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 Email: publications.information@tn.gov

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 File Date: 9/30/16
 Effective Date: 12/29/16

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Bureau of TennCare
Contact Person:	George Woods
Address:	310 Great Circle Road
Zip:	37243
Phone:	(615) 507-6446
Email:	george.woods@tn.gov

Revision Type (check all that apply):

- Amendments
 New
 Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-13-01	TennCare Long-Term Care Programs
Rule Number	Rule Title
1200-13-01-.02	Definitions
1200-13-01-.03	Nursing Facility (NF) Provider Reimbursement
1200-13-01-.05	TennCare CHOICES Program
1200-13-01-.10	Medical (Level of Care) Eligibility Criteria for TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE

(Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos.tn.gov/sites/default/files/forms/Rulemaking_Guidelines_August2014.pdf)

Rule 1200-13-01-.02 Definitions is amended by adding a new paragraph in alphabetical order, to be numbered appropriately, to read as follows:

Enhanced Respiratory Care (ERC). Specialized types of assistance provided to individuals with certain significant respiratory care needs as part of the medically necessary services delivered in an appropriately licensed and dual certified NF/SNF, consisting of Ventilator Weaning, Chronic Ventilator Care, or Tracheal Suctioning including Sub-Acute and Secretion Management, and for which a NF may, pursuant to these rules, be eligible to receive Enhanced Respiratory Care Reimbursement.

Paragraph (45) Enhanced Respiratory Care Reimbursement of Rule 1200-13-01-.02 Definitions is deleted in its entirety and replaced with a new Paragraph (45) which shall read as follows:

(45) Enhanced Respiratory Care Reimbursement. Specified levels of reimbursement (i.e., Ventilator Weaning, Chronic Ventilator Care, and Tracheal Suctioning, including Sub-Acute and Secretion Management) provided for ERC delivered by a dual certified NF/SNF that meets the requirements set forth in Rule 1200-13-01-.03(5) to persons determined by the Bureau or an MCO to meet specified medical eligibility or medical necessity criteria for such level of reimbursement.

Paragraph (145) Tracheal Suctioning Reimbursement of Rule 1200-13-01-.02 Definitions is deleted in its entirety and replaced with a new Paragraph (145) which shall read as follows:

(145) Tracheal Suctioning Reimbursement. The rate of reimbursement provided for NF services, including enhanced respiratory care assistance, delivered by a dual certified NF/SNF that meets the requirements set forth in Rule 1200-13-01-.03(5), to residents determined by the Bureau to meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(5)(d) or determined by their TennCare MCO to require short-term intensive respiratory intervention during the post-weaning period, which shall include documented progress in weaning from the tracheostomy. Tracheal Suctioning Reimbursement shall include two (2) distinct levels of reimbursement as follows:

- (a) Secretion Management Tracheal Suctioning Reimbursement for services delivered by a dual certified NF/SNF to persons who meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(5)(d) and have an approved PAE for such level of reimbursement; and
- (b) Sub-Acute Tracheal Suctioning Reimbursement for short-term intensive respiratory intervention delivered by a dual certified NF/SNF and determined by the person's TennCare MCO to be medically necessary during the post-weaning period, which shall include documented progress in weaning from the tracheostomy. Because Sub-Acute Tracheal Suctioning Reimbursement provides for intensive respiratory intervention during the period immediately following a person's liberation from the ventilator, Sub-Acute Tracheal Suctioning Reimbursement shall be provided only in a bed specifically licensed for ventilator care.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105 and 71-5-109.

Subparagraph (a) of Paragraph (2) of Rule 1200-13-01-.03 Nursing Facility (NF) Provider Reimbursement is amended by adding the word "member" after the phrase "Medicaid Eligible" so that as amended Subparagraph (a) shall read as follows:

- (a) Reimbursement for NF services provided to a Medicaid Eligible member enrolled in the TennCare Program shall be categorized according to the needs of the individual and the level of skilled and/or rehabilitative services required as specified in Rule 1200-13-01-.10.

Subparagraph (b) of Paragraph (2) of Rule 1200-13-01-.03 Nursing Facility (NF) Provider Reimbursement is amended by deleting the lower case letter "r" in the word "reimbursement" and inserting in its place a capital "R", and by deleting the phrase "SNF (Level 2) care" and inserting in its place the phrase "NF/SNF care", so that as amended Subparagraph (b) shall read as follows:

- (b) Level 2 or Enhanced Respiratory Care NF Reimbursement shall be provided only for beds that are

certified by both Medicaid and Medicare for the provision of NF/SNF care.

Paragraph (2) of Rule 1200-13-01-.03 Nursing Facility (NF) Provider Reimbursement is amended by adding new Subparagraphs (c), (d), and (e) which shall read as follows:

- (c) Effective July 1, 2016, each level of Enhanced Respiratory Care Reimbursement shall be an add-on payment to the NF's established Level 2 per diem rate or the NF's blended per diem rate, when established. The amount of the NF's add-on payment for each of the specified levels of reimbursement shall be based on the facility's performance on quality outcome and technology measures pursuant to a methodology established by TennCare. Quality outcome and technology measures, performance benchmarks, and the methodology to apply such measures and benchmarks to each of the specified levels of Enhanced Respiratory Care Reimbursement may be adjusted during FY 2016-2017 to ensure compliance with the Appropriations Act, Public Chapter 758, and no more frequently than annually thereafter in order to continuously improve the quality of care and quality of life outcomes experienced by individuals receiving Enhanced Respiratory Care in a NF.
- (d) Enhanced Respiratory Care Reimbursement shall be provided only for services authorized and delivered in a facility operating in compliance with conditions of reimbursement for Enhanced Respiratory Care specified in this rule, and in a bed specifically licensed for such purpose, as applicable. A NF shall not be eligible for Enhanced Respiratory Care Reimbursement if it does not meet the conditions for reimbursement, or for any Enhanced Respiratory Care services provided in excess of the facility's licensed capacity to provide such services, regardless of payer source. Because Sub-Acute Tracheal Suctioning Reimbursement provides for intensive respiratory intervention during the period immediately following a person's liberation from the ventilator, Sub-Acute Tracheal Suctioning Reimbursement shall be provided only in a bed specifically licensed for ventilator care.
- (e) A NF shall be eligible for Enhanced Respiratory Care Reimbursement only if the facility has submitted complete, accurate and timely quality measurement data as required by TennCare in order to determine the NF's quality performance.
 - 1. Quality measurement data shall be submitted by the NF on a monthly basis.
 - 2. A NF's add-on per diem payment for each specified level of Enhanced Respiratory Care Reimbursement provided for NF services shall be adjusted based on the NF's quality performance no more frequently than semi-annually.
 - 3. A NF shall not be entitled to Enhanced Respiratory Care Reimbursement for any NF services provided if the facility has not complied with quality performance reporting requirements, or if any such data is determined (including upon post-payment audit or review) to be inaccurate or incomplete.
 - 4. Any facility submitting false (including inaccurate or incomplete) quality performance data for purposes of Medicaid payment shall be subject to all applicable federal and state laws pertaining to the submission of false claims.

Paragraph (5) Conditions for Reimbursement of Enhanced Respiratory Care of Rule 1200-13-01-.03 Nursing Facility (NF) Provider Reimbursement is deleted in its entirety and replaced with a new Paragraph (5) which shall read as follows:

- (5) Conditions for Enhanced Respiratory Care Reimbursement.
 - (a) The Level 2 NF must enter into a provider agreement with one or more TennCare MCOs for the provision and reimbursement of ERC in a dual certified and licensed NF/SNF.
 - 1. A TennCare MCO shall, pursuant to T.C.A. § 71-5-1412, as amended, contract with any nursing facility for the provision of Medicaid NF services, but shall not be obligated to reimburse any NF for Enhanced Respiratory Care.
 - 2. Unless an exception is granted, a TennCare MCO shall not reimburse any NF for Enhanced Respiratory Care unless such NF was contracted by the MCO for Enhanced Respiratory Care

Reimbursement as of July 1, 2016. An MCO may request an exception from TennCare to the moratorium on reimbursement for Enhanced Respiratory Care upon the MCO's demonstration of the need for additional capacity or improved quality in the geographic area in which the NF is located, and the NF's compliance with all applicable conditions of Enhanced Respiratory Care Reimbursement specified in this paragraph.

