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THE CITADEL MOORESVILLE	550 GLENWOOD DRIVE MOORESVILLE, NC 28115

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F 000	INITIAL COMMENTS An unannounced onsite complaint investigation was conducted on 11/12/21. Additional information was obtained through 11/29/21. Therefore, the exit date was changed to 11/29/21. 3 of the 22 allegations investigated were substantiated and cited. Past-noncompliance was identified at: CFR. 483.10 at tag F580 at a scope and severity (J) CFR. 483.25 at tag F695 at a scope and severity (J) CFR. 483.35 at tag F726 at a scope and severity (J) CFR. 483.70 at tag F835 at a scope and severity (J) Tag F 695 constituted Substandard Quality of Care.	F 000		
F 580 SS=J	An extended survey was conducted on 11/24/21. Notify of Changes (Injury/Decline/Room, etc.) CFR(s): 483.10(g)(14)(i)-(iv)(15) §483.10(g)(14) Notification of Changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s) when there is- (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention; (B) A significant change in the resident's physical,	F 580		12/22/21

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Electronically Signed | 12/22/2021

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mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
(C) A need to alter treatment significantly (that is, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
(D) A decision to transfer or discharge the resident from the facility as specified in §483.15(c)(1)(ii).
(ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that all pertinent information specified in §483.15(c)(2) is available and provided upon request to the physician.
(iii) The facility must also promptly notify the resident and the resident representative, if any, when there is-
(A) A change in room or roommate assignment as specified in §483.10(e)(6); or
(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section.
(iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s).

§483.10(g)(15)
Admission to a composite distinct part. A facility that is a composite distinct part (as defined in §483.5) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under §483.15(c)(9).

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F 580	Continued From page 2 This REQUIREMENT is not met as evidenced by: Based on record reviews and staff, Respiratory Therapist and Medical Director (MD) interviews the facility failed to notify the Physician for clarification when a resident (Resident #1) was admitted on 10/18/21 with orders for a bilevel positive airway pressure (BiPaP) that did not include the settings or frequency for the non-invasive mechanical ventilator. In addition, Nurse Manager #1 did not contact the Physician when they were not able to reach the Respiratory Therapist on 10/18/21 for assistance with setting up the BiPaP. The morning of 10/19/21 Nurse #2 was approached by Resident #1's family member who asked why the non-invasive mechanical ventilator was not being used. Nurse #2 did not attempt to contact the Physician or Respiratory Therapy for assistance. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 1 resident reviewed for notification of changes. The findings included: Resident #1 was admitted into the facility on 10/18/21 with diagnoses which included Chronic Obstructive Pulmonary Disease (COPD) and respiratory failure. Review of Resident #1's hospital discharge summary dated 10/18/21 revealed he had a history of COPD chronic respiratory failure on home oxygen therapy and the use of a non-invasive mechanical ventilator machine. Review of Resident #1's hospital discharge	F 580	Past noncompliance: no plan of correction required.	

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orders dated 10/18/21 revealed an order for BiPaP use as needed. The review revealed the orders did not include BiPaP settings.

An interview conducted on 11/12/21 at 12:25 PM with Nurse #1 revealed he was working the evening Resident #1 was admitted into the facility. He stated the resident came after 3:00 PM on 10/18/21 and he received report from Emergency Medical Services (EMS) who stated that the resident's oxygen level would decrease very quickly when off of supplemental oxygen. EMS services had Resident #1 on a non-rebreather mask when he entered the facility and Nurse #1 kept the mask on for a short period in case his oxygen levels decreased. Nurse #1 stated he then changed the resident to a nasal cannula on 4 liters of supplemental oxygen. He stated Resident #1 wore the nasal cannula at 4 Liters the entire time he was working until 11:00 PM. He stated he was not aware that the family member with Resident #1 had brought in a non-invasive mechanical ventilator. He stated the Nurse Manager assisted him with the admission. The interview revealed Nurse Manager #1 had assessed the resident and obtained vital signs.

Review of a nursing progress note dated 10/18/21 at 7:11 PM written by Nurse Manager #1 revealed Resident #1 had arrived at the facility from the hospital. Resident #1 was documented as being on 4 liters of supplemental oxygen and would be using a BiPaP at night. Nurse Manager #1 documented she had contacted Respiratory Therapy to come an evaluate the residents BiPaP. Resident #1 was noted to be alert and oriented to person, place, and time. No vital signs were included in the initial assessment of Resident #1.

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Review of a nursing progress note dated 10/18/21 at 6:02 PM written by the Nurse Manager #1 revealed she had contacted Respiratory Therapy and spoke with the respiratory therapy company Staff Member #1 who said they would have someone come evaluate Resident #1's BiPaP. The note did not reveal the exact time the call was placed.

Review of a nursing progress note dated 10/18/21 at 10:13 PM written by the Nurse Manager #1 revealed she had called Respiratory Therapy and spoke with the respiratory therapy company Staff Member #2 who stated an on-call RT (Respiratory Therapist) would contact them again regarding Resident #1's BiPaP. The note did not reveal the exact time the call was placed.

An interview conducted on 11/12/21 at 2:02 PM with Nurse Manager #1 revealed she was working during the evening shift when Resident#1 was admitted on 10/18/21. She stated Nurse #1 was the hall nurse, but she assisted him with the admission. She stated Resident #1 was alert, oriented and talking with no respiratory distress. The interview revealed Resident #1 was wearing a nasal cannula with 4 liters of supplemental oxygen. She stated there was an order for Resident #1 to receive a BiPaP as needed so she called the respiratory therapy company and asked them to send someone out to assist the resident. She stated she hadn't heard anything back from the company, so she went into the room around 9:30 PM and Resident #1 stated he used his Non-invasive mechanical ventilator machine at home. Nurse Manager #1 stated she then took the machine from his bag and laid it onto his bed. She stated the machine was in pieces and she

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did not know how to put it together or turn it on. She stated she did not contact the Physician when the RT company did not respond. The interview revealed Resident #1 went to sleep without the non-invasive mechanical ventilator machine on the night of 10/18/21 and had not shown signs of respiratory distress.

An interview conducted on 11/16/21 at 9:15 AM with Nurse #6 revealed she was taking care of Resident #1 on 10/18/21 following Nurse #1 at 11:00 PM. She stated she knew he did not have his BiPaP in place, so she had checked his oxygen saturation level shortly after she took over at 11:00 PM and it was good. The interview revealed she could not remember the exact oxygen saturation level but stated it was greater than 92% on 4 liters of supplemental oxygen via nasal cannula. She stated Resident #1 did not seem like he was in any type of respiratory distress and did not mention his BiPaP machine. She stated she did not call the Physician because she knew Nurse Manager #1 had contacted the Respiratory Therapy company and thought someone was coming to set up Resident #1's machine.

An interview conducted on 11/12/21 at 12:06 PM with Nurse #2 revealed she took over care for Resident #1 at 7:00 AM on 10/19/21. She stated in report Nurse #6 stated the facility had received a new admission (Resident #1) and the hospital had sent the incorrect BiPaP machine with the resident. The nurse told Nurse #2 the resident had issues with hypoxia. Nurse #2 stated the resident's family member was in the room during the shift on 10/19/21. She stated the family member came to her around 8:45 AM asking why the residents non-invasive mechanical ventilator

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machine was not hooked up and she stated she told the family member that it was her understanding that another nurse had called respiratory therapy, and someone was supposed to come set up his machine. Nurse #2 stated she went into the resident's room when she was administering his morning medication and saw his non-invasive mechanical ventilator machine laying on his bed. Nurse #2 stated Resident #1 was experiencing labored breathing and was very anxious at that time, but she did not check his oxygen saturation level. After administering the breathing treatment, she stated the resident was able to calm down. Nurse #2 stated the resident was sitting at a 90-degree angle in the bed due to difficulty breathing. She stated the Medical Director was able to get in touch with the Respiratory Therapist (RT) who entered the building around 5:00 PM on 10/19/21 to see Resident #1. She stated when the RT checked Resident #1's oxygen saturation level it was 85% (normal oxygen saturation level greater than 92%) on 4 liters via nasal cannula.

Review of a Physician Order initiated by the RT on 10/19/21 at 5:33 PM revealed Resident #1's non-invasive mechanical ventilator machine was to be worn at night and as needed during naps. The order included the settings for non-invasive mechanical ventilator machine to deliver the BiPaP ventilation.

An interview conducted on 11/12/21 at 3:10 PM with the Medical Director (MD) revealed she had seen Resident #1 in his room on 10/19/21 at 9:00 PM. She stated she had an interaction with Nurse #2 earlier in the day regarding his non-invasive mechanical ventilator machine and was informed it had not been set up. She stated she

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immediately called the RT and the RT answered the phone right away and said she would be on her way to the facility. She stated she was told the nurse had tried to contact RT and was unsuccessful but stated she had no issues getting ahold of them and them responding. The interview revealed she had not been informed of Resident #1's non-invasive mechanical ventilator not being set up prior to Nurse #2 telling her while she was in the facility. The interview revealed for anyone who required the use of a non-invasive mechanical ventilator machine, not being on it could have a serious negative impact. That was why when she found out he needed his machine initiated she wanted it on as soon as possible. The interview revealed Resident #1 had been using the machine at home prior to admission in the hospital. She stated nobody had contacted her the night prior stating they couldn't get a RT to come initiate his machine. The interview revealed when she saw Resident #1 at 9:00 PM he had his non-invasive mechanical ventilator mask on and was lying in bed. She stated she stopped the machine for 2 minutes to speak to him and he started breathing at an abnormally fast rate with his lips pursed. The MD stated Resident #1 did not do well off of the non-invasive mechanical ventilator machine. She stated during the 10 minutes she was in his room the resident did not move his arms or try to move his arms. The MD stated she was notified 10/20/21 that Resident #1 was found with a nebulizer mask on his face and had expired. She stated she felt he had expired from hypoxia (lack of oxygen). The interview revealed she did not feel comfortable saying that his death was ultimately due to not receiving his non-invasive mechanical ventilator machine timely.

