STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345484	A. BUILDING _____ B. WING _____	11/24/2021

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TRANSYLVANIA REGIONAL HOSPITAL	260 HOSPITAL DRIVE BREVARD, NC 28712

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E 000	Initial Comments An unannounced recertification survey was conducted on 11/22/21 through 11/24/21. The facility was found in compliance with the requirement CFR 483.73, Emergency Preparedness. Event ID# K7U711.	E 000		
F 000	INITIAL COMMENTS An unannounced recertification survey was conducted on 11/22/21 through 11/24/21. Event ID# K7U711.	F 000		
F 636 SS=D	Comprehensive Assessments & Timing CFR(s): 483.20(b)(1)(2)(i)(iii) §483.20 Resident Assessment The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident's functional capacity. §483.20(b) Comprehensive Assessments §483.20(b)(1) Resident Assessment Instrument. A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following: (i) Identification and demographic information (ii) Customary routine. (iii) Cognitive patterns. (iv) Communication. (v) Vision. (vi) Mood and behavior patterns. (vii) Psychological well-being. (viii) Physical functioning and structural problems. (ix) Continence. (x) Disease diagnosis and health conditions.	F 636		12/22/21

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

Electronically Signed | 12/27/2021

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F 636	Continued From page 1 (xi) Dental and nutritional status. (xii) Skin Conditions. (xiii) Activity pursuit. (xiv) Medications. (xv) Special treatments and procedures. (xvi) Discharge planning. (xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS). (xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts. §483.20(b)(2) When required. Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2)(i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs. (i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or therapeutic leave.) (iii)Not less than once every 12 months. This REQUIREMENT is not met as evidenced by: Based on record review and interviews with staff, the facility failed to complete an Admission Minimum Data Set (MDS) within the first 14 days of admission for 1 of 5 residents reviewed for	F 636	The facility failed to complete an Admission Minimum Data Set (MDS) within the first 14 days of admission. The lack of program oversight for the MDS	

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F 636	Continued From page 2 accuracy (Resident #1). The findings included: Resident #1 was admitted from the hospital on 11/4/21 with diagnoses including diabetes mellitus and fracture of the right radius. Resident #1's medical record was reviewed and revealed an Admission MDS assessment with an Assessment Reference Date (ARD, the last day of the observation period that the assessment covers) of 11/10/2021 had not been completed as of 11/24/2021. This was 21 days after Resident #1's admission to the facility. During an interview on 11/24/21 at 9:09 AM the MDS Coordinator explained the Admission MDS assessment with an ARD of 11/10/2021 was due to be signed as completed on 11/24/21. During an interview on 11/24/21 at 11:15 AM the Director of Nursing (DON) explained the floor nurses do the required assessments and documentation needed to complete the MDS. The DON then gathers this information and sends it to the MDS Coordinator who is expected to input the data and submit the information for each resident.	F 636	submission process led to this deficiency. " On 12/21/2021, the standard CFR: 483.20(b)(1)(2)(i)(iii) and the finding from the recent survey were reviewed with the MDS coordinator by the Director of Nursing. " On 12/20/2021, an audit tool was created to monitor completion of timely MDS submission. The audit tool was sent to the MDS coordinator to complete on 100% of resident MDS□s " To ensure improvements have been made, beginning 12/27/2021, all MDS completions will be reviewed weekly by the Director of Nursing. Numerator: Total number of MDS submitted within 14 days of admission Denominator: Total number of submitted MDS□s reviewed Data related to the measure associated with this standard will be reported to the Transylvania Patient Safety & Quality Committee for 3 consecutive months for 100% compliance. Any late MDS submissions will be discussed with MDS coordinator and action plan revised as necessary until goal is met. " The Director of Nursing is responsible for implementing and overseeing the actions taken with this plan. Completion date of 12/22/21	
F 761 SS=D	Label/Store Drugs and Biologicals CFR(s): 483.45(g)(h)(1)(2)	F 761		12/22/21

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F 761	Continued From page 3 §483.45(g) Labeling of Drugs and Biologicals Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable. §483.45(h) Storage of Drugs and Biologicals §483.45(h)(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys. §483.45(h)(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. This REQUIREMENT is not met as evidenced by: Based on record review, observations and interviews with staff and family, the facility failed to secure and date an opened medication that was available for use for 1 of 4 Residents reviewed for medication storage. (Resident #155) Findings included: A review of the manufacturer's recommendation for Latanoprost ophthalmic solution indicated that an unopened bottle must be stored under	F 761	During the recent survey the surveyor observed a bottle of opened and undated eye drops at resident bedside. Staff were unaware to secure eyedrops and label with beyond use date after opening which led to this deficiency. " Beginning 12/20/21, the Director of Nursing provided education on medication security and beyond use dating requirements to nursing staff. Education is	