- (b) NFs providing Enhanced Respiratory Care services must be dual certified for the provision of Medicare SNF and Medicaid NF services, showing they have met the federal certification standards. Any NF participating in the TennCare Program shall be terminated by all TennCare MCOs as a TennCare provider if certification or licensure is terminated by CMS or the State.
- (c) NFs providing Ventilator Weaning or Chronic Ventilator Care services and NFs receiving short-term reimbursement at the Sub-Acute Tracheal Suctioning rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention, shall meet or exceed the following minimum standards:
 - 1. The NF shall ensure that medical direction of all Ventilator Weaning, Chronic Ventilator Care, and Sub-Acute Tracheal Suctioning services is provided by a physician licensed to practice in the State of Tennessee and board certified in pulmonary disease or critical care medicine as recognized by either the American Board of Medical Specialties or American Osteopathic Association, as applicable.
 - 2. A licensed respiratory care practitioner as defined by T.C.A. § 63-27-102, shall be on site in the ventilator care unit twenty four (24) hours per day, seven (7) days per week to provide:
 - (i) Ventilator care;
 - (ii) Administration of medical gases;
 - (iii) Administration of aerosol medications; and
 - (iv) Diagnostic testing and monitoring of life support systems.
 - 3. The NF shall ensure that an appropriate individualized POC is prepared for each resident receiving Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning. The POC shall be developed with input and participation from the medical director of the NF's Enhanced Respiratory Care program as described in Part 1.
 - 4. The NF shall establish admissions criteria to ensure the medical stability of ventilator-dependent residents prior to transfer from an acute care setting. The NF shall maintain documentation regarding the clinical evaluation of each resident who will receive Enhanced Respiratory Care for appropriateness of placement in the facility prior to admission.
 - 5. End tidal carbon dioxide (etCO₂) or transcutaneous monitoring of carbon dioxide and oxygen (tcCO₂) and continuous pulse oximetry measurements shall be available for all residents receiving Chronic Ventilator Care and provided based on the needs of each resident. For residents receiving Ventilator Weaning or Sub-Acute Tracheal Suctioning, continuous pulse oximetry shall be provided, and end tidal Carbon Dioxide (etCO₂) measurements shall be provided no less than every four (4) hours, and within one (1) hour following all vent parameter changes, or for residents receiving Sub-Acute Tracheal Suctioning, after all tracheostomy tube changes, tracheostomy capping trials, or the use of speaking devices.
 - 6. An audible, redundant external alarm system shall be connected to emergency power and/or battery back-up and located outside the room of each resident who is ventilator-dependent for the purpose of alerting staff of resident ventilator circuit disconnection or ventilator failure.
 - 7. Ventilator equipment (and ideally physiologic monitoring equipment) shall be connected to back-up generator power via clearly marked wall outlets.
 - 8. Ventilators shall be equipped with adequate back-up provisions, including:

- (i) Internal and/or external battery back-up systems to provide a minimum of eight (8) hours of power;
 - (ii) Sufficient emergency oxygen delivery devices (i.e., compressed gas or battery operated concentrators);
 - (iii) At least one (1) battery operated suction device available per every eight (8) residents on mechanical ventilator or with a tracheostomy; and
 - (iv) A minimum of one (1) patient-ready back-up ventilator which shall be available in the facility at all times.
9. The NF shall be equipped with current ventilator technology to encourage and enable maximum mobility and comfort, ideally weighing less than fifteen (15) pounds with various mounting options for portability (e.g., wheelchair, bedside table, or backpack).
10. The facility shall have an emergency preparedness plan specific to residents receiving Enhanced Respiratory Care (i.e., Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning) which shall specifically address total power failures (loss of power and generator), as well as other emergency circumstances.
11. The facility shall have a written training program, including an annual demonstration of competencies, for all staff caring for residents receiving Enhanced Respiratory Care (i.e., Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning), which shall include alarm response, positioning and transfers, care within licensure scope, and rescue breathing.
- (d) A NF contracted with one or more TennCare MCOs to receive Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning Reimbursement must be operating in compliance with Department of Health Rule 1200-08-06-.06(12) in order to be eligible for Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning Reimbursement. In addition, the NF shall provide attestation of its compliance with each of the requirements specified in Subparagraph (c) or shall submit a plan of correction regarding how it will achieve compliance with any condition not currently specified in Rule 1200-08-06-.06(12) no later than January 1, 2017, and shall maintain compliance on a continuous basis thereafter. As of January 1, 2017, a NF must be operating in compliance with all of the conditions specified in Subparagraph (c) in order to be eligible for Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning Reimbursement.
- (e) The standards set forth in Subparagraph (c) are not applicable for Secretion Management Tracheal Suctioning Reimbursement; however, the NF must meet standards specified in Subparagraph (f) below for Secretion Management Tracheal Suctioning Reimbursement.
- (f) A NF contracted with one or more TennCare MCOs to receive only Secretion Management Tracheal Suctioning Reimbursement shall meet or exceed the following minimum standards:
- 1. A licensed respiratory care practitioner as defined by T.C.A. § 63-27-102, shall be on site a minimum of weekly to provide:
 - (i) Clinical Assessment of each resident receiving Secretion Management Tracheal Suctioning (including Pulse Oximetry measurements);
 - (ii) Evaluation of appropriate humidification;
 - (iii) Tracheostomy site and neck skin assessment;
 - (iv) Care plan updates; and
 - (v) Ongoing education and training on patient assessment, equipment and treatment.
 - 2. The NF shall ensure that an appropriate individualized POC is prepared for each resident receiving Secretion Management Tracheal Suctioning. The POC shall be developed with input

and participation from a licensed respiratory care practitioner as defined by T.C.A. § 63-27-102. Medical direction, including POC development and oversight for persons receiving Sub-Acute Tracheal Suctioning shall be conducted in accordance with Subparagraph (c).