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An interview conducted with the Respiratory Therapist (RT) on 11/12/21 at 12:45 PM she stated she was contacted on 10/19/21 around 4:00 PM by the MD to initiate Resident #1's non-invasive mechanical ventilator machine. The RT stated when she arrived on 10/19/21 around 4:30 PM to the facility Resident #1's oxygen saturation level was 85-87 % on 4 liters of oxygen. She stated she had to use two pulse oximeters on his fingers to obtain a reading and his heart rate was 125. Resident #1 was observed by the RT to be short of breath and lying like a statue. The RT stated she asked Resident #1 if he was afraid to move and he responded with a yes due to being afraid to overexert himself. She stated after the Non-invasive mechanical ventilator machine was set up his heart rate was 68 beats per minute with an oxygen saturation level of 92%.

The facility Administrator was not available for interview during the time of the investigation.

The facility provided the following Corrective Action Plan with the correction date of 10/26/21:

1) Immediate Action for Resident Affected:
· Resident #1 expired on 10/20/21. Physician and Responsible Party was notified on 10/20/2021.
· On 10/20/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed via conference call with facility Interdisciplinary Team (IDT) and Regional Director of Operations (RDO), Regional Director of Clinical Services (RDCS) and Vice President of Clinical Services (VPCS) to discuss initial findings

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of event and to initiate immediate action plans based on immediate findings.
2) Identification of Others:
· On 10/24 and 10/25/2021, an audit was completed by the Director of Nursing of all current residents utilizing Non-Invasive Ventilator (NIV) which include bi-level positive airway pressure (Bi-Pap), continuous positive airway pressure (C-Pap) and non-invasive ventilation average volume assured pressure support-auto E-Pap (NIV/AVAPS-AE, brands such as trilogy) devices to ensure that physician orders include the device settings and frequency of use. Resident #2 identified for order clarification. There was no harm or adverse effects to Resident #2 and resident remains stable on current NIV settings.
· On 10/24/21, the Physician was notified by the Director of Nursing of orders needing clarification for Resident #2 ' s NIV/AVAPS-AE (Non-Invasive Ventilation) device. Resident #2 orders revised and implemented on 10/24/21 by the Director of Nursing and care plan revised on 10/25/21.
· On 10/25/2021, the respiratory therapist completed a review (and revision as appropriate) of current residents on NIV devices to ensure settings were accurate based upon physician orders. No further recommendations made.
· On 10/25/2021, all new admissions from 9/18-10/20/21 will be reviewed by the Director of Nursing/designee to ensure any resident requiring NIV devices per hospital discharge summary have appropriate orders to include settings and frequency of use. No additional residents were identified for correction.
· On 10/22/21, the VPCS and contracted District Director of Respiratory Therapy reviewed and revised policy "Non-Invasive Ventilation: IV/AVAPSA-E feature" to reflect and further clarify

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licensed nurses and Respiratory Therapists roles and responsibilities in the management of Bi-Pap, C-Pap and APAPS-AE NIV (brands such as Trilogy) devices.

3) Education/Systemic Change

· On 10/22/21, the VPCS provided education to the facility Administrator, DON and RDCS on the updated policy "Non-Invasive Ventilation: IV/AVAPSA-E feature" to include that effective immediately the facility shall no longer accept NIV/AVAPS-AE devices (brands such as trilogy) On 10/25/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed by the IDT and RDCS, RDO and VPCS a comprehensive corrective action plan was developed based on root cause analysis to address F580, F695, F726, and F835.

· By 10/25/21, all licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing (DON)/ designee on ensuring that the physician is notified of any delay in implementing physician orders including initiation of NIV devices. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, all licensed nursing staff including agency staff will be educated by the Director of Nursing/designee related to the admission process including verification and transcription of orders and immediately contacting the physician if clarifications are needed. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, the unit clerk and all licensed nursing staff including agency staff will

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be educated by the Director of Nursing /designee regarding the notification process which includes calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. In addition, if the resident is in any acute distress, he/she will immediately be sent to the emergency room for further evaluation. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· Effective 10/25/21, each nursing station will have the contact information for the contracted Respiratory Therapy company prominently posted. Respiratory therapy services are available after hours and on weekends.

· By 10/25/2021, the Admission Director will be educated by the Administrator/ designee on ensuring the respiratory therapist, unit clerk, and supply personnel are notified prior to admission when residents require NIV devices. Education also included for admissions to no longer accept NIV/AVAPS-AE, brands such as trilogy effective 10/25/21. The Admissions Director was also educated by the DON on 10/25/21 on C-PAP, Bi-PAP, and AVAPS-AE (Trilogy type) devices to identify the differences in the settings associated with these types of devices. The DON will maintain education records to validate staff competency for current and newly hired facility Admission staff. Staff will not be allowed to work until education completed.

· Effective 10/25/21, the Admission

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Director or Director of Nursing will ensure that the contracted respiratory therapy company will be notified at least 24 hours prior to an admission with physician orders for NIV device to ensure NIV device will be readily available prior to admission with the required settings verified.

· By 10/25/2021, the Admission Director and licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing on ensuring that ordered equipment/or devices are available with required setting and frequency orders when residents are admitted to the facility. The DON will maintain education records to validate staff competency for current and newly hired facility Admissions staff and facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, Licensed Nurses, Admissions Director, Medical Director and Social Services were educated by the Administrator on the facility clinical capabilities grid which specifies the care services provided by the facility to determine admission approval. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses, Admissions staff, Medical Director and Social Services staff. Staff will not be allowed to work until education completed.

· Effective 10/25/21, the facility will no longer accept NIV/ AVAPS-AE devices (brands such as trilogy) in the facility. The Admission Director received education on 10/25/21.

· By 10/25/2021, Licensed Nurses including agency licensed nurses will be educated on the facility policy revision date 10/22/21 "Non-Invasive Ventilation: IV/AVAPSA-E feature" to include competencies on the use of all NIV devices, required ongoing respiratory assessment

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documentation related NIV and oxygen therapy by the Respiratory Therapist and Director of Nursing. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/21, Certified Nurse Aides (CNA) including agency CNA will be educated by the Director of Nursing on the care of NIV residents including notifying the Licensed Nurses of any issues with the NIV including alarms, remaining with the resident until licensed nurse responds and not manipulating machine in any way. The DON will maintain education records to validate staff competency for current and newly hired facility and agency CNAs. Staff will not be allowed to work until education completed. Staff will not be allowed to work until education completed.

· Effective 10/25/2021, all education for above will be included in the orientation process to include new hire facility licensed nurses, agency licensed nurses, CNAs, and admission staff. These staff will not be allowed to work until education completed.

· Effective 10/25/21, new admission paperwork and physician orders will be reviewed by nursing management in morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for NIV devices and notification to physician of any order discrepancies for clarification. Nursing management was informed of review process during Ad Hoc QAPI meeting on 10/25/21 by the Administrator.

4) Monitoring Process:

· Beginning 10/25/21, 1) nursing management will review/audit new admission paperwork during morning clinical report to

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ensure the accuracy and timely implementation of physician s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification. Any discrepancies will be communicated to the physician for clarification and/or correction and 2) the Administrator/designee will review/audit nursing education files for new hires and agency staff to ensure staff competence of Bi-Pap and C-Pap NIV devices. Staff will not be allowed to work until education complete.

· Results of the audits will be documented on the "Quality Improvement Data Collection Sheet" and maintained in the plan of correction binder in the Administrator's office.

· On 10/25/21, the QAPI Committee was notified by the Administrator of delegation of QA monitoring responsibilities. The results of the monitoring will be discussed in the monthly QAPI committee meeting for at least three months, overseen by the Administrator, Director of Nursing, and the Medical Director. The interdisciplinary team will recommend revisions to the plan as indicated to maintain substantial compliance.

· Beginning 10/25/21, the RDCS and/or the RDO will review results of facility audits and QAPI minutes monthly for three months to ensure ongoing compliance with accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification.

The facility alleges compliance on 10/26/2021

The Corrective Action Plan was validated on 11/24/21 and concluded the facility implemented an acceptable corrective action plan on 10/26/21.

