STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345328	A. BUILDING _____ B. WING _____	C 04/09/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
GIVENS HEALTH CENTER	600 BARRETT LANE ASHEVILLE, NC 28803

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E 000	Initial Comments An unannounced recertification survey and complaint investigation were conducted on 03/29/21 through 04/09/21. The facility was found in compliance with the requirement CFR 483.73, Emergency Preparedness. Event ID #TZS211.	E 000		
F 000	INITIAL COMMENTS A recertification survey and complaint investigation were conducted on 03/29/21 with exit from the facility on 04/01/21. The survey team returned to the facility on 04/06/21 to validate the corrective action plan and conduct an extended survey with exit from the facility on 04/06/21. Additional information was obtained through 04/09/21; therefore, the exit date was changed to 04/09/21. There were six allegations investigated and one substantiated. Event ID# TZS211. Past non-compliance was identified at: CFR 483.25 at tag F 689 at a scope and severity of J. The tag F 689 constitued substandard quality of care. Non-compliance began on 12/25/20. The facility came back in compliance effective 12/28/20.	F 000		
F 582 SS=D	Medicaid/Medicare Coverage/Liability Notice CFR(s): 483.10(g)(17)(18)(i)-(v) §483.10(g)(17) The facility must-- (i) Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for	F 582		4/23/21

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

Electronically Signed | 04/23/2021

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F 582	Continued From page 1	F 582		

Medicaid of-
(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;
(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and
(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in §483.10(g)(17)(i)(A) and (B) of this section.

§483.10(g)(18) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/ Medicaid or by the facility's per diem rate.
(i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible.
(ii) Where changes are made to charges for other items and services that the facility offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.
(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.

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F 582	Continued From page 2 (iv) The facility must refund to the resident or resident representative any and all refunds due the resident within 30 days from the resident's date of discharge from the facility. (v) The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations. This REQUIREMENT is not met as evidenced by: Based on record review and staff interviews, the facility failed to provide the Centers for Medicare and Medicaid Services Skilled Nursing Facility Advanced Beneficiary Notice (form CMS-10055 SNF ABN) prior to a resident's discharge from Medicare Part A skilled services for 2 of 3 residents reviewed for beneficiary protection notification (Resident #12 and #35). Findings included: 1. Resident #12 was admitted to the facility on 1/20/21 to Medicare Part A skilled services. The Medicare Part A services ended on 3/15/21 and she remained in the facility. A review of the beneficiary protection notification documents provided for Resident #12 revealed Medicare Part A skilled services started on 1/20/21 and the last day of coverage was 3/15/21. The facility initiated the discharge from Medicare Part A with remaining benefit days. The form titled, "CMS-10123 Notice of Medicare Non-Coverage (NOMNC)" was provided to Resident #12's Responsible Party (RP) on 3/10/21. The form titled, "CMS-10055 SNF ABN" was not provided. During an interview on 3/31/21 at 9:57 AM the	F 582	Plan of Correction for Tag F 582 During the Survey, the surveyor noted that 2 of 3 residents reviewed for beneficiary protection notification were provided a NOMNC (CMS-10123), but failed to be provided a SNF-ABN (CMS-10055) as required. During the survey, the Social Worker confirmed that she had failed to do so as required. The SW was in-serviced on day of survey (3/31/2021) regarding proper notification by her supervisor (Life Enrichment Director) and the HC Administrator. Each affected resident was provided the required SNF-ABN AS OF 4/8/21. In order to ensure no other residents were affected in a similar manner each resident having an initiation, reduction, or termination of covered Medicare services since 4/1/21 was verified by the LE director to ensure proper notice was provided. The SW and LE Director conducted an audit beginning 4/1/21 of all Medicare Part A and B discharges since the beginning of the SW employment on January 13, 2020. Each resident or their representative noted on this audit to have not received the proper notification was	