3. The NF shall establish admissions criteria which meet the standard of care to ensure the medical stability of residents who will receive Secretion Management Tracheal Suctioning prior to transfer from an acute care setting. The NF shall maintain pre-admission documentation regarding the clinical evaluation of each resident who will receive Secretion Management Tracheal Suctioning for appropriateness of placement in the facility.
 4. Pulse oximetry measurements shall be provided at least daily with continuous monitoring available, based on the needs of each resident. For any resident being weaned from the tracheostomy, the following shall be provided:
 - (i) Continuous pulse oximetry monitoring; and
 - (ii) End tidal Carbon Dioxide (etCO₂) measurements at least every four (4) hours and within one (1) hour following tracheostomy tube changes, tracheostomy capping trials, or the use of speaking devices. Transcutaneous (tcCO₂) shall not be appropriate for intermittent monitoring.
 5. Mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy shall also be available for secretion management, as appropriate for the needs of each resident.
 6. Oxygen equipment shall be connected to back-up generator power via clearly marked wall outlets.
 7. Adequate back-up provisions shall be in place including:
 - (i) Sufficient emergency oxygen delivery devices (i.e. compressed gas or battery operated concentrators); and
 - (ii) At least one (1) battery operated suction device available per every eight (8) residents on mechanical ventilation or with a tracheostomy.
 8. The facility shall have an emergency preparedness plan specific to residents receiving Secretion Management Tracheal Suctioning which shall specifically address total power failures (loss of power and generator), as well as other emergency circumstances.
 9. The facility shall have a written training program, including an annual demonstration of competencies, for all staff caring for residents receiving Secretion Management Tracheal Suctioning which shall include alarm response, positioning and transfers, care within licensure scope, and rescue breathing.
- (g) When a NF establishes a "Tracheostomy Unit" by accepting Tracheal Suctioning Reimbursement, including Sub-Acute and Secretion Management, for more than three (3) residents on the same day the licensed respiratory care practitioner described in Part (f)1 shall be on site a minimum of daily for assessment, care management, and care planning of residents receiving Tracheal Suctioning.
- (h) A NF contracted with one or more TennCare MCOs to receive Secretion Management Tracheal Suctioning Reimbursement shall provide attestation of its compliance with each of the requirements specified in Subparagraph (f) or shall submit a plan of correction regarding how it will achieve compliance no later than January 1, 2017, and shall maintain compliance on a continuous basis thereafter. As of January 1, 2017, a NF must be operating in compliance with all of the conditions specified in Subparagraph (f) in order to be eligible for Secretion Management Tracheal Suctioning Reimbursement.
- (i) Eligibility for and access to ERC services by individuals from out of state is governed by 42 C.F.R. § 435.403. A NF shall not recruit individuals from other states to receive Enhanced Respiratory Care in Tennessee. A NF shall not be eligible to receive TennCare reimbursement for Enhanced Respiratory

Care services for a resident placed by another state or any agency acting on behalf of another state in making the placement because such services are not available in the individual's current state of residence, including residents admitted to the NF/SNF under the Medicare Skilled Nursing Facility care benefit when such benefit has been exhausted. The NF shall be responsible for arranging, prior to the resident's admission to the facility, Medicaid reimbursement for Enhanced Respiratory Care services from the Medicaid Agency of the state which placed the resident and which will commence when other payment sources (e.g., Medicare, private pay, but not TennCare) have been exhausted.

Paragraph (8) of Rule 1200-13-01-.03 Nursing Facility (NF) Provider Reimbursement is deleted in its entirety and replaced with a new Paragraph (8) which shall read as follows:

- (8) Enhanced Respiratory Care Reimbursement in a dual certified and licensed NF/SNF shall be made only by TennCare MCOs in accordance with this Chapter and rates established by the Bureau. Effective July 1, 2016, each level of Enhanced Respiratory Care Reimbursement shall be an add-on payment to the NF's established Level 2 per diem rate or the NF's blended per diem rate, when established. The amount of the NF's add-on payment for each of the specified levels of reimbursement shall be based on the facility's performance on quality outcome and technology measures pursuant to a methodology established by TennCare. Quality outcome and technology measures, performance benchmarks, and the methodology to apply such measures and benchmarks to each of the specified levels of Enhanced Respiratory Care Reimbursement may be adjusted during FY 2016-2017 to ensure compliance with the Appropriations Act, Public Chapter 758, and no more frequently than annually thereafter in order to continuously improve the quality of care and quality of life outcomes experienced by individuals receiving Enhanced Respiratory Care in a NF.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105 and 71-5-109.

Item (III) of Subpart (i) of Part 3. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Item (III) which shall read as follows:

- (III) A Member determined by TennCare to meet the medical eligibility criteria in Rule 1200-13-01-.10(5)(c) who would qualify for Chronic Ventilator Care or a Member determined by the Bureau to meet the medical eligibility criteria in Rule 1200-13-01-.10(5)(d) who would qualify for Secretion Management Tracheal Suctioning will have a Cost Neutrality Cap that reflects the higher payment that would be made to a NF for such care. For at least FY 2016-2017, the Cost Neutrality Cap for such CHOICES Group 2 member shall be based on the annualized cost of the applicable Enhanced Respiratory Care rate in effect as of June 30, 2016. Beginning July 1, 2017, the Cost Neutrality Cap for such CHOICES Group 2 member may be established based on the average annualized cost of the applicable level of Enhanced Respiratory Care Reimbursement using payments for such level of reimbursement during the FY 2016-2017 year. The Cost Neutrality Cap for such CHOICES Group 2 member shall be adjusted no more frequently than annually thereafter. There is no Cost Neutrality Cap based on the cost of Ventilator Weaning Reimbursement or Sub-Acute Tracheal Suctioning Reimbursement, as such services are available only on a short-term basis in a SNF or acute care setting.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105 and 71-5-109.

Subpart (iii) of Part 2. of Subparagraph (b) of Paragraph (5) of Rule 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE is amended by adding an apostrophe after the word "nurses" in the phrase "nurses aides" so that as amended Subpart (iii) shall read:

- (iii) A skilled rehabilitative service must be expected to improve the Applicant's condition. Restorative and maintenance nursing procedures (e.g., routine range of motion exercises; stand-by assistance during ambulation; applications of splints/braces by nurses and nurses' aides) shall not be considered sufficient to fulfill the requirement of (5)(b)2. Factors to be considered in the decision as to whether a rehabilitative service meets, or continues to meet, the requirement of (5)(b)2. shall include, but not be limited to, an assessment of the type of therapy and its frequency, the remoteness of the injury

or impairment, and the reasonable potential for improvement in the Applicant's functional capabilities or medical condition.

Subparagraph (c) of Paragraph (5) of Rule 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE is amended by adding a new sentence at the end of the Subparagraph so as amended Subparagraph (c) shall read as follows:

- (c) In order to be approved for TennCare-reimbursed care in a NF at the Chronic Ventilator rate of reimbursement, an Applicant must be ventilator dependent for at least 12 hours each day with an invasive patient end of the circuit (i.e., tracheostomy cannula). On a case-by-case basis, TennCare may, subject to additional medical review, authorize Chronic Ventilator Reimbursement for an Applicant who is ventilator dependent with a progressive neuromuscular disorder, spinal cord injury, or chronic respiratory failure and is ventilated using noninvasive positive pressure ventilation (NIPPV) by mask or mouthpiece for at least 12 hours each day in order to avoid or delay tracheostomy.

Subparagraph (d) of Paragraph (5) of Rule 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE is deleted in its entirety and replaced with a new Subparagraph (d) which shall read as follows:

- (d) In order to be approved by the Bureau for TennCare-reimbursed care in a NF at the Secretion Management Tracheal Suctioning rate of reimbursement:
 - 1. An Applicant must have a functioning tracheostomy and a copious volume of secretions, and require either:
 - (i) Invasive tracheal suctioning, at a minimum, once every three (3) hours with documented assessment pre- and post-suctioning; or
 - (ii) The use of mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy, at a minimum, three (3) times per day with documented assessment pre-and post.
 - (I) A copious volume of secretions shall be defined as 25 to 30 ml per day occurring over the course of the day, and not necessarily at every suctioning.
 - (II) The requirement for invasive tracheal suctioning, at a minimum, once every three (3) hours shall be applied as a marker of the severity of the Applicant's respiratory care needs. Secretion Management Tracheal Suctioning is not a scheduled intervention and shall not be performed as a medication would be delivered, i.e., at scheduled intervals (except as prescribed by an appropriately licensed health care professional practicing within the scope of his or her license). Rather, tracheal suctioning should be provided as clinically indicated, based on the needs of each person requiring such care; evidence of the need should be clearly and accurately documented. This could mean a shorter or longer interval at any point, but with a clinical need for invasive tracheal suctioning an average of every three (3) hours or more often in order to qualify for Secretion Management Tracheal Suctioning Reimbursement, except when mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy are used to manage secretions.
 - (III) When mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy are used to manage secretions, there must be documented evidence of the Applicant's copious secretions, but they are managed non-invasively using a cough assist device periodically or high flow molecular humidity continuously or at least three (3) times per day as ongoing treatment. The device is expected to provide ongoing relief of the copious volume of secretions, which shall not negate the need for intervention (and eligibility for Secretion Management Tracheal Suctioning Reimbursement), if absent the high flow device, the copious volume of secretions would require more invasive management.