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F 761	Continued From page 4 refrigeration at 36° to 46° Fahrenheit (F). Once a bottle of Latanoprost ophthalmic solution was opened for use, it could be stored at room temperature up to 77° F for 6 weeks. Resident #155 was admitted to the facility on 11/11/21 with diagnoses included glaucoma. The admission Minimum Data Set (MDS) was not completed at the time of this survey. On 11/22/21 at 12:24 PM, 1 bottle of opened and undated Latanoprost ophthalmic solution was observed next to the sink in Resident #155's room. The eye drop did not have a date to indicate when it was opened and was available for use. In an interview with the family member of Resident #155 on 11/22/21 at 12:25 PM, she stated Resident #155 received Latanoprost once daily at night and had never been assessed for self-administration of medication. She did not know how long the eye drop had been left unattended in the room so far. She added Resident #155 had mild confusion at night most of the times. During an interview with Nurse #1 on 11/22/21 at 12:34 PM she did not know why Latanoprost ophthalmic solution was left unattended by the second shift nurse in Resident #155's room. She acknowledged that the eye drop should be stored in the Pixel in medication storage room and dated when it was opened. She never administered Latanoprost to Resident #155 as she only worked in the first shift. She did not know which nurse had initially opened this eye drop.	F 761	occurring during daily huddles to ensure all staff receive education with their first working shift. " On 12/21/21, audit tools were developed to monitor medication security and beyond use dating. o Medication security will be monitored by the Director of Nursing through bi-weekly room audits. Any unsecured medications identified will be immediately secured and reviewed with the nursing staff. o Medication beyond use dating will be monitored by the Director of Pharmacy or designee through weekly medication audits. Any medication without the appropriate medication beyond use dating will be immediately discarded and reviewed with the nursing staff. " To ensure ongoing compliance with medication storage and beyond use dating, audits began 12/27/21 by Director of Nursing and Director of Pharmacy or designee. Numerator: Total number of resident rooms inspected without unsecure medications. Denominator: Total number of resident rooms inspected. Numerator: Total number of open multidose medications inspected with correct beyond use date labeling. Denominator: Total number of open multidose medications inspected. Data related to the measures associated with this standard will be reported to the	

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F 761	Continued From page 5 In an interview conducted on 11/23/21 at 10:51 AM, the Director of Pharmacy stated it was her expectation for the nurse to date the Latanoprost eye solution when it was opened and store it in the Pixel after it had been used. During a phone interview with Nurse #2 on 11/23/21 at 4:18 PM she confirmed she was working second shift on 11/21/21 and had administered Latanoprost to Resident #155 during the shift. She indicated that the eye drop had been in Resident #155's room before she used it on 11/21/21. After she had administered the eye drop, she put it back to the same spot and did not do anything to secure it. She did not notice the opened eye drop was not dated after it was opened. Nurse #2 acknowledged that it was unsafe and inappropriate to leave any medication unattended in the facility. In an interview conducted on 11/23/21 at 4:27 PM, the Director of Nursing (DON) explained the second shift nurse had forgotten to date and return Latanoprost to the Pixel after it was administered. It was her expectation for the nurse to date Latanoprost when it was opened and store it in the Pixel after each administration.	F 761	Transylvania Patient Safety & Quality Committee for 3 consecutive months for 100% compliance. " The Director of Nursing is responsible for implementing and overseeing the actions taken with this plan. Completion date of 12/22/2021.	
F 812 SS=E	Food Procurement,Store/Prepare/Serve-Sanitary CFR(s): 483.60(i)(1)(2) §483.60(i) Food safety requirements. The facility must - §483.60(i)(1) - Procure food from sources approved or considered satisfactory by federal, state or local authorities. (i) This may include food items obtained directly from local producers, subject to applicable State	F 812		12/22/21