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F 580	Continued From page 15 The facility amended the notification process to include calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. The Corrective Action Plan was reviewed during QAPI meeting held on 10/25/21. The weekly monitoring logs residents requiring a BiPaP/ CPAP were reviewed from October 2021 to November 2021 with no concerns identified. Review of the nursing staff in-service sheets on non-invasive mechanical ventilator training revealed the nursing staff had initialed as receiving the in-service training. Interviews conducted with nursing staff from first, second and third shifts revealed they had received the in-service as stated by the facility. The staff verified they had received in-servicing on notification, abuse, neglect, change of condition and use of a BiPap/CPAP machine.	F 580		
F 609 SS=D	Reporting of Alleged Violations CFR(s): 483.12(c)(1)(4) §483.12(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must: §483.12(c)(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events	F 609		12/23/21

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F 609	Continued From page 16 that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures. §483.12(c)(4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken. This REQUIREMENT is not met as evidenced by: Based on record review and staff interview, the facility failed to send an initial report to the State Agency for 1 of 2 residents reviewed for respiratory care (Resident #1). Findings included: On 11/16/21 at 5:50 PM the Director of Nursing and Corporate Compliance Consultant were notified of Immediate Jeopardy related to a lack of necessary care and services for a compromised resident that was dependent upon a non-invasive mechanical ventilator. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). An interview conducted on 11/12/21 at 4:54 PM	F 609	1. Resident #1 expired on 10/20/21 and corrective action is not applicable. 2. On 12/22/21, the Administrator completed a review of grievances from 11/21-12/21/21 to ensure any alleged violations of abuse, neglect, exploitation, or mistreatment including injuries of unknown source and misappropriation of resident property were reported to the NC State Agency per guidelines. Two (2) allegations identified were reported accordingly. 3. On 12/22/21, the Regional Director of Operations completed education with the facility Administrator and Director of Nursing on reporting alleged violations of abuse, neglect, exploitation, or	

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F 609	Continued From page 17 with the Director of Nursing (DON) revealed the facility Administrator was the staff member who filed the initial reports. The DON stated at the time of the incident the facility was in between Administrators and after conducting an investigation she did not feel like an initial report needed to be completed. The facility Administrator was not available for interview during the time of the investigation. On 12/07/2021 a search in the 24-hour and 5-day investigation reporting system revealed no facility self-report for this incident.	F 609	mistreatment including injuries of unknown source and misappropriation of resident property were reported to the NC State Agency per guidelines. The Administrator or Director of Nursing will report alleged violations to NC State Agency immediately but, not later than 2 hours if the allegation involves abuse or results in bodily harm or not later than 24 hours if the events that cause the allegation do not involve abuse or result in bodily harm. Results of the investigation will be submitted within 5 working days of the incident. Newly hired Administrators and Directors of Nursing will receive education upon hire. 4. The Administrator and/or Director of Nursing will monitor grievances weekly for three (3) months to ensure reporting of alleged violations per guidelines. The Administrator will report findings of the monitoring to the Interdisciplinary Team (IDT) during QAPI meetings monthly for three (3) months and will make changes to the plan as necessary to maintain compliance with reporting of alleged violations.	
F 695 SS=J	Respiratory/Tracheostomy Care and Suctioning CFR(s): 483.25(i) § 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	F 695		12/22/21

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F 695	Continued From page 18 care plan, the residents' goals and preferences, and 483.65 of this subpart. This REQUIREMENT is not met as evidenced by: Based on record reviews and staff, Respiratory Therapist, Medical Director (MD) and clinical respiratory provider interviews the facility failed to provide necessary respiratory care and services to a resident with a compromised respiratory status who was dependent on bilevel positive airway pressure (BiPaP). Resident #1 was admitted on 10/18/21 with orders for a bilevel positive airway pressure (BiPaP) that did not include the settings or frequency for the non-invasive mechanical ventilator. The facility failed to clarify orders for the BiPaP on admission or involve respiratory therapy and as a result the BiPaP machine was not set up until the evening of 10/19/21. In addition, the facility failed to complete and document on-going comprehensive assessments of the resident's respiratory status and ensure Resident #1 had continuous oxygen. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 2 resident reviewed for respiratory care. The findings included: Resident #1 was admitted into the facility on 10/18/21 with diagnosis which included chronic obstructive pulmonary disease (COPD) and respiratory failure. Resident #1's hospital discharge summary dated 10/18/21 revealed he had a history of COPD chronic respiratory failure on home oxygen	F 695	Past noncompliance: no plan of correction required.	

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therapy and the use of a non-invasive mechanical ventilator machine.

Resident #1's hospital discharge orders dated 10/18/21 revealed an order for BiPaP use as needed. The review revealed the orders did not include BiPaP settings, orders for oxygen therapy or any orders for a nebulizer treatment.

Resident #1's Physician order dated 10/18/21 at 6:23 PM revealed an order for supplemental oxygen at 4 liters continuously via nasal cannula initiated by the Nurse Manager #1.

An interview conducted on 11/15/21 at 2:51 PM with the Admissions Coordinator for the facility revealed she had seen Resident #1 in the hospital. She stated she was unaware that he used a non-invasive mechanical ventilator machine but knew he had orders for a BiPaP. She stated she usually read the hospital discharge summary but did not see where it talked about his non-invasive mechanical ventilator machine. She stated the facility was not supposed to admit residents with a non-invasive mechanical ventilator machine. She stated they had another resident on a non-invasive mechanical ventilator machine and wasn't sure why he was admitted.

An interview conducted on 11/12/21 at 12:25 PM with Nurse #1 revealed he was working the evening Resident #1 was admitted into the facility. He stated the resident came after 3:00 PM on 10/18/21 and he received report from Emergency Medical Services (EMS) who stated that the resident's oxygen level would decrease very quickly when off supplemental oxygen. EMS services had Resident #1 on a non-rebreather

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mask when he entered the facility and Nurse #1 kept the mask on for a short period in case his oxygen levels decreased. Nurse #1 stated he then changed the resident to a nasal cannula on 4 liters of supplemental oxygen. He stated Resident #1 wore the nasal cannula at 4 Liters the entire time he was working until 11:00 PM. He stated he was not aware that the family member with Resident #1 had brought in a non- invasive mechanical ventilator. He stated the Nurse Manager assisted him with the admission. The interview revealed Nurse Manager #1 had assessed the resident and obtained vital signs.

A nursing progress note dated 10/18/21 at 6:02 PM written by the Nurse Manager #1 revealed she had contacted Respiratory Therapy and spoke with the respiratory therapy company Staff Member #1 who said they would have someone come evaluate Resident #1's BiPaP. The note did not reveal the exact time the call was placed.

A nursing progress note dated 10/18/21 at 10:13 PM written by the Nurse Manager #1 revealed she had called Respiratory Therapy and spoke with the respiratory therapy company Staff Member #2 who stated an on-call RT (Respiratory Therapist) would contact them again regarding Resident #1's BiPaP. The note did not reveal the exact time the call was placed.

An interview conducted on 11/12/21 at 2:02 PM with Nurse Manager #1 revealed she was working during the evening shift when Resident#1 was admitted on 10/18/21. She stated Nurse #1 was the hall nurse, but she assisted him with the admission. She stated Resident #1 was alert, oriented and talking with no respiratory distress. The interview revealed Resident #1 was wearing

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a nasal cannula with supplemental oxygen at 4 liters. She stated there was an order for Resident #1 to receive a BiPaP as needed so she called the respiratory therapy company and asked them to send someone out to assist the resident. She stated she hadn't heard anything back from the company, so she went into the room around 9:30 PM and Resident #1 stated he used his non-invasive mechanical ventilator machine at home. Nurse Manager #1 stated she then took the machine from his bag and laid it onto his bed. She stated the machine was in pieces and she did not know how to put it together or turn it on. She stated she did not contact the Physician when the RT company did not respond. The interview revealed Resident #1 went to sleep without the non-invasive mechanical ventilator machine on the night of 10/18/21 and had not shown signs of respiratory distress.

Resident #1's vital signs revealed an oxygen saturation level documented on 10/19/21 at 1:07 AM by Nurse #6 of 96% (normal range for oxygen saturation level is greater than 92%) on room air.

An interview conducted on 11/16/21 at 9:15 AM with Nurse #6 revealed she was taking care of Resident #1 on 10/18/21 following Nurse #1 at 11:00 PM. She stated she knew he did not have his BiPaP in place, so she had checked his oxygen saturation level shortly after she took over at 11:00 PM and it was good. The interview revealed she could not remember the exact oxygen saturation level but stated it was greater than 92% on 4 liters of supplemental oxygen via nasal cannula. She stated Resident #1 did not seem like he was in any type of respiratory distress and did not mention his BiPaP machine. She stated she did not call the Physician because

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she knew Nurse Manager #1 had contacted the Respiratory Therapy company and thought someone was coming to set up Resident #1's machine. Nurse #6 stated the vital signs she entered on 10/19/21 at 1:07 AM should have indicated oxygen via nasal cannula. Nurse #6 confirmed the flow meter was set at 4 L/min.

Resident #1's vital signs revealed an oxygen saturation level documented on 10/19/21 at 10:57 AM by Nurse #2 of 94% receiving supplemental oxygen via nasal cannula.