2. The suctioning (or airway clearance, as applicable) must be required to remove excess secretions and/or aspirate from the trachea, which cannot be removed by the Applicant's spontaneous effort. Suctioning of the nasal or oral cavity does not qualify for this higher level of reimbursement. An MCO may authorize, based on medical necessity, short-term payment at the Sub-Acute Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention during the post-weaning period which shall include documented progress in weaning from the tracheostomy.
3. A PAE for Secretion Management Tracheal Suctioning Reimbursement shall be approved for no more than a period of thirty (30) days. Clinical review and approval of a new PAE shall be required for ongoing coverage, which shall include evaluation of clinical progress and the NF's efforts to improve secretion management through alternative methods. TennCare may, on a case-by-case basis, approve a PAE for Secretion Management Tracheal Suctioning Management Reimbursement for a period of more than thirty (30) days, e.g., if a person has ALS (amyotrophic lateral sclerosis) or another progressive neuromuscular disorder, spinal cord injury, or chronic respiratory failure, or is in a persistent vegetative state, and evidence clearly supports that ongoing secretion management tracheal suctioning is expected to continue.
4. A NF who has an approved PAE for Tracheal Suctioning Reimbursement for any resident as of July 1, 2016 shall be entitled to continue to receive such level of reimbursement no later than July 31, 2016 (or any earlier date that may be specified in the approved PAE). The NF shall submit a new PAE for such resident no later than July 19, 2016 in order to determine whether Secretion Management Tracheal Suctioning Reimbursement will be continued, or whether a different level of NF reimbursement is appropriate.

Subparagraph (e) of Paragraph (5) of Rule 1200-13-01-10 Medical (Level of Care) Eligibility Criteria for TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE is deleted in its entirety and replaced with a new Subparagraph (e) which shall read as follows:

- (e) Determination of medical necessity and authorization for Ventilator Weaning Reimbursement, or short-term payment at the Sub-Acute Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention shall be managed by the Enrollee's MCO.

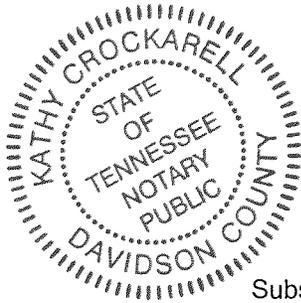
Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105 and 71-5-109.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of finance and Administration (board/commission/ other authority) on 09/22/2016 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 07/15/16

Rulemaking Hearing(s) Conducted on: (add more dates). 09/12/16



Date: 9/22/16

Signature: Wendy Long MD

Name of Officer: Wendy Long, M.D., M.P.H.
Director, Bureau of TennCare

Title of Officer: Tennessee Department of Finance and Administration

Subscribed and sworn to before me on: 9/22/16

Notary Public Signature: Kathy Crockarell

My commission expires on: 1/8/2019

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Stately III
Herbert H. Stately III
Attorney General and Reporter

9/29/2016
Date

Department of State Use Only

Filed with the Department of State on: 9/30/16

Effective on: 12/29/16

Tre Hargett
Tre Hargett
Secretary of State

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PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

HCFA received comments from six individuals or entities concerning these rules. The comments and HCFA's responses to the comments are summarized below.

Several commenters expressed concern about the requirement in the rule for a new PreAdmission Evaluation (PAE) every 30 days for tracheal suctioning patients. These commenters suggested that the requirement is unduly onerous, or would not allow for timely authorization for current ERC patients. In response, HCFA modified the rule in order to allow longer timeframes on a case-by-case basis for patients with certain conditions.

Several commenters expressed concern that a significant number of hospital referrals would be denied admission to certain facilities due to inability to meet patients' needs with the new reimbursement structure. HCFA clarified that it does not anticipate that the changes implemented by the rule will increase denials of referral for hospital admission, except where appropriate. HCFA noted that one of the most serious concerns observed in onsite reviews was the lack of clear admission criteria that would ensure patients were stable enough for transfer from the hospital to the facility prior to admission. The rule includes admission criteria requirements, and also includes hospital readmissions and unanticipated deaths as quality outcomes measures in part to help address these concerns.

Several commenters expressed concern that quality rankings which partially depend on weaning rates was unfair to facilities which provide services for unweanable patients, such as individuals with neuromuscular disease. HCFA noted that liberation from a ventilator—the primary objective of the ERC program since its inception—is a critical quality outcome measure with tremendous potential to impact the quality of life of individuals with chronic respiratory needs.

Several commenter expressed concern that the quality data were not verified by a third party. HCFA noted the extensive training, technical assistance, measurement, review, and notification activities that contributed to the establishment of initial ERC program benchmarks and setting the initial quality-adjusted reimbursement rates. One commenter indicated that the fiscal impact of these rules would be detrimental to facilities providing ERC services and recommended that the rule not be adopted. HCFA noted the need to managed spending growth in the area of ERC services, and the need to implement the budget reduction required by the FY 2016-2017 budget. HCFA also noted, however, that the primary focus of the rule is to improve the quality of care and quality of life experienced by individuals with ERC needs. HCFA reiterated the extensive planning and public notice activities that contributed to the development of the rule. Several other commenters suggested that the calculated savings associated with these rules were "short-sighted" and did not account for cost savings in other settings, such as HCBS, long-term acute care, and hospitals. HCFA noted the need to manage spending growth in enhanced respiratory care settings at a sustainable level over time.

One commenter suggested that the requirements for carbon dioxide monitoring for ventilator and tracheostomy patients in the rule exceed the monitoring that occurs in intensive care units and questioned the appropriateness of the requirements. HCFA disagreed that it is appropriate to compare skilled nursing facilities to intensive care settings, which typically have a one-to-one caregiver-to-patient ratio and more advanced monitoring resources. HCFA maintains that the requirements in the rule are appropriate and necessary to ensure patient safety.

Several commenters requested information about the basis for the requirement in the rule for a minimum of 12 hours of non-invasive ventilator support to qualify for ventilator reimbursement. In response, HCFA noted that this requirement is not a standard of care, but rather a requirement for receiving higher ERC reimbursement.

One commenter asked that the requirement in the rule for suctioning every three hours to qualify for Secretion Management reimbursement was excessive. Another commenter noted that pneumonias are possible in patients with minimal secretions. In response, HCFA noted that nursing facilities have long provided for the routine suctioning needs of their patients, and that the higher level of reimbursement for Secretion Management is intended for those patients who have excessive volumes of secretions, or who would have such volumes absent

the use of appropriate airway clearance devices. HCFA modified the rule to provide additional clarity about what constitutes a copious volume of secretions and the frequency of suctioning or airway clearance.

One commenter suggested that the three-times-a-day requirement for mechanical airway clearance in the rule is excessive. In response, HCFA noted that not every patient who requires some level of suctioning or airway clearance will need such assistance three times a day, and the higher level of reimbursement for Secretion Management is intended for those patients who have excessive volumes of secretions, or who would have such volumes absent the use of appropriate airway clearance devices.

One commenter suggested that other modalities for airway management, such as saline-triggered cough in neuro-impaired patients and the management of excessive oral secretions in neuromuscular patients, should be included in HCFA airway clearance policies. HCFA referred the commenter to AARP Guidelines for Endotracheal Suctioning of Mechanically Ventilated Patients with Artificial Airways, and noted that these alternative modalities for airway management should not be routinely performed prior to performing endotracheal suctioning.