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F 582	Continued From page 3 Social Worker (SW) confirmed Resident #12 remained in the facility after skilled services were terminated. The services were terminated by the facility on 3/15/21. The SW notified Resident #12's RP on 3/9/21 skilled services were being terminated and provided the CMS-10123 NOMNC form. The SW explained she used a chart to determine which forms to include for notification. After review of her chart the SW revealed she had misread the information and if a resident remained in the facility with skilled Medicare Part A benefit days remaining both the CMS-10123 NOMNC and CMS-10055 SNF ABN forms should be provided to the resident or RP. During an interview on 03/31/21 11:55 AM the Administrator explained when a resident remained in the facility and Medicare Part A services were terminated with remaining benefit days, he would expect both the CMS-10123 NOMNC and CMS-10055 SNF ABN forms be provided in the case of Resident #12. The Administrator explained the SW was new in her position and might not have understood both forms were needed for notification. 2. Resident #35 was admitted to the facility on 10/1/19 to Medicare Part A skilled services. The Medicare Part A services ended on 2/10/21 and she remained in the facility. A review of the beneficiary protection notification documents provided for Resident #35 revealed Medicare Part A skilled services started on 12/11/20 and the last day of coverage was 2/10/21. The facility initiated the discharge from Medicare Part A with remaining benefits days. The form titled, "CMS-10123 Notice of Medicare Non-Coverage (NOMNC)" was signed by	F 582	provided the correct notification, all of these being completed as of 4/23/2021. In order to prevent reoccurrence of this type of error in the future, the facility□s SNF Notification Procedures chart was reviewed and updated to ensure accuracy. Also, further training was provided for the SW and other employees who provide back up for notification regarding proper notification to beneficiaries. This in-service was done by the Life Enrichment Director and completed on 4/19/2021. The LE Director will audit all notifications from 4/1/21-5/1/21 to ensure correct notifications are provided. The LE Director will further do random audits at least weekly until 6/1/21. These audits will be documented and retained. Ongoing compliance will be monitored as noted in a Performance Improvement Plan (PIP). A PIP was was initiated 3/11/21 to address orientation of SW to new position which included CMS required notifications. On 3/31/21 a more specific PIP was initiated focused on the notification process. This PIP requires the LE Director to provide her Audits and surveillance to the QAPI Committee on a monthly basis for ongoing monitoring and oversight until 6/1/2021 or until the QAPI Committee determines that ongoing, consistent compliance has been achieved. The completion date is 4/23/21.	

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F 582	Continued From page 4 Resident #35 on 2/5/21. The form titled, "CMS-10055 SNF ABN" was not provided. During an interview on 3/31/21 at 10:05 AM the SW confirmed Resident #35 remained in the facility after skilled services were terminated. The services were terminated by the facility on 2/10/21. The SW notified Resident #12 on 2/5/21 skilled services were being terminated and provided the CMS-10123 NOMNC form. The SW explained she used a chart to determine which forms to include for notification. After review of her chart the SW revealed she misread the information and if a resident remained in the facility with skilled Medicare Part A benefit days remaining both the CMS-10123 NOMNC and CMS-10055 SNF ABN forms should be provided to the resident or RP. During an interview on 03/31/21 11:55 AM the Administrator explained when a resident remained in the facility and Medicare Part A services were terminated with remaining benefit days, he would expect both the CMS-10123 NOMNC and CMS-10055 SNF ABN forms be provided in the case of Resident #35. The Administrator explained the SW was new in her position and might not have understood both forms were needed for notification.	F 582		
F 583 SS=B	Personal Privacy/Confidentiality of Records CFR(s): 483.10(h)(1)-(3)(i)(ii) §483.10(h) Privacy and Confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records. §483.10(h)(l) Personal privacy includes	F 583		4/23/21

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F 583	Continued From page 5	F 583		

accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

§483.10(h)(2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

§483.10(h)(3) The resident has a right to secure and confidential personal and medical records.
(i) The resident has the right to refuse the release of personal and medical records except as provided at §483.70(i)(2) or other applicable federal or state laws.
(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.
This REQUIREMENT is not met as evidenced by:
Based on observations and staff interviews, the facility failed to protect a resident's personally identifiable information and protected health information (PII/PHI) by leaving confidential medical information unattended in an area accessible to the public on of 1 of 3 medication cart laptops (Hall A/B/C).

The findings include:

Plan of Correction for Tag F583
During the Survey, the surveyor noted that Med Aid 1 (MA#1) failed to minimize the laptop screen or close the cover allowing Resident #1□s PHI to be visible to others.

No PHI was disclosed during this incident as witnessed by the surveyor. The Employee immediately corrected the issue when informed of it by the surveyor.

