiPAP/CPAP, tracheostomy and/or suctioning, and some facilities provide chest tube and mechanical ventilation services/care.

Based upon its facility assessment, the resident population, diagnosis, staffing, resources and staff skills/knowledge, the facility must determine whether it has the capability and capacity to provide the needed respiratory care/services for a resident with a respiratory diagnosis or syndrome that requires specialized respiratory care and/or services. This includes at a minimum, sufficient numbers of qualified professional staff, established resident care policies and staff trained and knowledgeable in respiratory care before admitting a resident that requires those services.

Resident Care Policies

The facility, in collaboration with the medical director, director of nurses, and respiratory therapist, as appropriate, must assure that resident care policies and procedures for respiratory care and services, are developed, according to professional standards of practice, prior to admission of a resident requiring specific types of respiratory care and services. (Also refer to F841, §483.70(h) Medical Director) The policies and procedures, based on the type of respiratory care and services provided, may include, but are not limited to:

- Oxygen services, including the safe handling, humidification, cleaning, storage, and dispensing of oxygen;
- Types of respiratory exercises provided such as coughing/deep breathing and if provided therapeutic percussion/vibration and bronchopulmonary drainage;
- Aerosol drug delivery systems (nebulizers/metered-dose inhalers) and medications (preparation and/or administration) used for respiratory treatments;
- BiPAP/CPAP treatments;
- Delineation for all aspects of the provision of mechanical ventilation/tracheostomy care, including monitoring, oversight and supervision of mechanical ventilation, tracheostomy care and suctioning, and how to set, monitor and respond to ventilator alarms;
- Emergency care which includes staff training and competency for implementation of emergency interventions for, at a minimum, cardiac/respiratory complications, and include provision of appropriate equipment at the resident's bedside for immediate access, such as for unplanned extubation;
- Procedures to follow in the advent of adverse reactions to respiratory treatments or interventions, including mechanical ventilation, tracheostomy care and provision of oxygen;
- Respiratory assessment including who can conduct each aspect of the assessment, what is contained in an assessment, when and how it is conducted, the type of documentation required;
- Maintenance of equipment for respiratory care in accordance with the manufacturer specifications and consistent with federal, state, and local laws and regulations, such as oxygen equipment, or equipment for mechanical ventilation if provided, how and by whom the equipment is serviced and how it is maintained;

- Emergency power for essential equipment such as mechanical ventilation, if provided;
- Infection control measures during implementation of care, handling, cleaning, storage and disposal of equipment, supplies, biohazardous waste and including infection control practices for mechanical ventilation/tracheostomy care including the use of humidifiers; and
- Posting of cautionary and safety signs indicating the use of oxygen; and

Staffing and Qualified Personnel

Refer to §483.65 specialized rehabilitative services, for review of provision of services by qualified personnel. When providing respiratory care, the facility must, based on professional standards of practice:

- Have sufficient numbers of trained, competent, qualified staff, consistent with State practice acts/laws; and
- Identify who is authorized to perform each type of respiratory care service, such as responding to mechanical ventilator alarms, suctioning and tracheostomy care.

NOTE: Surveyors are expected to determine the scope of practice and state laws regarding who may provide mechanical ventilation and/or tracheostomy care in their state.

Monitoring and Documentation of Respiratory Services/Response
Staff should document, based on current professional standards of practice, the assessment and monitoring of the resident's respiratory condition, including response to therapy provided, and any changes in the respiratory condition. Depending on the type of respiratory services the resident receives, physician orders and the individualized respiratory care plan, documentation should include, as appropriate:

- Vital signs, including the respiratory rate;
- Chest movement and respiratory effort, and the identification of abnormal breath sounds;
- Signs of dyspnea, cyanosis, coughing, whether position affects breathing, characteristics of sputum, signs of potential infection, or the presence of behavioral changes that may reflect hypoxia including anxiety, apprehension, level of consciousness; and
- Instructions for the resident on how to participate/assist in the respiratory treatments as appropriate.

The attending practitioner must be immediately notified of significant changes in condition, and the medical record must reflect the notification, response and interventions implemented to address the resident's condition. Also, refer to§483.10(g)(14) F580 for notification of physician, family of significant changes.