One commenter questioned the basis for certain changes to the definitions of particular services. In response, HCFA noted that these definitions have been in place since 2010 and are not changed by this rule, except to distinguish between the different types of Tracheal Suctioning Reimbursement – Sub-Acute and Secretion Management – and to include (based on clinical best practices) the ability to approve Ventilator Care reimbursement under certain circumstances for individuals who are ventilated using noninvasive positive pressure ventilation by mask or mouthpiece for at least 12 hours each day in order to avoid or delay tracheostomy.

One commenter suggested that the provision of the rule that specifies that TennCare MCOs will not contract with any nursing facility for ERC services unless such NF was contracted by the MCO for ERC as of July 1, 2016, was contrary to state law. In response, HCFA modified the rule to clarify that the provision in question addresses reimbursement of nursing facilities for ERC services, not contracts with nursing facilities.

One commenter expressed concern about the provision in the rule concerning the responsibility of nursing facilities for arranging Medicaid reimbursement for ERC services from other states, as appropriate, when individuals from other states are placed in Tennessee facilities. This commenter suggested that the rule be modified to only apply when another state requests placements in Tennessee facilities for one of their citizens. HCFA noted that federal regulation establishes the responsibilities of nursing facilities relating to placements in out-of-state institutions.

One commenter objected to the rule on the basis that TennCare should not “take over the management role in respiratory units.” In response, HCFA noted that the rule does not purport to assume management of any healthcare provider, and emphasized the intent of the rule to use public resources responsibly and to support the delivery of high-quality care by establishing reasonable expectations regarding standards of care and outcomes facilities should demonstrate in order to receive enhanced reimbursement.

One commenter suggested that facilities’ quality rankings should not be based in part on the availability of certain types of equipment, on the basis that not all facilities can afford certain equipment. In response, HCFA noted that the higher rates of reimbursement paid for ERC services carry a reasonable expectation of investment in the technologies and staff needed to provide quality care and achieve quality outcomes. This commenter specifically suggested that beepers/pagers are not necessary when facility staff remain in the patient area. HCFA noted that beepers/pagers are not required by the rule, but that the rule is intended to recognize facilities that upgrade to more advanced warning/safety technology.

One commenter suggested that the end-tidal carbon dioxide (ETCO₂) monitoring requirements in the rule are “unwarranted.” In response, HCFA noted that the requirements are based on clinical guidance, and that the efficacy of such guidelines has been documented in multiple studies. Another commenter objected to the rule on the basis that the requirements in the rule do not reflect evidence-based medical requirements. In response, HCFA noted the extensive involvement of nationally recognized experts in the development of the rule.

One commenter suggested that the PreAdmission Evaluation (PAE) process is slow and time-consuming. In response, HCFA noted that the PAE process is not affected by this rule. HCFA continues to process PAEs within no more than eight business days, and typically much faster.

One commenter suggested that the 10LPM concentrator requirement for all ventilator patients is “unwarranted.” In response, HCFA noted that this is not a requirement of this rule. Rather, it is a requirement by Health Care Facilities, the licensing and certification entity, when there is no piped gas in the facility, and outside the scope of this rulemaking.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

The rules are not anticipated to have an effect on small businesses.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

The rules are not anticipated to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rules are being promulgated to replace emergency rules which clarified the requirements which must be met by providers of services as well as the payment methodology for reimbursement for Enhanced Respiratory Care services provided through the TennCare Long-Term Services and Supports program.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The Rules are lawfully adopted by the Bureau of TennCare in accordance with §§ 4-5-202, 71-5-105 and 71-5-109.

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The persons and entities most directly affected by these Rules are the TennCare enrollees, providers, and managed care contractors. The governmental entity most directly affected by these Rules is the Bureau of TennCare, Tennessee Department of Finance and Administration.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

The Rules were approved by the Tennessee Attorney General. No additional opinion was given or requested.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

The promulgation of these rules is anticipated to decrease state government expenditures by \$755,500, as reported in the Health Care Finance and Administration Fiscal Year Budget Reduction Plan and incorporated in the Appropriations Act.

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Donna K. Tidwell
Deputy General Counsel

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Donna K. Tidwell
Deputy General Counsel

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

310 Great Circle Road
Nashville, TN 37243
(615) 507-6852
donna.tidwell@tn.gov

(l) Any additional information relevant to the rule proposed for continuation that the committee requests.

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Rules
of
Tennessee Department of Finance
and Administration
Bureau of TennCare

Chapter 1200-13-01
TennCare Long-Term Care Programs

1200-13-01-.02 Definitions.

- # Enhanced Respiratory Care (ERC). Specialized types of assistance provided to individuals with certain significant respiratory care needs as part of the medically necessary services delivered in an appropriately licensed and dual certified NF/SNF, consisting of Ventilator Weaning, Chronic Ventilator Care, or Tracheal Suctioning including Sub-Acute and Secretion Management, and for which a NF may, pursuant to these rules, be eligible to receive Enhanced Respiratory Care Reimbursement.
- (45) Enhanced Respiratory Care Reimbursement. Specified levels of reimbursement (i.e., Ventilator Weaning, Chronic Ventilator Care, and Tracheal Suctioning, and Ventilator Weaning including Sub-Acute and Secretion Management) provided for NF ERC services delivered by a dual certified NF/SNF that meets the requirements set forth in Rule 1200-13-01-.03(5) to persons determined by the Bureau or an MCO to meet specified medical eligibility or medical necessity criteria for such level of reimbursement.
- (145) Tracheal Suctioning Reimbursement. The rate of reimbursement provided for NF services, including enhanced respiratory care assistance, delivered by a dual certified NF/SNF that meets the requirements set forth in Rule 1200-13-01-.03(5), to residents determined by the Bureau to meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(5)(e) or determined by an their TennCare MCO to require short-term intensive respiratory intervention during the post-weaning period, which shall include documented progress in weaning from the tracheostomy. Tracheal Suctioning Reimbursement shall include two (2) distinct levels of reimbursement as follows:
- (a) Secretion Management Tracheal Suctioning Reimbursement for services delivered by a dual certified NF/SNF to persons who meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(5)(e) and have an approved PAE for such level of reimbursement; and
- (b) Sub-Acute Tracheal Suctioning Reimbursement for short-term intensive respiratory intervention delivered by a dual certified NF/SNF and determined by the person's TennCare MCO to be medically necessary during the post-weaning period, which shall include documented progress in weaning from the tracheostomy. Because Sub-Acute Tracheal Suctioning Reimbursement provides for intensive respiratory intervention during the period immediately following a person's liberation from the ventilator, Sub-Acute Tracheal Suctioning Reimbursement shall be provided only in a bed specifically licensed for ventilator care.

1200-13-01-.03 Nursing Facility (NF) Provider Reimbursement.

- (2) Level 1, Level 2, and Enhanced Respiratory Care NF Reimbursement.
- (a) Reimbursement for NF services provided to a Medicaid Eligible member enrolled in the TennCare Program shall be categorized according to the needs of the individual and the level of skilled and/or rehabilitative services required as specified in Rule 1200-13-01-.10.
- (b) Level 2 or Enhanced Respiratory Care NF Reimbursement shall be provided only for beds that are certified for by both Medicaid and Medicare for the provision of NF/SNF (Level-2) care.
- (c) Effective July 1, 2016, each level of Enhanced Respiratory Care Reimbursement shall be an add-on payment to the NF's established Level 2 per diem rate or the NF's blended per diem rate, when established. The amount of the NF's add-on payment for each of the specified levels of reimbursement shall be based on the facility's performance on quality outcome and technology measures pursuant to a methodology established by TennCare. Quality outcome and technology

measures, performance benchmarks, and the methodology to apply such measures and benchmarks to each of the specified levels of Enhanced Respiratory Care Reimbursement may be adjusted during FY 2016-2017 to ensure compliance with the Appropriations Act, Public Chapter 758, and no more frequently than annually thereafter in order to continuously improve the quality of care and quality of life outcomes experienced by individuals receiving Enhanced Respiratory Care in a NF.