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F 812	Continued From page 6 and local laws or regulations. (ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices. (iii) This provision does not preclude residents from consuming foods not procured by the facility. §483.60(i)(2) - Store, prepare, distribute and serve food in accordance with professional standards for food service safety. This REQUIREMENT is not met as evidenced by: Based on observations, record review, and staff interview the facility failed to remove food ready for use with signs of spoilage and after the use by date for 1 of 1 walk-in cooler and the facility failed to remove foods ready for use by the use by date for 1 of 1 dry food storage area. This practice had the potential to affect food served to residents. The findings included: Initial tour of the kitchen was completed on 11/22/21 at 10:22 AM with the Executive Chef (EC). Observations of the walk-in refrigerator revealed a half full zip lock gallon size bag of sliced pepperoni with a use by date of 9/8/21 with several slices turning gray in color. Observation of the of the dry storage area revealed a large bag of dry peanuts labeled with an expiration date of 8/18/21, an opened 5-pound bag of quinoa with a use by date 11/15/21. During an interview on 11/22/21 at 10:22 AM the EC revealed foods should not be stored after the use by date and should be thrown away. The EC stated it was the responsibility of kitchen staff to label foods when opened and remove when out	F 812	During the recent survey the surveyor observed food in the refrigerator and dry storage area of the kitchen past the use by dates. The lack of leadership oversight for removal of expired items may have led to this deficiency. " Following the survey on 11/29/21, the Dietary Manager and Executive Chef reviewed all food items in the dry storage and refrigerated areas and discarded any food items outside of the labeled expiration dates. " On 11/29/21 and 12/07/21 during daily huddle, the Dietary Manager provided education to all dietary staff using the Morrisons Food Service Policy Food and Supply Storage. Education included the storage life, labeling and removal of dry, frozen and refrigerated foods. Staff were re-oriented to the Storage Life of Foods Reference List located on all refrigerators and dry storage areas to ensure proper labeling will occur for food items. As of 12/21/21 100% of the dietary staff have received food storage education.	

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F 812	Continued From page 7 of date. The EC revealed kitchen staff were expected to use the labels generated by an automated system that printed the date food items were opened and the date it should be used by.	F 812	" To ensure improvements have been made, beginning 11/29/21, the Dietary Manager and /or the Executive Chef have made daily rounds to verify all food products are appropriately labeled, any item not within date is immediately discarded. " Beginning 12/02/21, Dietary Manager and / or the Executive Chef complete a weekly audit tool for each food storage location within the Dietary Department. Numerator: Total number of dietary storage areas reviewed with food items dated and stored properly Denominator: Total number of dietary storage areas reviewed Data related to the measure associated with this standard will be reported to the Transylvania Patient Safety & Quality Committee for 3 consecutive months for 95% compliance. Any non-compliance with appropriately dated food items will be discussed with the dietary team and action plan revised as necessary until goal is met. " The Dietary Manager is responsible for implementing and overseeing the actions taken with this plan. Completion date of 12/22/21	
F 886 SS=E	COVID-19 Testing-Residents & Staff CFR(s): 483.80 (h)(1)-(6) §483.80 (h) COVID-19 Testing. The LTC facility must test residents and facility staff, including	F 886		12/22/21

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F 886	Continued From page 8	F 886		

individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

§483.80 (h)((1) Conduct testing based on parameters set forth by the Secretary, including but not
limited to:
(i) Testing frequency;
(ii) The identification of any individual specified in this paragraph diagnosed with
COVID-19 in the facility;
(iii) The identification of any individual specified in this paragraph with symptoms
consistent with COVID-19 or with known or suspected exposure to COVID-19;
(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;
(v) The response time for test results; and
(vi) Other factors specified by the Secretary that help identify and prevent the
transmission of COVID-19.

§483.80 (h)((2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

§483.80 (h)((3) For each instance of testing:
(i) Document that testing was completed and the results of each staff test; and
(ii) Document in the resident records that testing was offered, completed (as appropriate
to the resident's testing status), and the results of each test.

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F 886	Continued From page 9 §483.80 (h)((4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19. §483.80 (h)((5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested. §483.80 (h)((6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results. This REQUIREMENT is not met as evidenced by: Based on record review and interviews with staff and the Division Director of Infection Prevention the facility failed to test unvaccinated staff based on the Center for Disease Control and Prevention (CDC) community transmission levels per the guidelines of the Centers for Medicare and Medicaid Services (CMS) before allowing to work for 3 of 3 staff reviewed for Covid-19. This failure occurred during a global pandemic. The findings included: A review of the facility's Infection Prevention Plan (IPP) with a revision date of 3/12/21 stated the facility would comply with the current CDC guidelines to reduce the transmission of infectious agents. The IPP will be based on the level of risk related to the community	F 886	During the recent survey it was identified that the facility failed to COVID test unvaccinated staff based on the CDC community transmission level per CMS guidance. Lack of understanding of the CDC and CMS guidelines for staff that worked less than twice a week led to the non-compliance. " On 12/3/21, a team consisting of Director of Infection Prevention, Director of Laboratory, Director of Nursing, CEO/CNO, Director of Clinical Operations, Staff Health Clinical Supervisor and Accreditation met to review twice a week testing requirements. " On 12/17/21, the team developed a plan for all unvaccinated staff to be tested	