An interview conducted on 11/12/21 at 12:06 PM with Nurse #2 revealed she took over care for Resident #1 at 7:00 AM on 10/19/21. She stated in report Nurse #6 stated the facility had received a new admission (Resident #1) and the hospital had sent the incorrect BiPaP machine with the resident. The nurse told Nurse #2 the resident had issues with hypoxia. Nurse #2 stated the resident's family member was in the room during the shift on 10/19/21. She stated the family member came to her around 8:45 AM asking why the residents non-invasive mechanical ventilator machine was not hooked up and she stated she told the family member that it was her understanding that another nurse had called respiratory therapy, and someone was supposed to come set up his machine. Nurse #2 stated she went into the resident's room when she was administering his morning medication and saw his non-invasive mechanical ventilator machine laying on his bed. Nurse #2 stated Resident #1 was experiencing labored breathing and was very anxious at that time, but she did not check his oxygen saturation level. After administering the breathing treatment, she stated the resident was able to calm down. Nurse #2 stated the resident

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was sitting at a 90-degree angle in the bed due to difficulty breathing. She stated the Medical Director was able to get in touch with the Respiratory Therapist (RT) who entered the building around 5:00 PM on 10/19/21 to see Resident #1. She stated when the RT checked Resident #1's oxygen saturation level it was 85% (normal oxygen saturation level greater than 92%) on 4 liters via nasal cannula.

A Physician Order initiated by the RT on 10/19/21 at 5:33 PM revealed Resident #1's non-invasive mechanical ventilator machine was to be worn at night and as needed during naps. The order included the settings for non-invasive mechanical ventilator machine to deliver the BiPaP ventilation

Resident #1's Medication Administration Record (MAR) revealed an order dated 10/19/21 for Ipratropium-Albuterol Solution 0.5-2.5 milligrams/3 milliliters inhale orally via nebulizer every 4 hours for shortness of breath. The review revealed the nebulizer solution was not administered for the 12:00 AM dose. Nurse #3 documented Resident #1 was sleeping.

Review of a nursing progress note dated 10/20/21 at 12:00 AM written by Nurse #3 revealed Resident #1 was administered Diltiazem (a medication used to treat high blood pressure) tablet 30 milligrams via feeding tube. The note stated Resident #1 was receiving oxygen via his non-invasive mechanical ventilator machine. Around 1:50 AM Resident #1 was found with his nebulizer mask on and unresponsive. The non-invasive mechanical ventilator mask was immediately reapplied, and his oxygen saturation level checked with no reading. CPR was initiated at 1:55 AM and 911 was called. EMS arrived to

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the facility at 2:00 AM and Resident #1 was pronounced as expired at 2:07 AM.

An interview conducted on 11/12/21 at 12:21 PM with Nurse #3 revealed she received report from Nurse #2 on 10/19/21 at 7:00 PM for Resident #1. She stated the RT was not in the building when she received report, but Nurse #2 took her into the room and tried to show her how to use the non-invasive mechanical ventilator machine. She stated Resident #1 had taken the mask off to eat supper so when she and Nurse #2 entered the room Nurse #2 reapplied the residents mask since he had finished his supper meal. She stated she went into the room at 8:30 PM to check the resident's blood sugar and administer his medications via his feeding tube. The interview revealed she returned to the room around 9:00 PM looking for humidification for the resident's oxygen and he was still on the non-invasive mechanical ventilator machine. Nurse #3 stated at midnight she went into the room to administer the resident's medication and he was in no respiratory distress. She stated she administered his blood pressure medication via feeding tube, the resident was awake at the time she was in the room. Nurse #3 stated the resident had a breathing treatment ordered for midnight however she didn't administer it because she didn't want to touch his non-invasive mechanical ventilator mask. Nurse #3 stated around 1:30 AM she walked by Resident #1's room and saw he did not have his non-invasive mechanical ventilator mask on but had his nebulizer mask on with no supplemental oxygen hooked to it and no other tubing hooked. The resident just had the nebulizer mask on his face. She stated when she walked in the room, she did not see him breathing and checked for a pulse. She yelled for another

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nurse to call 911 and come into the room, and they initiated cardiopulmonary resuscitation (CPR) but were unable to revive the resident. Nurse #3 stated Resident #1's nebulizer mask had been on his bedside dresser and the resident must have reached over, took his Non-invasive mechanical ventilator mask off and replaced it with his nebulizer treatment mask himself. She stated she did not hear an alarm coming from the non-invasive mechanical ventilator machine, but she believed it was on. Nurse #3 stated she had received no training regarding a non-invasive mechanical ventilator machine before or after the incident. She stated nobody had asked her anything about the incident.

Resident #1's vital signs revealed an oxygen saturation level documented on 10/20/21 at 1:29 AM by Nurse #3 of 95% receiving supplemental oxygen via nasal cannula.

A follow-up interview conducted on 11/15/21 at 3:24 PM with Nurse #3 revealed Resident #1's vital signs must have been entered by mistake. She stated at 1:29 AM his oxygen saturation level was not 95%.

An interview conducted on 11/16/21 at 9:10 AM with Nurse #4 revealed she was working on the 300 hall on the morning of 10/20/21. She stated Nurse #3 calmly went up to Nurse Manger #2 and stated Resident #1 was unresponsive. Nurse Manger #2 then ran to call a code. Nurse #4 responded with Nurse #5 to the room while Nurse #3 stayed at the nurse's station to call EMS. She stated when she entered the room Resident #1 was laying in the bed and felt cold to the touch. She stated he had a nebulizer mask on, but the tubing was incorrect and not connected to the

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nebulizer machine. She did not hear the nebulizer machine running. Resident #1 had no supplemental oxygen on. Nurse #4 stated she and Nurse #5 felt for a pulse but neither nurse could feel one. She stated Nurse #3 had said she thought she felt a pulse when she reported it to Nurse Manager #2, so they began to initiate CPR. She stated they performed CPR unit EMS arrived. The interview revealed she saw the non-invasive mechanical ventilator machine, but it looked like it hadn't been on the resident stating it along with the mask was on his bedside dresser and didn't remember seeing it turned on. She stated she had to place oxygen on him via nasal cannula prior to initiating CPR. The interview revealed that afterwards the nurses were discussing what had happened and Nurse #3 stated to her she had been scared to touch his non-invasive mechanical ventilator machine and that's why she hadn't administered his 12:00 AM breathing treatment. She stated in the past she knew non-invasive mechanical ventilator machines had an alarm if they became disconnected from a resident. The interview revealed she had not heard any alarms coming from Resident #1's room during the shift.

An interview conducted on 11/16/21 at 9:41 AM with Nurse Manager #2 revealed Nurse #3 came to her and said she had a resident who was unresponsive. Nurse Manager #2 stated she ran into his room with Nurse #4 and Nurse #5. She stated she told Nurse #3 to call EMS, the resident's family and to get his paperwork together. She stated when she entered the room Resident #1 was laying on his back lifeless. The interview revealed she could not feel a pulse and there was no rise or fall to his chest. Resident #1 was not wearing supplemental oxygen, nor did

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she see his non-invasive mechanical ventilator machine. She stated the resident was cool to the touch. Nurse Manager #2 obtained the AED (Automated External Defibrillator) while Nurse #4 initiated CPR. The nurses continued CPR until EMS arrived and pronounced the resident expired at 2:07 AM. She stated she did not hear any alarms coming from his room or hear the nebulizer machine running.

A voicemail was left for Nurse #5 who worked on 10/19/21 during third shift with no return phone call.

A voicemail was left for the third shift Nurse Aide working on 10/19/21 with no return phone call.

Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen).

An interview conducted on 11/12/21 at 3:10 PM with the Medical Director (MD) revealed she had seen Resident #1 in his room on 10/19/21 at 9:00 PM. She stated she had an interaction with the hall nurse earlier in the day regarding his non-invasive mechanical ventilator machine and was informed it had not been set up. She stated she immediately called RT in which the RT answered the phone right away and said she would be on her way to the facility. She stated she was told the nurse had tried to contact RT and was unsuccessful but stated she had no issues getting ahold of them and them responding. The MD stated she was originally told that the facility did not accept residents on non-invasive mechanical ventilator machines, but they had two residents on them. The interview

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revealed for anyone who required the use of a non-invasive mechanical ventilator machine, not being on it could have a serious negative impact. That was why when she found out he needed his machine initiated she wanted it on as soon as possible. The interview revealed Resident #1 had been using the machine at home prior to admission in the hospital. She stated nobody had contacted her on 10/18/21 stating they couldn't get a RT to come initiate his machine. The interview revealed when she saw Resident #1 at 9:00 PM he had his non-invasive mechanical ventilator mask on and was lying in bed. She stated she stopped the machine for 2 minutes to speak to him and he started breathing at an abnormally fast rate with his lips pursed. The MD stated Resident #1 did not do well off of the non-invasive mechanical ventilator machine. She stated during the 10 minutes she was in his room the resident did not move his arms or try to move his arms. The MD stated she was notified that Resident #1 was found with a nebulizer mask on his face and had expired. She stated she felt he had expired from hypoxia (lack of oxygen). The interview revealed she did not feel comfortable saying that his death was ultimately due to not receiving his non-invasive mechanical ventilator machine timely.