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F 583	Continued From page 6 A continuous observation on 3/31/2021 from 12:30 PM to 12:33 PM revealed an unattended medication cart found in the hallway by Hall A/B/C nursing station with the laptop computer turned on and visibly displaying Resident's #1 PHI. The laptop displaying Resident #1 PHI was observed unattended for 3:00 minutes before the Medication Aide #1 (MA#1) exited a resident's room and returned to the med cart. An interview was conducted on 3/31/21, at 12:33 PM with the Medication Aide #1 (MA#1) revealed he should had minimized the laptop screen or closed the laptop's cover as to not reveal the resident's PHI. He stated he forgot to minimize the laptop screen. MA#1 then closed the laptop cover and locked the medication cart. An interview with the Medication Aide Educator #1 (MAE#1), revealed MA#1 was a nursing assistant (NA) who completed his education and course work for Medication Aide and was under supervised training from 1/26/21 through 2/4/2021 and signed off as competent to pass medications. MAE#1 revealed the facility training components which included security of PII/PHI with blanking the computer screen. An interview with Nurse #1 revealed she had mentored MA#1 on 2/19/2021 medication passes and provided observations on 6 residents including; drug prescription name, dose and form, observations of administration, and reconciliation of physician drug orders. Nurse #1 revealed MA#1 had no medications errors, locked his med-cart and minimized his laptop screen while he left his cart unattended. She felt he was competent.	F 583	When the Director of Nursing was informed of the above situation, she immediately directed the floor supervisor to immediately review facility protocol for resident information protection with the MA#1. MA#1 was monitored closely by supervisor for the remainder of the shift to ensure no further compromise of PUI occurred. In order to ensure no other residents were affected in a similar manner, MA#1 was removed from the schedule as a med aide effective 4/1/21. He was verbally counseled at the time of the incident, and on April 14, 2021, received a written counseling regarding facility policies related to resident information privacy. Further, all team members at Givens Estates Health Center were in-serviced on PHI Privacy by the Clinical Nurse Educator and Director of Nursing 4/6/21-4/19/21. This training reinforced the annual training that all team members continue to receive from required web-based training, individual monitoring, and annual skills check offs by Nursing leadership. To prevent reoccurrence of this type of error in the future, Daily surveillance of all nurses and Medications Aids by Director of Nursing and nursing supervisors for compliance is documented until 5/01/21. Nursing Supervisors will continue to monitor and address any observed noncompliance immediately with staff involved and document any noted non-compliance to be reported in the monthly QAPI meetings..	

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F 583	Continued From page 7 Interview with the Administrator and Director of Nursing (DON) revealed MA#1 received his certification as a Medication Aide from formal training and facility competency provided by their education department. The DON stated MA#1 should had closed the laptop computer screen before he left the medication cart unattended.	F 583	Ongoing compliance will be monitored as noted in the Performance Improvement Plan (PIP) that was initiated 4/1/21. This PIP addresses PHI privacy and directs the DON to report her Audits and surveillance to the QAPI Committee on a monthly basis for ongoing monitoring and oversight until 6/1/ 2021 or until the QAPI Committee determines that ongoing, consistent compliance has been achieved. The completion date is 4/23/21.	
F 607 SS=D	Develop/Implement Abuse/Neglect Policies CFR(s): 483.12(b)(1)-(3) §483.12(b) The facility must develop and implement written policies and procedures that: §483.12(b)(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property, §483.12(b)(2) Establish policies and procedures to investigate any such allegations, and §483.12(b)(3) Include training as required at paragraph §483.95, This REQUIREMENT is not met as evidenced by: Based on record review and staff interviews, the facility failed to: 1) ensure staff implemented the facility's abuse policies and procedures in the area of reporting when staff did not immediately inform facility administration of suspected employee to resident abuse which resulted in a delay in the facility investigating the allegation of abuse and 2) failed to report an abuse allegation	F 607	Plan of Correction for Tag 607 During the Survey, the surveyor noted the facility failed to implement the policies and procedures for abuse prevention and failed to report an allegation of abuse to the HCPR within 2 hours of being notified. The allegation of abuse was reported and fully investigated once administration was	4/23/21

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F 607	Continued From page 8 to the Health Care Personnel Registry (HCPR) within 2 hours of being notified for 1 of 3 sampled residents reviewed for abuse (Resident #7). Findings included: The facility policy titled, Abuse/Neglect Prohibition Policy with revised date of 11/20/17, read in part: "the facility has a zero tolerance for resident abuse of any kind. An employee should take the following action upon observation of signs or symptoms of suspected abuse or neglect: immediately report any incident to the Administrator or immediate supervisor who will report the incident to the Administrator. There will be a complete and thorough investigation performed by the Administrator or designee. This means all staff and other witnesses will be interviewed. All reports of alleged incidents of abuse, neglect, exploitation, involuntary seclusion and misappropriation of resident property should be reported to the Administrator immediately and other proper licensing and regulations enforcement agencies as follows: abuse - no later than 2 hours following the allegation. Staff identified as not having reported "reportable" information will be counseled." The initial investigative report submitted by the facility to the HCPR noted an allegation type of resident abuse and neglect involving Nurse Aide (NA) #2 and Resident #7 was reported by Dietary Aide (DA) #1 on 03/08/21 at 10:30 AM. It was further noted the alleged incident occurred on 03/07/21 and the report was faxed to HCPR on 03/08/21 at 2:17 PM. During a telephone interview on 04/01/21 at 12:11 PM, DA #1 stated on 03/07/21 she witnessed NA	F 607	aware of the incident the following morning. The employees involved were in-serviced immediately after making the report to ensure timely reporting per facility policies. In order to ensure no other residents were affected in a similar manner, departmental inservices performed by Nursing and Dining Departments on 3/8/21 and 3/11/21 addressed timely reporting of any allegation of Abuse and Neglect. Further, all team members in each department were in-serviced on Abuse and neglect reporting policies 4/6/21-4/19/21 This in-service supplemented the annual web-based training required of all team members, as well as that. In addition, all team members continue to be trained on abuse and neglect reporting as part of their new hire orientation and the policies are also in the annual updates of the employee handbooks which all staff are provided. Facility leadership was further trained on 3/31/21 and 4/1/21 by the Administrator. This training reinforced for the leadership that the regulations require timely reporting and proper investigation. Facility leadership was instructed to immediately involve the DON, Administrator, or LE Director and to collaborate with them to ensure any and all allegations of abuse are reported to HCPR within 2 hours of the occurrence. In order to prevent reoccurrence of this type of error in the future, all employees will continue to be required to complete mandatory annual training regarding abuse and neglect reporting. In addition,	