(d) Enhanced Respiratory Care Reimbursement shall be provided only for services authorized and delivered in a facility operating in compliance with conditions of reimbursement for Enhanced Respiratory Care specified in this rule, and in a bed specifically licensed for such purpose, as applicable. A NF shall not be eligible for Enhanced Respiratory Care Reimbursement if it does not meet the conditions for reimbursement, or for any Enhanced Respiratory Care services provided in excess of the facility's licensed capacity to provide such services, regardless of payer source. Because Sub-Acute Tracheal Suctioning Reimbursement provides for intensive respiratory intervention during the period immediately following a person's liberation from the ventilator, Sub-Acute Tracheal Suctioning Reimbursement shall be provided only in a bed specifically licensed for ventilator care.

(e) A NF shall be eligible for Enhanced Respiratory Care Reimbursement only if the facility has submitted complete, accurate and timely quality measurement data as required by TennCare in order to determine the NF's quality performance.

1. Quality measurement data shall be submitted by the NF on a monthly basis.

2. A NF's add-on per diem payment for each specified level of Enhanced Respiratory Care Reimbursement provided for NF services shall be adjusted based on the NF's quality performance no more frequently than semi-annually.

3. A NF shall not be entitled to Enhanced Respiratory Care Reimbursement for any NF services provided if the facility has not complied with quality performance reporting requirements, or if any such data is determined (including upon post-payment audit or review) to be inaccurate or incomplete.

4. Any facility submitting false (including inaccurate or incomplete) quality performance data for purposes of Medicaid payment shall be subject to all applicable federal and state laws pertaining to the submission of false claims.

(5) Conditions for Reimbursement of Enhanced Respiratory Care Reimbursement.

(a) The Level 2 NF must enter into a provider agreement with one or more TennCare MCOs for the provision and reimbursement of ventilator weaning, chronic ventilator services and/or tracheal suctioning in a level 2 certified and licensed NF-ERC in a dual certified and licensed NF/SNF.

1. A TennCare MCO shall, pursuant to T.C.A. § 71-5-1412, as amended, contract with any nursing facility for the provision of Medicaid NF services, but shall not be obligated to reimburse any NF for Enhanced Respiratory Care.

2. Unless an exception is granted, a TennCare MCO shall not reimburse any NF for Enhanced Respiratory Care unless such NF was contracted by the MCO for Enhanced Respiratory Care Reimbursement as of July 1, 2016. An MCO may request an exception from TennCare to the moratorium on reimbursement for Enhanced Respiratory Care upon the MCO's demonstration of the need for additional capacity or improved quality in the geographic area in which the NF is located, and the NF's compliance with all applicable conditions of Enhanced Respiratory Care Reimbursement specified in this paragraph.

(b) NFs providing (Medicare SNFs and TennCare NFs providing enhanced respiratory care services in a Level 2 NF) must be certified by Medicare, showing they have met the federal certification standards. Enhanced Respiratory Care services must be dual certified for the provision of Medicare SNF and Medicaid NF services, showing they have met the federal certification standards. Any of these NFs participating in the TennCare Program shall be terminated by all TennCare MCOs as a TennCare provider if certification or licensure is canceled by CMS or the State.

(c) NFs providing Ventilator Weaning or Chronic Ventilator Care services and NFs receiving short-term reimbursement at the Sub-Acute Tracheal Suctioning Rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention, shall also meet or exceed the following minimum standards:

1. The NF shall ensure that medical direction of all Ventilator Weaning, Chronic Ventilator Care, and Sub-Acute Tracheal Suctioning services is provided by a physician licensed to practice in the State of Tennessee and board certified in pulmonary disease or critical care medicine as recognized by either the American Board of Medical Specialties or American Osteopathic Association, as applicable.

42. A licensed respiratory care practitioner as defined by T.C.A. § 63-27-102(7), shall be on site in the ventilator care unit twenty four (24) hours per day, seven (7) days per week to provide:

- (i) Ventilator care;
- (ii) Administration of medical gases;
- (iii) Administration of aerosol medications; and
- (iv) Diagnostic testing and monitoring of life support systems.

23. ~~The NF shall ensure that an appropriate individualized POC is prepared for each resident requiring ventilator services~~ receiving Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning. The POC shall be developed with input and participation from the medical director of the NF's Enhanced Respiratory Care program as described in Part 1 a pulmonologist or a physician with experience in ventilator care.

34. The NF shall establish admissions criteria to ensure the medical stability of ventilator-dependent residents prior to transfer from an acute care setting. The NF shall maintain documentation regarding the clinical evaluation of each resident who will receive Enhanced Respiratory Care for appropriateness of placement in the facility prior to admission.

45. End tidal carbon dioxide (etCO₂) or transcutaneous monitoring of carbon dioxide and oxygen (tcCO₂) and continuous pulse oximetry measurements shall be available for all residents receiving Chronic Ventilator Care and provided based on the needs of each resident. For residents receiving Ventilator Weaning or Sub-Acute Tracheal Suctioning, continuous pulse oximetry shall be provided, and end tidal Carbon Dioxide (etCO₂) measurements shall be provided no less than every four (4) hours, and within one (1) hour following all vent-parameter changes, or for residents receiving Sub-Acute Tracheal Suctioning, after all tracheostomy tube changes, tracheostomy capping trials, or the use of speaking devices.

~~Arterial Blood Gas (ABG) shall be readily available in order to document the resident's acid base status and/or End Tidal Carbon Dioxide (etCO₂) and continuous pulse oximetry measurements should be performed in lieu of ABG studies.~~

56. An audible, redundant external alarm system shall be connected to emergency power and/or battery back-up and located outside of each the room of each resident who is ventilator-dependent resident's room for the purpose of alerting caregivers ~~of resident disconnection-~~ staff of resident ventilator circuit disconnection or ventilator failure.

67. Ventilator equipment (and ideally physiologic monitoring equipment) shall be connected to ~~electrical outlets connected to back-up generator power via clearly marked wall outlets.~~

78. Ventilators shall be equipped with adequate back-up systems provisions, including:-

- (i) Internal and/or external battery back-up systems to provide a minimum of eight (8) hours of power;

- (ii) Sufficient emergency oxygen delivery devices (i.e., compressed gas or battery operated concentrators);
- (iii) At least one (1) battery operated suction device available per every eight (8) residents on mechanical ventilator or with a tracheostomy; and
- (iv) A minimum of one (1) patient-ready back-up ventilator which shall be available in the facility at all times.

89. The NF shall be equipped to employ the use of current ventilator technology consistent with meeting residents' needs for mobility and comfort with current ventilator technology to encourage and enable maximum mobility and comfort, ideally weighing less than fifteen (15) pounds with various mounting options for portability (e.g., wheelchair, bedside table, or backpack).

910. The facility shall have an emergency preparedness plan specific to residents receiving Enhanced Respiratory Care (i.e., Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning) which shall specifically address total power failures (loss of power and generator), as well as other emergency circumstances. A (one) back-up ventilator shall be available at all times in the facility.

11. The facility shall have a written training program, including an annual demonstration of competencies, for all staff caring for residents receiving Enhanced Respiratory Care (i.e., Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning), which shall include alarm response, positioning and transfers, care within licensure scope, and rescue breathing.