An interview conducted with the Respiratory Therapist (RT) on 11/12/21 at 12:45 PM revealed she was contacted on 10/19/21 around 4:00 PM by the MD to initiate Resident #1's non-invasive mechanical ventilator machine. The RT stated when she arrived around 4:30 PM to the facility Resident #1's oxygen saturation level was 85-87 % on 4 liters of oxygen. She stated she had to use two pulse oximeters on his fingers to obtain a reading and his heart rate was 125. Resident #1

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was observed by the RT to be short of breath and lying like a statue. The RT stated she asked Resident #1 if he was afraid to move and he responded with a yes due to being afraid to overexert himself. She stated after the non-invasive mechanical ventilator machine was set up his heart rate was 68 beats per minute with an oxygen saturation level of 92%. The RT stated she educated Nurse #2 on use of the machine and had asked her to demonstrate how to use it. She stated she asked the nurse to educate the oncoming nurses because she knew the facility staff was not familiar with use of a non-invasive mechanical ventilator machine. The RT stated she stayed in the facility and placed her notes and orders into the Point Click Care system as she always did and left the building. The next day the RT contacted the Director of Nursing to ask how Resident #1 was and was told he had expired during the night. She stated she was told he was found with a nebulizer mask on his face and knew he had orders for a breathing treatment at midnight. She stated she immediately thought the nurse on duty had not hooked his supplemental oxygen up with his nebulizer treatment when she administered it. The RT stated when she logged into the system, she saw the nurse had documented she did not administer the breathing treatment because the resident was asleep. The RT stated it didn't make sense to her because she had seen the resident prior and felt he could not have changed the mask himself. She stated with his breathing he wouldn't have lasted 2 minutes without the use of supplemental oxygen and the non-invasive mechanical ventilator machine should have been alarming if it had been removed. She stated the only way it wouldn't have been was if someone had silenced it and Resident #1 wouldn't have been able to

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reach it on his bedside dresser. She stated following the incident she was asked to have a meeting with the Director of Nursing and Corporate team where she told them the nurses were not educated to care for a resident with a non-invasive mechanical ventilator machine. She stated she was asked to provide a 4-day in-service to staff following the incident on the weekend.

A follow-up interview conducted on 11/16/21 at 11:15 AM with the Respiratory Therapist revealed the settings were for the BiPaP mode of the non-invasive mechanical ventilator machine. She stated she always wrote for BiPaP to be on at night and as needed for naps because they could not be on longer than 12 hours consistently. The RT stated she had spoken with the resident's family member who told her he was wearing it more frequently at home since he had become sick. The Respiratory Therapist stated she had told the facility to not accept residents without BiPaP settings included on their hospital discharge summary, but that Resident #1 came to the facility without an order including his BiPaP settings. She stated she remembered when she was setting up the machine and showing Nurse #2 how to use the machine it kept alarming, and she was having to press the silence button because it was not yet on his face. She stated once it was on his face someone would have had to of hit the silence button for the machine to stop alarming. The Respiratory Therapist stated the facility did not have a policy prior to 10/22/21 for accepting admissions on a non-invasive mechanical ventilator machine. The interview revealed the RT felt Resident #1 was still in an acute condition and needed close monitoring.

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On 11/12/21 at 1:30 PM an interview was conducted with the District Manager from the Respiratory Therapy company. She stated she was notified by the facility that they could not get in touch with the RT company after Resident #1 had expired, so she had the corporate team pull all of the call logs from the dates of 10/18/21 and 10/19/21. She stated the facility had contacted the agency on 10/19/21 at 2:24 PM for a different resident in which the RT responded and was not notified about Resident #1. She stated prior to that the company was contacted on 10/16/21. The interview revealed the company had no record of the facility contacting them regarding Resident #1 except for when the Medical Director had directly called the RT on her cell phone at 4:30 PM no prior calls were seen on the call log. She stated the RTs only have 10 minutes to respond after they obtain a call.

An interview conducted on 11/12/21 at 4:54 PM with the Director of Nursing (DON) revealed the facility had a policy that allowed them to accept non-invasive mechanical ventilator residents as long as the machine remained on the BiPaP setting. The DON stated Resident #1 came from the hospital with orders for a BiPaP as needed. She stated Nurse Manager #1 called the Respiratory Therapy company using number located at the nurse's desk twice during her shift, but nobody responded. She stated the Nurse Manager said she had spoken to someone, but she felt that the call was routed to a different region incorrectly by the company. She stated if the order is as needed then Respiratory Therapy initiates the machine. When asked if it was normal for a resident to have to wait a day and a half for initiation of a non-invasive mechanical ventilator machine, she stated no that was not

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normal. She stated she had asked Nurse #3 what happened to Resident #1 and did not question it any farther. The interview revealed the facility had started an in-service on non-invasive mechanical ventilator machines after the incident for 4 days taught by the Respiratory Therapist and the District Manager of the RT company.

A follow up interview conducted on 11/16/21 at 4:36 PM with the Director of Nursing revealed she did not always communicate with the Admissions Coordinator regarding new admissions in the facility. She stated she was unaware Resident #1 required a BiPaP or non-invasive mechanical ventilator machine. The DON stated she had not seen Resident #1's hospital discharge summary. The interview revealed she would have expected the Admissions Coordinator to communicate to her if a resident required a BiPaP or non-invasive mechanical ventilator machine. She stated residents don't always have orders prior to entering the facility. The interview revealed the Admissions Coordinator should have notified Respiratory Therapy prior to Resident #1's arrival into the facility. She stated when the facility becomes aware of a resident needing BiPaP they notify Respiratory Therapy and obtain a BiPaP machine that was kept in the facility for resident use. The DON stated she learned about the resident needing a BiPaP on 10/18/21 after he was in the facility it was her understanding the nurses had attempted to contact Respiratory Therapy on 10/18/21 and that they were coming to set up his non-invasive mechanical ventilator machine.

The facility Administrator was not available for interview during the time of the investigation.

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An interview was conducted on 11/19/21 at 10:45 AM with a representative from a clinical respiratory provider specializing in ventilator therapy. He explained BiPaP was static therapy which was non-reactive to any change in patient needs. On the other hand, AVAPS-AE (Average Volume Assured Pressure Support- Auto EPAP) mode automatically adjusts ventilation to patients' breathing patterns, to meet their changing needs over time. The interview revealed the system was a higher level of support but not life sustaining. The non- invasive mechanical ventilator could set end expiratory pressure and had a flow tracking function to sense if the resident was still exhaling air in order to prevent a next breath from being delivered prematurely. He stated there was no way to disable the low pressure alarm if the patient was disconnected from the device, however staff could silence the alarm by pushing the button on the front of the machine, but it would only stop the alarm for one minute. He stated if the machine was unplugged there was a battery back-up and explained when the battery got down to 20 minutes of run time remaining a more aggressive alarm would begin to sound and at 10 minutes remaining time an even louder alarm would sound that cannot be silenced using the alarm silence button. He stated the only way there would be no alarm is if the machine was turned off.

An interview conducted on 11/17/21 at 10:30 AM with Family Member #1 revealed she was in the facility on 10/19/21 at the front desk due to the facility only allowing one person to see Resident #1. Resident #1 was being quarantined as a new admission. She stated Family Member #2 was in the room with the resident. She stated she stopped the Director of Nursing (DON) in the hall

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and was asking her why Resident #1 had gone the night prior without his BiPaP machine and also had no breathing treatments. The interview revealed the family was on high alert because Resident #1 was so weak and had been extremely short of breath the day before on 10/18/21 and on 10/19/21. She stated she left the facility, but Family Member #2 stayed in the facility until 6:00 PM with Resident #1. She stated at 1:30 AM she received a call from Nurse #3 stating Resident #1 was unresponsive, so she called Family Member #2 and they began to drive to the facility. She stated she received a second call shortly after stating Resident #1 had expired. Family Member #1 stated Nurse #3 told her she had just given him his medication and then found him stating he had changed his mask. Family Member #1 confirmed with Family Member #2 that Resident #1 was short of breath on 10/19/21 prior to the Respiratory Therapist entering the building and applying his non-invasive mechanical ventilator machine. Family Member #1 stated Resident #1's non-invasive mechanical ventilator mask had to be applied for him prior to entering the hospital and while in the hospital. She stated she stated that Resident #1 could not remove his mask by himself in the weak state he was in.

The facility provided the following Corrective Action Plan with the correction date of 10/26/21:

1) Immediate Action for Resident Affected:
· Resident #1 expired on 10/20/21. Physician and Responsible Party was notified on 10/20/2021.
· On 10/20/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI)

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meeting was completed via conference call with facility Interdisciplinary Team (IDT) and Regional Director of Operations (RDO), Regional Director of Clinical Services (RDCS) and Vice President of Clinical Services (VPCS) to discuss initial findings of event and to initiate immediate action plans based on immediate findings.

2) Identification of Others:

· On 10/24 and 10/25/2021, an audit was completed by the Director of Nursing of all current residents utilizing Non-invasive Ventilator (NIV) which include bi-level positive airway pressure (Bi-Pap), continuous positive airway pressure (C-Pap) and non-invasive ventilation average volume assured pressure support-auto E-Pap (NIV/AVAPS-AE, brands such as trilogy) devices to ensure that physician orders include the device settings and frequency of use. Resident #2 identified for order clarification. There was no harm or adverse effects to Resident #2 and resident remains stable on current NIV settings.

· On 10/24/21, the Physician was notified by the Director of Nursing of orders needing clarification for Resident #2 ' s NIV/AVAPS-AE (Non-invasive Ventilation) device. Resident #2 orders revised and implemented on 10/24/21 by the Director of Nursing and care plan revised on 10/25/21.

· On 10/25/2021, the respiratory therapist completed a review (and revision as appropriate) of current residents on NIV devices to ensure settings were accurate based upon physician orders. No further recommendations made.