Modalities/Respiratory Therapy/Care/Services

A variety of respiratory therapy modalities and care may be provided in the nursing home, including coughing/deep breathing, therapeutic percussion/vibration and postural drainage, aerosol/nebulizers, humidification, and therapeutic gas administration, BiPAP or CPAP, tracheostomy care and tracheal suctioning, and mechanical ventilation and oxygenation support.

Coughing/deep breathing, therapeutic percussion/vibration and bronchopulmonary drainage

If a resident has written orders for postural drainage, chest percussion, and vibration to increase the mobility of pulmonary secretions, the care plan must include, based upon the resident's assessments and identified needs, the type of exercise, including when and how often provided. The resident's record should reflect how staff are monitoring the condition of the resident prior to, during and after the treatments, and, as appropriate, vital signs including the respiratory rate, pulse oximetry, presence of dyspnea, and/or signs of infection. The record should reflect the resident's response to the treatment and notification of the practitioner if necessary for a change in the resident's condition or as necessary, the need to revise or alter the respiratory care provided. Refer to §483.10(g)(14) F580 for notification of physician of significant changes.

Respiratory medications via aerosol generators

There are three common types of aerosol generators used for inhaled drug delivery:

- A small-volume nebulizer (SVN);
- A pressurized metered-dose inhaler (pMDI); and
- A dry-powder inhaler (DPI).

NOTE: For information related to aerosol delivery devices include, for example, the specific devices' manufacturers guidelines for use; and " Guide to Aerosol Delivery Devices for Physicians, Nurses, Pharmacists and Other Health Care Professionals" American Association for Respiratory Care 2013 http://www.aarc.org//app/uploads/2014/08/aerosol_guide_pro.pdf

Oxygen (O_2) Therapy

Oxygen therapy may be provided through various types of supply and delivery systems. Equipment may include the provision of oxygen through nasal cannulas, trans-tracheal oxygen catheters, oxygen canisters, cylinders or concentrators.

For a resident receiving oxygen therapy, the resident's record must reflect ongoing assessment of the resident's respiratory status, response to oxygen therapy and include, at a minimum, the attending practitioner's orders and indication for use. In addition, the record should include the type of respiratory equipment to use, baseline SpO_2 levels and to initiate and/or discontinue oxygen therapy. If the resident is ambulatory with his/her oxygen delivery system, the resident must be informed of safety precautions and

prohibitions for oxygen, such as where smoking is allowed or other hazardous areas, and staff should monitor to assure the resident adheres to the safety rules for oxygen. The resident's care plan should identify the interventions for oxygen therapy, based upon the resident's assessment and orders, such as, but not limited to:

- The type of oxygen delivery system;
- When to administer, such as continuous or intermittent and/or when to discontinue;
- Equipment settings for the prescribed flow rates;
- Monitoring of SpO_2 levels and/or vital signs, as ordered; and
- Based upon the individual resident's risks, if applicable, monitoring for complications, such as skin integrity issues related to the use of a nasal cannula.

NOTE: For reference, American Association for Respiratory Care Clinical Practice Guideline -Oxygen Therapy in the Home or Alternate Site Health Care Facility —2007 Revision & Update P1063-1067- http://www.rcjournal.com/cpgs/pdf/08.07.1063.pdf

Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) refers to apnea syndromes due primarily to collapse of the upper airway during sleep. Nonpharmacologic medical treatments may include weight reduction, tongue-retaining devices, positive airway pressure modalities such as continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BiPAP). CPAP involves the administration of air usually through the nose by an external device at a fixed pressure to maintain the patency of the upper airway. BiPAP is similar to CPAP but the devices are capable of generating two adjustable pressure levels. Other treatment methods for OSA may include the use of medications surgical procedures.

For a resident with OSA, the resident's record must reflect ongoing assessment of the resident's respiratory status, response to therapy and include, at a minimum, the attending practitioner's orders and indication for use. In addition, the record should include the equipment settings, when to use the equipment and humidification as appropriate.

The care plan should identify the interventions for OSA, based upon the resident's assessment and orders, such as, but not limited to:

- The type of equipment and settings, and
- When to administer; and;
- Based upon the individual resident's risks, if applicable, monitoring for complications.