(d) A NF contracted with one or more TennCare MCOs to receive Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning Reimbursement must be operating in compliance with Department of Health rule 1200-08-06-.06(12) in order to be eligible for Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning Reimbursement. In addition, the NF shall provide attestation of its compliance with each of the requirements specified in Subparagraph (c) or shall submit a plan of correction regarding how it will achieve compliance with any condition not currently specified in 1200-08-06-.06(12) no later than January 1, 2017, and shall maintain compliance on a continuous basis thereafter. As of January 1, 2017, a NF must be operating in compliance with all of the conditions specified in Subparagraph (c) in order to be eligible for Ventilator Weaning, Chronic Ventilator Care, or Sub-Acute Tracheal Suctioning Reimbursement.

~~Except as provided in (c) above, the standards set forth in (c) are not applicable for Tracheal Suctioning Reimbursement; however, the NF must ensure the availability of necessary equipment, supplies, and appropriately trained and licensed nurses or licensed respiratory therapists to perform the specified tasks.~~

(e) The standards set forth in Subparagraph (c) are not applicable for Secretion Management Tracheal Suctioning Reimbursement; however, the NF must meet standards specified in Subparagraph (f) below for Secretion Management Tracheal Suctioning Reimbursement.

~~If the resident has available resources to apply toward payment, including Patient Liability as determined by DHS, or TPL, which may include LTC insurance benefits, the payment made by the Bureau is the per diem rate established by the Bureau minus the resident's available resources.~~

(f) A NF contracted with one or more TennCare MCOs to receive only Secretion Management Tracheal Suctioning Reimbursement shall meet or exceed the following minimum standards:

1. A licensed respiratory care practitioner as defined by T.C.A. § 63-27-102, shall be on site a minimum of weekly to provide:

- (i) Clinical Assessment of each resident receiving Secretion Management Tracheal Suctioning (including Pulse Oximetry measurements);

- (ii) Evaluation of appropriate humidification;
 - (iii) Tracheostomy site and neck skin assessment;
 - (iv) Care plan updates; and
 - (v) Ongoing education and training on patient assessment, equipment and treatment.
- 2. The NF shall ensure that an appropriate individualized POC is prepared for each resident receiving Secretion Management Tracheal Suctioning. The POC shall be developed with input and participation from a licensed respiratory care practitioner as defined by T.C.A. § 63-27-102. Medical direction, including POC development and oversight for persons receiving Sub-Acute Tracheal Suctioning shall be conducted in accordance with Subparagraph (c).
- 3. The NF shall establish admissions criteria which meet the standard of care to ensure the medical stability of residents who will receive Secretion Management Tracheal Suctioning prior to transfer from an acute care setting. The NF shall maintain pre-admission documentation regarding the clinical evaluation of each resident who will receive Secretion Management Tracheal Suctioning for appropriateness of placement in the facility.
- 4. Pulse oximetry measurements shall be provided at least daily with continuous monitoring available, based on the needs of each resident. For any resident being weaned from the tracheostomy, the following shall be provided:
 - (i) Continuous pulse oximetry monitoring; and
 - (ii) End tidal Carbon Dioxide (etCO₂) measurements at least every four (4) hours and within one (1) hour following tracheostomy tube changes, tracheostomy capping trials, or the use of speaking devices. Transcutaneous (tcCO₂) shall not be appropriate for intermittent monitoring.
- 5. Mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy shall also be available for secretion management, as appropriate for the needs of each resident.
- 6. Oxygen equipment shall be connected to back-up generator power via clearly marked wall outlets.
- 7. Adequate back-up provisions shall be in place including:
 - (i) Sufficient emergency oxygen delivery devices (i.e. compressed gas or battery operated concentrators); and
 - (ii) At least one (1) battery operated suction device available per every eight (8) residents on mechanical ventilation or with a tracheostomy.
- 8. The facility shall have an emergency preparedness plan specific to residents receiving Secretion Management Tracheal Suctioning which shall specifically address total power failures (loss of power and generator), as well as other emergency circumstances.
- 9. The facility shall have a written training program, including an annual demonstration of competencies, for all staff caring for residents receiving Secretion Management Tracheal Suctioning which shall include alarm response, positioning and transfers, care within licensure scope, and rescue breathing.
- (g) When a NF establishes a "Tracheostomy Unit" by accepting Tracheal Suctioning Reimbursement, including Sub-Acute and Secretion Management, for more than three (3) residents on the same day the licensed respiratory care practitioner described in Part (f)1 shall be on site a minimum of daily for assessment, care management, and care planning of residents receiving Tracheal Suctioning.
- (h) A NF contracted with one or more TennCare MCOs to receive Secretion Management Tracheal

Suctioning Reimbursement shall provide attestation of its compliance with each of the requirements specified in Subparagraph (f) above, or shall submit a plan of correction regarding how it will achieve compliance no later than January 1, 2017, and shall maintain compliance on a continuous basis thereafter. As of January 1, 2017, a NF must be operating in compliance with all of the conditions specified in Subparagraph (f) in order to be eligible for Secretion Management Tracheal Suctioning Reimbursement.

- (i) Eligibility for and access to ERC services by individuals from out of state is governed by 42 C.F.R. § 435.403. A NF shall not recruit individuals from other states to receive Enhanced Respiratory Care in Tennessee. A NF shall not be eligible to receive TennCare reimbursement for Enhanced Respiratory Care services for a resident placed by another state or any agency acting on behalf of another state in making the placement because such services are not available in the individual's current state of residence, including residents admitted to the NF/SNF under the Medicare Skilled Nursing Facility care benefit when such benefit has been exhausted. The NF shall be responsible for arranging, prior to the resident's admission to the facility, Medicaid reimbursement for Enhanced Respiratory Care services from the Medicaid Agency of the state which placed the resident and which will commence when other payment sources (e.g., Medicare, private pay, but not TennCare) have been exhausted.
- (8) Enhanced Respiratory Care Reimbursement in a dual certified and licensed NF/SNF shall be made only by TennCare MCOs in accordance with this Chapter and rates established by the Bureau. Effective July 1, 2016, each level of Enhanced Respiratory Care Reimbursement shall be an add-on payment to the NF's established Level 2 per diem rate or the NF's blended per diem rate, when established. The amount of the NF's add-on payment for each of the specified levels of reimbursement shall be based on the facility's performance on quality outcome and technology measures pursuant to a methodology established by TennCare. Quality outcome and technology measures, performance benchmarks, and the methodology to apply such measures and benchmarks to each of the specified levels of Enhanced Respiratory Care Reimbursement may be adjusted during FY 2016-2017 to ensure compliance with the Appropriations Act, Public Chapter 758, and no more frequently than annually thereafter in order to continuously improve the quality of care and quality of life outcomes experienced by individuals receiving Enhanced Respiratory Care in a NF.

~~Reimbursement for enhanced respiratory care services in a Medicare-certified and licensed Level 2 SNF shall be made only by TennCare MCOs in accordance with this Chapter and rates established by the Bureau.~~

1200-13-01-.05 TennCare CHOICES Program.

- (4) Enrollment in TennCare CHOICES. Enrollment into CHOICES shall be processed by the Bureau as follows:

- (c) Individual Cost Neutrality Cap.

- 3. Calculating a Group 2 Member's Individual Cost Neutrality Cap.

- (i) Each Group 2 Member will have an Individual Cost Neutrality Cap that is based on the average cost of the level of NF reimbursement that would be paid if the Member were institutionalized in a NF as set forth in Items (I) through (III) below. CHOICES Group 2 does not offer an alternative to hospital level of care.