· On 10/25/2021, all new admissions from 9/18-10/20/21 will be reviewed by the Director of Nursing/designee to ensure any resident requiring NIV devices per hospital discharge summary have appropriate orders to include settings and frequency of use. No additional residents were

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identified for correction.

· On 10/22/21, the VPCS and contracted District Director of Respiratory Therapy reviewed and revised policy "Non-invasive Ventilation: IV/AVAPSA-E feature" to reflect and further clarify licensed nurses and Respiratory Therapists roles and responsibilities in the management of Bi-Pap, C-Pap and APAPS-AE NIV (brands such as Trilogy) devices.

3) Education/Systemic Change

· On 10/22/21, the VPCS provided education to the facility Administrator, DON and RDCS on the updated policy "Non-invasive Ventilation: IV/AVAPSA-E feature" to include that effective immediately the facility shall no longer accept NIV/AVAPS-AE devices (brands such as trilogy) On 10/25/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed by the IDT and RDCS, RDO and VPCS a comprehensive corrective action plan was developed based on root cause analysis to address F580, F695, F726, and F835.

· By 10/25/21, all licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing (DON)/ designee on ensuring that the physician is notified of any delay in implementing physician orders including initiation of NIV devices. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, all licensed nursing staff including agency staff will be educated by the Director of Nursing/designee related to the admission process including verification and transcription of orders and immediately contacting the physician if clarifications are needed. The DON will maintain education records to validate

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staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, the unit clerk and all licensed nursing staff including agency staff will be educated by the Director of Nursing /designee regarding the notification process which includes calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. In addition, if the resident is in any acute distress, he/she will immediately be sent to the emergency room for further evaluation. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· Effective 10/25/21, each nursing station will have the contact information for the contracted Respiratory Therapy company prominently posted. Respiratory therapy services are available after hours and on weekends.

· By 10/25/2021, the Admission Director will be educated by the Administrator/ designee on ensuring the respiratory therapist, unit clerk, and supply personnel are notified prior to admission when residents require NIV devices. Education also included for admissions to no longer accept NIV/AVAPS-AE, brands such as trilogy effective 10/25/21. The Admissions Director was also educated by the DON on 10/25/21 on C-PAP, Bi-PAP, and AVAPS-AE (Trilogy type) devices to identify the differences in the settings associated with these types of

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devices. The DON will maintain education records to validate staff competency for current and newly hired facility Admission staff. Staff will not be allowed to work until education completed.

· Effective 10/25/21, the Admission Director or Director of Nursing will ensure that the contracted respiratory therapy company will be notified at least 24 hours prior to an admission with physician orders for NIV device to ensure NIV device will be readily available prior to admission with the required settings verified.

· By 10/25/2021, the Admission Director and licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing on ensuring that ordered equipment/or devices are available with required setting and frequency orders when residents are admitted to the facility. The DON will maintain education records to validate staff competency for current and newly hired facility Admissions staff and facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, Licensed Nurses, Admissions Director, Medical Director and Social Services were educated by the Administrator on the facility clinical capabilities grid which specifies the care services provided by the facility to determine admission approval. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses, Admissions staff, Medical Director and Social Services staff. Staff will not be allowed to work until education completed.

· Effective 10/25/21, the facility will no longer accept NIV/ AVAPS-AE devices (brands such as trilogy) in the facility. The Admission Director received education on 10/25/21.

· By 10/25/2021, Licensed Nurses

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including agency licensed nurses will be educated on the facility policy revision date 10/22/21 "Non-invasive Ventilation: IV/AVAPSA-E feature" to include competencies on the use of all NIV devices, required ongoing respiratory assessment documentation related NIV and oxygen therapy by the Respiratory Therapist and Director of Nursing. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/21, Certified Nurse Aides (CNA) including agency CNA will be educated by the Director of Nursing on the care of NIV residents including notifying the Licensed Nurses of any issues with the NIV including alarms, remaining with the resident until licensed nurse responds and not manipulating machine in any way. The DON will maintain education records to validate staff competency for current and newly hired facility and agency CNAs. Staff will not be allowed to work until education completed. Staff will not be allowed to work until education completed.

· Effective 10/25/2021, all education for above will be included in the orientation process to include new hire facility licensed nurses, agency licensed nurses, CNAs, and admission staff. These staff will not be allowed to work until education completed.

· Effective 10/25/21, new admission paperwork and physician orders will be reviewed by nursing management in morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for NIV devices and notification to physician of any order discrepancies for clarification. Nursing management was informed of review process during Ad Hoc QAPI meeting on 10/25/21 by the

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Administrator.
4) Monitoring Process:
· Beginning 10/25/21, 1) nursing management will review/audit new admission paperwork during morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification. Any discrepancies will be communicated to the physician for clarification and/or correction and 2) the Administrator/designee will review/audit nursing education files for new hires and agency staff to ensure staff competence of Bi-Pap and C-Pap NIV devices. Staff will not be allowed to work until education complete.
· Results of the audits will be documented on the "Quality Improvement Data Collection Sheet" and maintained in the plan of correction binder in the Administrator ' s office.
· On 10/25/21, the QAPI Committee was notified by the Administrator of delegation of QA monitoring responsibilities. The results of the monitoring will be discussed in the monthly QAPI committee meeting for at least three months, overseen by the Administrator, Director of Nursing, and the Medical Director. The interdisciplinary team will recommend revisions to the plan as indicated to maintain substantial compliance.
· Beginning 10/25/21, the RDCS and/or the RDO will review results of facility audits and QAPI minutes monthly for three months to ensure ongoing compliance with accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification.

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F 695	Continued From page 41 The facility alleges compliance on 10/26/2021 The Corrective Action Plan was validated on 11/24/21 and concluded the facility implemented an acceptable corrective action plan on 10/26/21. The facility amended the notification process to include calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. The Corrective Action Plan was reviewed during QAPI meeting held on 10/25/21. The weekly monitoring logs residents requiring a BiPaP/ CPAP were reviewed from October 2021 to November 2021 with no concerns identified. Review of the nursing staff in-service sheets on non-invasive mechanical ventilator training revealed the nursing staff had initialed as receiving the in-service training. Interviews conducted with nursing staff from first, second and third shifts revealed they had received the in-service as stated by the facility. The staff verified they had received in-servicing on notification, abuse, neglect, change of condition and use of a BiPap/CPAP machine.	F 695		
F 726 SS=J	Competent Nursing Staff CFR(s): 483.35(a)(3)(4)(c) §483.35 Nursing Services The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest	F 726		12/22/21

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F 726	Continued From page 42 practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at §483.70(e). §483.35(a)(3) The facility must ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care. §483.35(a)(4) Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs. §483.35(c) Proficiency of nurse aides. The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care. This REQUIREMENT is not met as evidenced by: Based on record reviews and staff, Respiratory Therapist and Medical Director (MD) interviews the facility failed to ensure nursing staff could demonstrate competency to provide for and to meet the respiratory care needs of a resident with a compromised respiratory status. Resident #1 was admitted into the facility on 10/18/21 with diagnosis which included chronic obstructive pulmonary disease (COPD) and respiratory failure. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic	F 726	Past noncompliance: no plan of correction required.	

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respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 2 resident reviewed for competent nursing staff.

The findings included:

This tag is cross referred to:

F 580: Based on record reviews and staff, Respiratory Therapist and Medical Director (MD) interviews the facility failed to notify the Physician for clarification when a resident (Resident #1) was admitted on 10/18/21 with orders for a bilevel positive airway pressure (BiPaP) that did not include the settings or frequency for the non-invasive mechanical ventilator. In addition, Nurse Manager #1 did not contact the Physician when they were not able to reach the Respiratory Therapist on 10/18/21 for assistance with setting up the BiPaP. The morning of 10/19/21 Nurse #2 was approached by Resident #1's family member who asked why the non-invasive mechanical ventilator was not being used. Nurse #2 did not attempt to contact the Physician or Respiratory Therapy for assistance. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 1 resident reviewed for notification of changes.

F 695: Based on record reviews and staff, Respiratory Therapist, Medical Director (MD) and clinical respiratory provider interviews the facility failed to provide necessary respiratory care and services to a resident with a compromised respiratory status who was dependent on bilevel positive airway pressure (BiPaP). Resident #1 was admitted on 10/18/21 with orders for a bilevel

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positive airway pressure (BiPaP) that did not include the settings or frequency for the non-invasive mechanical ventilator. The facility failed to clarify orders for the BiPaP on admission or involve respiratory therapy and as a result the BiPaP machine was not set up until the evening of 10/19/21. In addition, the facility failed to complete and document on-going comprehensive assessments of the resident's respiratory status and ensure Resident #1 had continuous oxygen. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 2 resident reviewed for respiratory care.

The facility provided the following Corrective Action Plan with the correction date of 10/26/21:

1) Immediate Action for Resident Affected:
· Resident #1 expired on 10/20/21. Physician and Responsible Party was notified on 10/20/2021.
· On 10/20/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed via conference call with facility Interdisciplinary Team (IDT) and Regional Director of Operations (RDO), Regional Director of Clinical Services (RDCS) and Vice President of Clinical Services (VPCS) to discuss initial findings of event and to initiate immediate action plans based on immediate findings.
2) Identification of Others:
· On 10/24 and 10/25/2021, an audit was completed by the Director of Nursing of all current residents utilizing Non-invasive Ventilator (NIV) which include bi-level positive airway pressure

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(Bi-Pap), continuous positive airway pressure (C-Pap) and non-invasive ventilation average volume assured pressure support-auto E-Pap (NIV/AVAPS-AE, brands such as trilogy) devices to ensure that physician orders include the device settings and frequency of use. Resident #2 identified for order clarification. There was no harm or adverse effects to Resident #2 and resident remains stable on current NIV settings.