Respiratory Services for Mechanical Ventilation *and/or* Tracheostomy/Tracheotomy Care

The guidance related to care of residents receiving mechanical ventilation applies to facilities who provide this type of care. Mechanical ventilation is defined as a life support system designed to replace and/or support normal ventilatory lung function. A ventilator-assisted individual (VAI) may require mechanical aid for breathing to augment or replace

spontaneous ventilatory efforts to achieve medical stability or maintain life. Persons requiring long term invasive ventilatory support have demonstrated:

- An inability to become completely weaned from invasive ventilatory support; or
- A progression of disease etiology that requires increasing ventilatory support.

Due to the clinically complex nature of the provision of care for a resident receiving mechanical ventilation, there must be an active, ongoing interdisciplinary approach to the resident's care, including but not limited to participation as needed, by the physician/practitioner, pulmonologist, registered nurse, pharmacist, dietitian, speech therapist, respiratory therapist, physical and/or occupational therapist, and the resident/representative. The facility, in collaboration with the attending practitioner, must provide a comprehensive assessment of the resident's respiratory needs. The facility must provide an assessment of resident specific communication methodologies, including assessing current visual/hearing needs, cognition, level of consciousness, and identifying potential methods for communication such as writing, communication cards/boards, and/or computer access. The results of the assessment must be used in the development and implementation of a person centered care plan.

A resident receiving mechanical ventilation and/or tracheostomy care is dependent on staff to provide care according to the practitioner's orders, the comprehensive assessment and individualized care plan, including, but not limited to communication, positioning and range of motion, nutrition, hydration, ADL's, bladder and bowel management, monitoring for resident specific risks for possible complications, psychosocial needs, as well as mechanical ventilation and tracheostomy care including suctioning as appropriate. The facility must provide consistent, implementation of all aspects of care related to the provision of mechanical ventilation and tracheostomy care, in accordance with accepted professional standards of practice, including emergency interventions as appropriate.

Staff must be trained and competent in application of life support interventions in case of emergency situations such as cardiac and/or respiratory complications related to mechanical ventilation and environmental emergencies such as power outages.

Care plan for Mechanical Ventilation/Tracheostomy Care
Based upon the resident assessment, attending practitioner's orders, and professional standards of practice, the facility, including the resident/representative, to the extent possible, must develop and implement a care plan that includes appropriate interventions for respiratory care. The facility must develop a care plan based on the resident's individualized assessment that may include:

- Communication needs and methods;
- Positioning, skin Integrity and redistribution of pressure (i.e., use of specialized mattresses/equipment/positioning);
- Nutritional support (specialized care such as enteral nutrition);
- Bowel and bladder management;
- Provision of oral and eye care;

- Monitoring for psychosocial needs such as depression or anxiety;
- As ordered by the practitioner, and/or as appropriate, monitoring respirations and respiratory rates, heart rates, presence of cyanosis, dusky coloring or other color changes related to respiratory/circulatory conditions, symmetry of chest expansion/movement, diaphoresis, lethargy, vital signs and parameters including pulse oximetry;
- Care of a resident who is cognitively impaired and may exhibit restlessness and pulling at tubing;
- Adjunctive interventions, as appropriate, such as medications, aerosol (bronchodilators), chest physiotherapy, oxygen therapy, and/or secretion clearance devices; and
- Identification of resident specific risks for possible complications, that may include:
  - Unplanned extubation;
  - Aspiration and the potential for respiratory infection (tracheal bronchitis, ventilator associated pneumonia (VAP));
  - Nutritional complications related to tube feedings, gastric distress;
  - Increased or decreased CO_2 levels;
  - Development of oral or ocular ulcers,
  - Barotrauma;
  - Deep vein thrombosis due to immobility; and/or
  - Airway complications such as tracheal infections, mucous plugging, tracheal erosion and/or stenosis;
- Advance directives, if any;
- Type of ventilator equipment, settings, and alarms, (Refer to physicians orders, and manufacturers specifications for use and care); and
- Type and size of airway and care of artificial airway.

PROCEDURE: §483.25(i)
Use the Respiratory Care Critical Element (CE) Pathway, along with the above interpretive guidelines when determining if the facility provides the necessary care and services to ensure that a resident receives the respiratory care and services as ordered to meet his/her needs.

Surveyors should use the guidance above as general information about the professional standards of practice regarding the provision of care under this tag. It is not intended to prescribe a clinical course for a specific resident.