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F 886	Continued From page 10 environment. The responsibility for implementing and overseeing all regulation and/or recommendations which involve infection prevention issues including recommendations from the CDC and regulations for healthcare facilities both local, state, and federal. A review of the CDC website titled, "Covid-19 Integrated County View" revealed community transmission levels for the location of the facility from 9/1/21 to 10/19/21 were high and from 10/20/21 to 11/24/21 were substantial. A review of the CMS guidelines for routine testing intervals of unvaccinated staff revealed when the community transmission levels were substantial or high staff were tested for Covid-19 twice a week. A review of unvaccinated staff test records revealed Nurse Aide (NA) #1 was scheduled to work on and tested for Covid-19 on 9/23, 9/28, 9/30, 10/6, 10/12, 10/20, 11/1, 11/4, 11/11 and 11/15 and received all negative results. A review of unvaccinated staff test records revealed NA #2 was scheduled to work on and tested for Covid-19 on 9/30, 10/6, 10/13, 10/19, 10/25, 11/3, 11/8 and received all negative results. A review of unvaccinated staff test records revealed Nurse #1 was scheduled to work on and tested for Covid-19 on 9/22, 9/28, 10/1, 10/5, 10/13, 10/15, 10/27, 11/1, 11/3, 11/5, 11/10, 11/15, and 11/19 and received all negative results. During an interview on 11/23/21 at 1:03 PM the	F 886	for COVID twice a week when community transmission levels are substantial or high. o Nursing staff will collect nasal swab sample twice a week and send to the lab with a lab requisition. o COVID -19 PCR test is ordered and packaged by the lab and sent to referral lab. Beginning 12/24/21, COVID-19 rapid molecular test is ordered and processed by the lab and resulted in 15 minutes. o Staff Health Advanced Practitioner will review all test results. " To ensure ongoing compliance, twice weekly audits began 12/27/21 by the Director of Nursing or designee to ensure that routine testing is being completed per the CMS/CDC guidelines. Numerator: Total number of unvaccinated staff with routine testing for COVID as required by CDC and CMS guidance based on community transmission levels. Denominator: Total number of unvaccinated staff. Data related to the measure associated with this standard will be reported to the Transylvania Patient Safety & Quality Committee for 3 consecutive months for 100% compliance. Any non-compliance with appropriate COVID testing will be reviewed with employee and Executive Leadership " The CEO/CNO is responsible for overseeing the implementation and the actions taken with this plan.	

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TRANSYLVANIA REGIONAL HOSPITAL	260 HOSPITAL DRIVE BREVARD, NC 28712

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F 886	Continued From page 11 Division Director of Infection Prevention (DDIP) revealed testing of unvaccinated staff was done weekly based on the state recommendations. The DDIP revealed the Director of Nursing (DON) kept the staff vaccination records. During an interview on 11/23/21 at 2:50 PM the DON revealed the plan for testing unvaccinated staff was based on their work schedule. The DON explained unvaccinated staff were tested on the day they worked using the polymerase chain reaction (PCR) test for COVID-19 and results were obtained within 48 hours. The DON revealed unvaccinated staff were not required to test twice a week if they didn't work on the unit. The DON revealed the DDIP checked the community transmission levels for the county and provided guidance on testing unvaccinated employees. The DON revealed none of the staff who worked on the unit and none of the residents had tested positive for Covid-19 since the unit reopened in 09/2021. A second interview was conducted with the DON on 11/23/21 at 4:34 PM. The DON revealed she didn't feel it was necessary to ask employees to come in on off days to be tested a second time and wasn't aware it was mandatory to test unvaccinated staff twice a week based on the community transmission levels. A second interview was conducted with DDIP on 11/24/21 at 11:59 AM. The DDIP stated the facility policy was to follow the CMS guidelines for routine testing of unvaccinated staff.	F 886	Completion date of 12/22/21	