· On 10/24/21, the Physician was notified by the Director of Nursing of orders needing clarification for Resident #2 s NIV/AVAPS-AE (Non-invasive Ventilation) device. Resident #2 orders revised and implemented on 10/24/21 by the Director of Nursing and care plan revised on 10/25/21.

· On 10/25/2021, the respiratory therapist completed a review (and revision as appropriate) of current residents on NIV devices to ensure settings were accurate based upon physician orders. No further recommendations made.

· On 10/25/2021, all new admissions from 9/18-10/20/21 will be reviewed by the Director of Nursing/designee to ensure any resident requiring NIV devices per hospital discharge summary have appropriate orders to include settings and frequency of use. No additional residents were identified for correction.

· On 10/22/21, the VPCS and contracted District Director of Respiratory Therapy reviewed and revised policy "Non-invasive Ventilation: IV/AVAPSA-E feature" to reflect and further clarify licensed nurses and Respiratory Therapists roles and responsibilities in the management of Bi-Pap, C-Pap and APAPS-AE NIV (brands such as Trilogy) devices.

3) Education/Systemic Change

· On 10/22/21, the VPCS provided education to the facility Administrator, DON and

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RDCS on the updated policy "Non-invasive Ventilation: IV/AVAPSA-E feature" to include that effective immediately the facility shall no longer accept NIV/AVAPS-AE devices (brands such as trilogy) On 10/25/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed by the IDT and RDCS, RDO and VPCS a comprehensive corrective action plan was developed based on root cause analysis to address F580, F695, F726, and F835.

· By 10/25/21, all licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing (DON)/ designee on ensuring that the physician is notified of any delay in implementing physician orders including initiation of NIV devices. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, all licensed nursing staff including agency staff will be educated by the Director of Nursing/designee related to the admission process including verification and transcription of orders and immediately contacting the physician if clarifications are needed. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, the unit clerk and all licensed nursing staff including agency staff will be educated by the Director of Nursing /designee regarding the notification process which includes calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy

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company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. In addition, if the resident is in any acute distress, he/she will immediately be sent to the emergency room for further evaluation. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· Effective 10/25/21, each nursing station will have the contact information for the contracted Respiratory Therapy company prominently posted. Respiratory therapy services are available after hours and on weekends.

· By 10/25/2021, the Admission Director will be educated by the Administrator/ designee on ensuring the respiratory therapist, unit clerk, and supply personnel are notified prior to admission when residents require NIV devices. Education also included for admissions to no longer accept NIV/AVAPS-AE, brands such as trilogy effective 10/25/21. The Admissions Director was also educated by the DON on 10/25/21 on C-PAP, Bi-PAP, and AVAPS-AE (Trilogy type) devices to identify the differences in the settings associated with these types of devices. The DON will maintain education records to validate staff competency for current and newly hired facility Admission staff. Staff will not be allowed to work until education completed.

· Effective 10/25/21, the Admission Director or Director of Nursing will ensure that the contracted respiratory therapy company will be notified at least 24 hours prior to an admission with physician orders for NIV device to ensure NIV device will be readily available prior to admission with the required settings verified.

· By 10/25/2021, the Admission Director

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and licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing on ensuring that ordered equipment/or devices are available with required setting and frequency orders when residents are admitted to the facility. The DON will maintain education records to validate staff competency for current and newly hired facility Admissions staff and facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, Licensed Nurses, Admissions Director, Medical Director and Social Services were educated by the Administrator on the facility clinical capabilities grid which specifies the care services provided by the facility to determine admission approval. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses, Admissions staff, Medical Director and Social Services staff. Staff will not be allowed to work until education completed.

· Effective 10/25/21, the facility will no longer accept NIV/ AVAPS-AE devices (brands such as trilogy) in the facility. The Admission Director received education on 10/25/21.

· By 10/25/2021, Licensed Nurses including agency licensed nurses will be educated on the facility policy revision date 10/22/21 "Non-invasive Ventilation: IV/AVAPSA-E feature" to include competencies on the use of all NIV devices, required ongoing respiratory assessment documentation related NIV and oxygen therapy by the Respiratory Therapist and Director of Nursing. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

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· By 10/25/21, Certified Nurse Aides (CNA) including agency CNA will be educated by the Director of Nursing on the care of NIV residents including notifying the Licensed Nurses of any issues with the NIV including alarms, remaining with the resident until licensed nurse responds and not manipulating machine in any way. The DON will maintain education records to validate staff competency for current and newly hired facility and agency CNAs. Staff will not be allowed to work until education completed. Staff will not be allowed to work until education completed.

· Effective 10/25/2021, all education for above will be included in the orientation process to include new hire facility licensed nurses, agency licensed nurses, CNAs, and admission staff. These staff will not be allowed to work until education completed.

· Effective 10/25/21, new admission paperwork and physician orders will be reviewed by nursing management in morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for NIV devices and notification to physician of any order discrepancies for clarification. Nursing management was informed of review process during Ad Hoc QAPI meeting on 10/25/21 by the Administrator.

4) Monitoring Process:

· Beginning 10/25/21, 1) nursing management will review/audit new admission paperwork during morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification. Any discrepancies will be communicated to the physician for clarification and/or correction and 2) the Administrator/designee will review/audit nursing

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education files for new hires and agency staff to ensure staff competence of Bi-Pap and C-Pap NIV devices. Staff will not be allowed to work until education complete.

· Results of the audits will be documented on the "Quality Improvement Data Collection Sheet" and maintained in the plan of correction binder in the Administrator ' s office.

· On 10/25/21, the QAPI Committee was notified by the Administrator of delegation of QA monitoring responsibilities. The results of the monitoring will be discussed in the monthly QAPI committee meeting for at least three months, overseen by the Administrator, Director of Nursing, and the Medical Director. The interdisciplinary team will recommend revisions to the plan as indicated to maintain substantial compliance.

· Beginning 10/25/21, the RDCS and/or the RDO will review results of facility audits and QAPI minutes monthly for three months to ensure ongoing compliance with accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification.

The facility alleges compliance on 10/26/021.

The Corrective Action Plan was validated on 11/24/21 and concluded the facility implemented an acceptable corrective action plan on 10/26/21. The facility amended the notification process to include calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the

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THE CITADEL MOORESVILLE	550 GLENWOOD DRIVE MOORESVILLE, NC 28115

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F 726	Continued From page 51 facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. The Corrective Action Plan was reviewed during QAPI meeting held on 10/25/21. The weekly monitoring logs residents requiring a BiPaP/ CPAP were reviewed from October 2021 to November 2021 with no concerns identified. Review of the nursing staff in-service sheets on non-invasive mechanical ventilator training revealed the nursing staff had initialed as receiving the in-service training. Interviews conducted with nursing staff from first, second and third shifts revealed they had received the in-service as stated by the facility. The staff verified they had received in-servicing on notification, abuse, neglect, change of condition and use of a BiPap/CPAP machine.	F 726		
F 835 SS=J	Administration CFR(s): 483.70 §483.70 Administration. A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. This REQUIREMENT is not met as evidenced by: Based on record reviews and Respiratory Therapist, Medical Director (MD) and Administrative staff interviews the facility failed to provide oversight for effective admission procedures and decisions, and systems for effective and necessary delivery of care for a resident with a compromised respiratory status and dependency on BiPap ventilation using a non-invasive mechanical ventilator. Review of	F 835	Past noncompliance: no plan of correction required.	12/22/21

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Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 2 residents reviewed for Administration.

The findings included:

This tag is cross referred to:

F 580: Based on record reviews and staff, Respiratory Therapist and Medical Director (MD) interviews the facility failed to notify the Physician for clarification when a resident (Resident #1) was admitted on 10/18/21 with orders for a bilevel positive airway pressure (BiPaP) that did not include the settings or frequency for the non-invasive mechanical ventilator. In addition, Nurse Manager #1 did not contact the Physician when they were not able to reach the Respiratory Therapist on 10/18/21 for assistance with setting up the BiPaP. The morning of 10/19/21 Nurse #2 was approached by Resident #1's family member who asked why the non-invasive mechanical ventilator was not being used. Nurse #2 did not attempt to contact the Physician or Respiratory Therapy for assistance. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 1 resident reviewed for notification of changes.

F 695: Based on record reviews and staff, Respiratory Therapist, Medical Director (MD) and clinical respiratory provider interviews the facility failed to provide necessary respiratory care and services to a resident with a compromised

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respiratory status who was dependent on bilevel positive airway pressure (BiPaP). Resident #1 was admitted on 10/18/21 with orders for a bilevel positive airway pressure (BiPaP) that did not include the settings or frequency for the non-invasive mechanical ventilator. The facility failed to clarify orders for the BiPaP on admission or involve respiratory therapy and as a result the BiPaP machine was not set up until the evening of 10/19/21. In addition, the facility failed to complete and document on-going comprehensive assessments of the resident's respiratory status and ensure Resident #1 had continuous oxygen. Review of Resident #1's Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 2 resident reviewed for respiratory care.