Summary of Procedure
Briefly review the most recent comprehensive assessments, comprehensive care plan and orders to identify whether the facility has assessed and developed an individualized care plan based on professional standards of practice and provided by qualified, competent staff. During this review, identify the extent to which the facility has implemented interventions in accordance with the resident's needs, goals for care and professional standards of practice, consistently across all shifts. This information will guide observations and interviews to be made in order to corroborate concerns identified.

NOTE: Always observe for visual cues of psychosocial distress and harm (see Appendix P, Guidance on Severity and Scope Levels and Psychosocial Outcome Severity Guide).

NOTE: If noncompliance with respiratory care provided by nursing services is related to staff competency issues, also consider F725, §483.35(a)(3), Nursing Services

KEY ELEMENTS OF NONCOMPLIANCE §483.25(i)
To cite deficient practice at F695, the surveyor's investigation will generally show that the facility failed to do one or more of the following:

- Provide necessary respiratory care and services, such as oxygen therapy, treatments, mechanical ventilation, tracheostomy care, and/or suctioning; or
- Provide necessary respiratory care consistent with professional standards of practice, the resident's care plan, goals and preferences.

DEFICIENCY CATEGORIZATION §483.25(i)
In addition to actual or potential physical harm, always consider whether psychosocial harm has occurred when determining severity level (See Appendix P, Section IV, E, Psychosocial Outcome Severity Guide).

Examples of Severity Level 4 Noncompliance: Immediate Jeopardy to Resident Health or Safety includes but *is* not limited to:

- The facility failed to assure that staff provided appropriate tracheostomy care including suctioning as ordered by the resident's physician and based on professional standards of practice, to use the appropriate suctioning technique. During observations the resident experienced respiratory distress, and expressed ongoing anxiety and fear related to difficulty breathing. Staff interviewed was not aware of the physician's orders for tracheal suctioning and were not aware of the techniques to use during the suctioning treatment. Staff stated this was the first time they were scheduled to work in this unit, and had no prior experience in providing ventilator or tracheostomy care. This lack of knowledge of how to provide this specialized care including the technique for suctioning increases the likelihood for psychosocial harm, respiratory distress, obstruction of airways, and potentially death.

- The facility failed to provide emergency equipment available for accidental extubation for a resident on mechanical ventilation with a tracheostomy. (An extubation creates an emergency situation that requires that an obturator be readily available that can be used by competent staff for reinsertion). Upon interview, staff were not aware of the location of emergency equipment or how to use it in case of accidental extubation. As a result, it is likely any resident who experienced an accidental extubation would suffer serious harm or death.

Examples of Severity Level 3 Noncompliance, Actual Harm that is not Immediate Jeopardy includes but is not limited to:

- The facility failed to provide consistent oxygen therapy for a resident who required oxygen during periods of activity. Over a weekend, a resident's oxygen supply was depleted, and staff failed to order replacement oxygen. As a result, the resident experienced dyspnea when dressing, expressed increasing anxiety due to difficulty in "getting his/her breath when ambulating, and refused to go to the dining room for meals, or to take a shower, due to being short of breath.
- Facility failed to consistently implement a method for communication that had been established with a resident who was unable to verbally communicate due to being on a mechanical ventilator. The resident had indicated that a clipboard be used for him to write down requests and/or concerns, but night staff cleaning the room, removed it from the resident's bedside and placed it in an area inaccessible by the resident. This had occurred several times, according to the resident who expressed anger to the surveyor when he was interviewed and provided the clipboard. He wrote that staff told him/her to relax and calm down when he could not access the communication board. The resident wrote that he feels isolated, afraid and upset when he cannot use the preferred communication method. He indicated that he did not feel as if staff could be trusted to meet his concerns, and began to cry.

Examples of Severity Level 2 Noncompliance: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy include but are not limited to:

- The facility failed to assure that a resident had a portable supply of oxygen to take along when attending activities as ordered by the attending practitioner. The resident stayed in her room on oxygen and missed the activity programs she usually participated in. The resident stated that she was upset to have to miss the programs because staff failed to order her portable supply of oxygen.
- The facility failed to consistently perform coughing/deep breathing exercises as ordered for a resident, however, no increase or exacerbation of respiratory symptoms as a result of the lack of exercises was identified.

Severity Level 1: No actual harm with potential for minimal harm
The failures of the facility to provide appropriate care and services to provide respiratory care, including oxygen therapy, respiratory treatments and/or mechanical ventilation and tracheostomy care places a resident at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.