- (III) A Member determined by TennCare to meet the medical eligibility criteria in Rule 1200-13-01-.10(5)(c) who would qualify for Chronic Ventilator Care or a Member determined by the Bureau to meet the medical eligibility criteria in Rule 1200-13-01-.10(5)(d) who would qualify for Secretion Management Tracheal Suctioning will have a Cost Neutrality Cap that reflects the higher payment that would be made to a NF for such care. For at least FY 2016-2017, the Cost Neutrality Cap for such CHOICES Group 2 member shall be based on the annualized cost of the applicable Enhanced Respiratory Care rate in effect as of June 30, 2016. Beginning July 1, 2017, the Cost Neutrality Cap for such CHOICES Group 2 member may be established based on the average annualized cost of the applicable level of Enhanced Respiratory Care Reimbursement using payments for

such level of reimbursement during the FY 2016-2017 year. The Cost Neutrality Cap for such CHOICES Group 2 member shall be adjusted no more frequently than annually thereafter. There is no Cost Neutrality Cap based on the cost of Ventilator Weaning Reimbursement or Sub-Acute Tracheal Suctioning Reimbursement, as such services are available only on a short-term basis in a SNF or acute care setting.

~~A Member who would qualify for the Enhanced Respiratory Care Reimbursement for persons who are chronically ventilator dependent, or for persons who have a functioning tracheostomy that requires frequent suctioning through the tracheostomy will have a Cost Neutrality Cap that reflects the higher payment that would be made to the NF for such care. There is no Cost Neutrality Cap for Ventilator Weaning Reimbursement, as such service is available only on a short-term basis in a SNF or acute care setting.~~

1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE.

(5) Criteria for Medicaid Level 2 and Enhanced Respiratory Care Reimbursement of Care in a NF.

(b) An Applicant must meet both of the following criteria in order to be approved for Medicaid Level 2 reimbursement of care in a NF:

2. Need for Inpatient Skilled Nursing or Rehabilitative Services on a Daily Basis: The Applicant must have a physical or mental condition, disability, or impairment that requires skilled nursing or rehabilitative services on a daily basis or skilled rehabilitative services at least five days per week when skilled rehabilitative services constitute the primary basis for the approval of the PAE. The Applicant must require such services at a greater frequency, duration, or intensity than, for practical purposes, would be provided through a daily home health visit. In addition, the Applicant must be mentally or physically unable to perform the needed skilled services or the Applicant must require skilled services which, in accordance with accepted medical practice, are not usually and customarily self-performed. For interpretation of this rule, the following shall apply:

(iii) A skilled rehabilitative service must be expected to improve the Applicant's condition. Restorative and maintenance nursing procedures (e.g., routine range of motion exercises; stand-by assistance during ambulation; applications of splints/braces by nurses and nurses' aides) shall not be considered sufficient to fulfill the requirement of (5)(b)2. Factors to be considered in the decision as to whether a rehabilitative service meets, or continues to meet, the requirement of (5)(b)2. shall include, but not be limited to, an assessment of the type of therapy and its frequency, the remoteness of the injury or impairment, and the reasonable potential for improvement in the Applicant's functional capabilities or medical condition.

(c) In order to be approved for TennCare-reimbursed care in a NF at the Chronic Ventilator rate of reimbursement, an Applicant must be ventilator dependent for at least 12 hours each day with an invasive patient end of the circuit (i.e., tracheostomy cannula). On a case-by-case basis, TennCare may, subject to additional medical review, authorize Chronic Ventilator Reimbursement for an Applicant who is ventilator dependent with a progressive neuromuscular disorder, spinal cord injury, or chronic respiratory failure and is ventilated using noninvasive positive pressure ventilation (NIPPV) by mask or mouthpiece for at least 12 hours each day in order to avoid or delay tracheostomy.

(d) In order to be approved by the Bureau for TennCare-reimbursed care in a NF at the Secretion Management Tracheal Suctioning rate of reimbursement:

1. An Applicant must have a functioning tracheostomy and a copious volume of secretions, and require either:

(i) Invasive tracheal suctioning, at a minimum, once every three (3) hours with documented

assessment pre- and post-suctioning; or

(ii) The use of mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy, at a minimum, three (3) times per day with documented assessment pre-and post.

(I) A copious volume of secretions shall be defined as 25 to 30 ml per day occurring over the course of the day, and not necessarily at every suctioning.

(II) The requirement for invasive tracheal suctioning, at a minimum, once every three (3) hours shall be applied as a marker of the severity of the Applicant's respiratory care needs. Secretion Management Tracheal Suctioning is not a scheduled intervention and shall not be performed as a medication would be delivered, i.e., at scheduled intervals (except as prescribed by an appropriately licensed health care professional practicing within the scope of his or her license). Rather, tracheal suctioning should be provided as clinically indicated, based on the needs of each person requiring such care; evidence of the need should be clearly and accurately documented. This could mean a shorter or longer interval at any point, but with a clinical need for invasive tracheal suctioning an average of every three (3) hours or more often in order to qualify for Secretion Management Tracheal Suctioning Reimbursement, except when mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy are used to manage secretions.

(III) When mechanical airway clearance devices and/or heated high flow molecular humidification via the tracheostomy are used to manage secretions, there must be documented evidence of the Applicant's copious secretions, but they are managed non-invasively using a cough assist device periodically or high flow molecular humidity continuously or at least three (3) times per day as ongoing treatment. The device is expected to provide ongoing relief of the copious volume of secretions, which shall not negate the need for intervention (and eligibility for Secretion Management Tracheal Suctioning Reimbursement), if absent the high flow device, the copious volume of secretions would require more invasive management.

2. The suctioning (or airway clearance, as applicable) must be required to remove excess secretions and/or aspirate from the trachea, which cannot be removed by the Applicant's spontaneous effort. Suctioning of the nasal or oral cavity does not qualify for this higher level of reimbursement. An MCO may authorize, based on medical necessity, short-term payment at the Sub-Acute Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention during the post-weaning period which shall include documented progress in weaning from the tracheostomy.

3. A PAE for Secretion Management Tracheal Suctioning Reimbursement shall be approved for no more than a period of thirty (30) days. Clinical review and approval of a new PAE shall be required for ongoing coverage, which shall include evaluation of clinical progress and the NF's efforts to improve secretion management through alternative methods. TennCare may, on a case-by-case basis, approve a PAE for Secretion Management Tracheal Suctioning Management Reimbursement for a period of more than thirty (30) days, e.g., if a person has ALS (amyotrophic lateral sclerosis) or another progressive neuromuscular disorder, spinal cord injury, or chronic respiratory failure, or is in a persistent vegetative state, and evidence clearly supports that ongoing secretion management tracheal suctioning is expected to continue.

4. A NF who has an approved PAE for Tracheal Suctioning Reimbursement for any resident as of July 1, 2016 shall be entitled to continue to receive such level of reimbursement no later than July 31, 2016 (or any earlier date that may be specified in the approved PAE). The NF shall submit a new PAE for such resident no later than July 19, 2016 in order to determine whether Secretion Management Tracheal Suctioning Reimbursement will be continued, or whether a different level of NF reimbursement is appropriate.

~~In order to be approved by the Bureau for TennCare-reimbursed care in a NF at the Tracheal Suctioning rate of reimbursement, an Applicant must have a functioning tracheostomy and require suctioning through the tracheostomy, at a minimum, multiple times per eight (8) hour shift. The suctioning must be required to remove excess secretions and/or aspirate from the trachea, which cannot be removed by the Applicant's spontaneous effort. Suctioning of the nasal or oral cavity does not qualify for this higher level of reimbursement. An MCO may authorize, based on medical necessity, short term payment at the Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention during the post-weaning period.~~

- (e) ~~Determination of medical necessity and authorization for TennCare Reimbursement of Ventilator Weaning services Reimbursement, or short-term payment at the Sub-Acute Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention shall be managed by the Enrollee's MCO.~~

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