F 726: Based on record reviews and staff, Respiratory Therapist and Medical Director (MD) interviews the facility failed to ensure nursing staff could demonstrate competency to provide for and to meet the respiratory care needs of a resident with a compromised respiratory status. Resident #1 was admitted into the facility on 10/18/21 with diagnosis which included chronic obstructive pulmonary disease (COPD) and respiratory failure. Review of Resident #1 ' s Death Certificate revealed he expired on 10/20/21 at 2:07 AM. The cause of death was listed as acute and chronic respiratory failure with hypoxia (lack of oxygen). This failure affected 1 of 2 resident reviewed for competent nursing staff.

The facility provided the following Corrective Action Plan with the correction date of 10/26/21:

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1) Immediate Action for Resident Affected:
· Resident #1 expired on 10/20/21. Physician and Responsible Party was notified on 10/20/2021.
· On 10/20/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed via conference call with facility Interdisciplinary Team (IDT) and Regional Director of Operations (RDO), Regional Director of Clinical Services (RDCS) and Vice President of Clinical Services (VPCS) to discuss initial findings of event and to initiate immediate action plans based on immediate findings.
2) Identification of Others:
· On 10/24 and 10/25/2021, an audit was completed by the Director of Nursing of all current residents utilizing Non-invasive Ventilator (NIV) which include bi-level positive airway pressure (Bi-Pap), continuous positive airway pressure (C-Pap) and non-invasive ventilation average volume assured pressure support-auto E-Pap (NIV/AVAPS-AE, brands such as trilogy) devices to ensure that physician orders include the device settings and frequency of use. Resident #2 identified for order clarification. There was no harm or adverse effects to Resident #2 and resident remains stable on current NIV settings.
· On 10/24/21, the Physician was notified by the Director of Nursing of orders needing clarification for Resident #2's NIV/AVAPS-AE (Non-invasive Ventilation) device. Resident #2 orders revised and implemented on 10/24/21 by the Director of Nursing and care plan revised on 10/25/21.
· On 10/25/2021, the respiratory therapist completed a review (and revision as appropriate) of current residents on NIV devices to ensure settings were accurate based upon physician

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orders. No further recommendations made.

· On 10/25/2021, all new admissions from 9/18-10/20/21 will be reviewed by the Director of Nursing/designee to ensure any resident requiring NIV devices per hospital discharge summary have appropriate orders to include settings and frequency of use. No additional residents were identified for correction.

· On 10/22/21, the VPCS and contracted District Director of Respiratory Therapy reviewed and revised policy "Non-invasive Ventilation: IV/AVAPSA-E feature" to reflect and further clarify licensed nurses and Respiratory Therapists roles and responsibilities in the management of Bi-Pap, C-Pap and APAPS-AE NIV (brands such as Trilogy) devices.

3) Education/Systemic Change

· On 10/22/21, the VPCS provided education to the facility Administrator, DON and RDCS on the updated policy "Non-invasive Ventilation: IV/AVAPSA-E feature" to include that effective immediately the facility shall no longer accept NIV/AVAPS-AE devices (brands such as trilogy) On 10/25/21, an Ad Hoc Quality Assurance Performance Improvement (QAPI) meeting was completed by the IDT and RDCS, RDO and VPCS a comprehensive corrective action plan was developed based on root cause analysis to address F580, F695, F726, and F835.

· By 10/25/21, all licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing (DON)/ designee on ensuring that the physician is notified of any delay in implementing physician orders including initiation of NIV devices. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

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· By 10/25/2021, all licensed nursing staff including agency staff will be educated by the Director of Nursing/designee related to the admission process including verification and transcription of orders and immediately contacting the physician if clarifications are needed. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/2021, the unit clerk and all licensed nursing staff including agency staff will be educated by the Director of Nursing /designee regarding the notification process which includes calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. In addition, if the resident is in any acute distress, he/she will immediately be sent to the emergency room for further evaluation. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· Effective 10/25/21, each nursing station will have the contact information for the contracted Respiratory Therapy company prominently posted. Respiratory therapy services are available after hours and on weekends.

· By 10/25/2021, the Admission Director will be educated by the Administrator/ designee on ensuring the respiratory therapist, unit clerk, and supply personnel are notified prior to admission when residents require NIV devices.

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F 835	Continued From page 57 Education also included for admissions to no longer accept NIV/AVAPS-AE, brands such as trilogy effective 10/25/21. The Admissions Director was also educated by the DON on 10/25/21 on C-PAP, Bi-PAP, and AVAPS-AE (Trilogy type) devices to identify the differences in the settings associated with these types of devices. The DON will maintain education records to validate staff competency for current and newly hired facility Admission staff. Staff will not be allowed to work until education completed. · Effective 10/25/21, the Admission Director or Director of Nursing will ensure that the contracted respiratory therapy company will be notified at least 24 hours prior to an admission with physician orders for NIV device to ensure NIV device will be readily available prior to admission with the required settings verified. · By 10/25/2021, the Admission Director and licensed nursing staff including agency licensed nurses will be educated by the Director of Nursing on ensuring that ordered equipment/or devices are available with required setting and frequency orders when residents are admitted to the facility. The DON will maintain education records to validate staff competency for current and newly hired facility Admissions staff and facility and agency licensed nurses. Staff will not be allowed to work until education completed. · By 10/25/2021, Licensed Nurses, Admissions Director, Medical Director and Social Services were educated by the Administrator on the facility clinical capabilities grid which specifies the care services provided by the facility to determine admission approval. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses, Admissions staff, Medical Director and Social Services staff. Staff	F 835		

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will not be allowed to work until education completed.

· Effective 10/25/21, the facility will no longer accept NIV/ AVAPS-AE devices (brands such as trilogy) in the facility. The Admission Director received education on 10/25/21.

· By 10/25/2021, Licensed Nurses including agency licensed nurses will be educated on the facility policy revision date 10/22/21 "Non-invasive Ventilation: IV/AVAPSA-E feature" to include competencies on the use of all NIV devices, required ongoing respiratory assessment documentation related NIV and oxygen therapy by the Respiratory Therapist and Director of Nursing. The DON will maintain education records to validate staff competency for current and newly hired facility and agency licensed nurses. Staff will not be allowed to work until education completed.

· By 10/25/21, Certified Nurse Aides (CNA) including agency CNA will be educated by the Director of Nursing on the care of NIV residents including notifying the Licensed Nurses of any issues with the NIV including alarms, remaining with the resident until licensed nurse responds and not manipulating machine in any way. The DON will maintain education records to validate staff competency for current and newly hired facility and agency CNAs. Staff will not be allowed to work until education completed. Staff will not be allowed to work until education completed.

· Effective 10/25/2021, all education for above will be included in the orientation process to include new hire facility licensed nurses, agency licensed nurses, CNAs, and admission staff. These staff will not be allowed to work until education completed.

· Effective 10/25/21, new admission paperwork and physician orders will be reviewed

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by nursing management in morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for NIV devices and notification to physician of any order discrepancies for clarification. Nursing management was informed of review process during Ad Hoc QAPI meeting on 10/25/21 by the Administrator.

4) Monitoring Process:

· Beginning 10/25/21, 1) nursing management will review/audit new admission paperwork during morning clinical report to ensure the accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification. Any discrepancies will be communicated to the physician for clarification and/or correction and 2) the Administrator/designee will review/audit nursing education files for new hires and agency staff to ensure staff competence of Bi-Pap and C-Pap NIV devices. Staff will not be allowed to work until education complete.

· Results of the audits will be documented on the "Quality Improvement Data Collection Sheet" and maintained in the plan of correction binder in the Administrator ' s office.

· On 10/25/21, the QAPI Committee was notified by the Administrator of delegation of QA monitoring responsibilities. The results of the monitoring will be discussed in the monthly QAPI committee meeting for at least three months, overseen by the Administrator, Director of Nursing, and the Medical Director. The interdisciplinary team will recommend revisions to the plan as indicated to maintain substantial compliance.

· Beginning 10/25/21, the RDCS and/or the RDO will review results of facility audits and

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QAPI minutes monthly for three months to ensure ongoing compliance with accuracy and timely implementation of physician ' s orders for Bi-Pap and C-Pap NIV devices and notification to physician of any order discrepancies for clarification.

The facility alleges compliance on 10/26/2021

The Corrective Action Plan was validated on 11/24/21 and concluded the facility implemented an acceptable corrective action plan on 10/26/21. The facility amended the notification process to include calling the respiratory therapy company customer service number to notify the Respiratory Therapist of all new admission requiring NIV devices and any other respiratory needs of current residents. If the respiratory therapy company does not respond within 10 minutes, the facility will reattempt x 1, if no response the MD will be immediately contacted for further orders. The Corrective Action Plan was reviewed during QAPI meeting held on 10/25/21.

The weekly monitoring logs residents requiring a BiPaP/ CPAP were reviewed from October 2021 to November 2021 with no concerns identified. Review of the nursing staff in-service sheets on non-invasive mechanical ventilator training revealed the nursing staff had initialed as receiving the in-service training. Interviews conducted with nursing staff from first, second and third shifts revealed they had received the in-service as stated by the facility. The staff verified they had received in-servicing on notification, abuse, neglect, change of condition and use of a BiPap/CPAP machine.