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F 607	Continued From page 9 #2 redirecting Resident #7 in the hallway and felt NA #2's behavior toward Resident #7 "was not right." DA #1 verified she did not report what she observed to the Nurse or Administration on 03/07/21. DA #1 confirmed she received abuse education and was instructed to report any suspicion of abuse immediately; however, she thought she had to report her concerns to the Dining Services Director (DSD) and didn't want to call him at home on a Sunday. She added she reported the incident to the DSD the morning of 03/08/21 and provided a written statement. During an interview on 04/01/21 at 10:27 AM, the DSD confirmed DA #1 spoke with him on 03/08/21 at 9:00 AM to report suspicion of abuse involving NA #2 and Resident #7 that allegedly occurred the evening of 03/07/21. After talking with DA #1, he reported to the Administrator and Director of Nursin (DON) what DA #1 had alleged and was told to have DA #1 write a statement. The DSD confirmed dietary staff received abuse training which included reporting and DA #1 was reminded on 03/08/21 that going forward, she needed to report any concerns of abuse immediately. During an interview on 03/31/21 at 10:55 AM, the DON confirmed on 03/08/21 she was notified of the allegation of abuse that allegedly occurred the evening of 03/07/21 between NA #2 and Resident #7 and an investigation was initiated. During a second interview on 04/01/21 at 8:30 AM, the DON explained staff were instructed to report any suspicion of abuse immediately to their supervisor who would then notify her and/or the Administrator in order for them to conduct at timely investigation.	F 607	in person in-services will be held annually in addition to the required annual Web based training. Further, Abuse and neglect reporting will be a standing agenda item on each department's scheduled departmental meetings. Ongoing compliance will be monitored as noted in a Performance Improvement Plan (PIP). A PIP was was initiated 3/10/21 This PIP requires the Administrator to ensure all new hires are properly in-serviced on reporting protocols, and to report QAPI Committee on a monthly basis for ongoing monitoring and oversight until 6/1/2021 or until the QAPI Committee determines that ongoing, consistent compliance has been achieved. The Administrator, DON, and LE Director will jointly review any future allegations of abuse or neglect to ensure they were reported in a timely manner as required, and they will jointly report this review of compliance to the QAPI Committee. The completion date is 4/23/21.	

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F 607	Continued From page 10 During an interview on 04/01/21 at 3:25 PM, the Administrator explained facility staff received abuse education annually and were trained to report any abuse concerns immediately. He confirmed they were notified on 03/08/21 at 10:30 AM of an abuse allegation that allegedly occurred the evening of 03/07/21 involving NA #2 and Resident #7. The Administrator verified the initial report was not submitted to the HCPR until 2:17 PM on 03/08/21. The Administrator stated he would have expected for DA #1 to report her concerns to the nurse supervisor when the alleged incident occurred on 03/07/21 which would have allowed them to initiate an investigation timelier and submit a report to the HCPR within the 2-hour regulatory time frame.	F 607		
F 689 SS=J	Free of Accident Hazards/Supervision/Devices CFR(s): 483.25(d)(1)(2) §483.25(d) Accidents. The facility must ensure that - §483.25(d)(1) The resident environment remains as free of accident hazards as is possible; and §483.25(d)(2)Each resident receives adequate supervision and assistance devices to prevent accidents. This REQUIREMENT is not met as evidenced by: Based on observations, record review and Physician and staff interviews, the facility failed to prevent a cognitively impaired resident with known wandering and exiting seeking behaviors from exiting the facility unsupervised and remaining outside in weather temperature of 14 degrees Fahrenheit, without staff knowledge, increasing the likelihood for hypothermia (low	F 689	Past noncompliance: no plan of correction required.	4/23/21

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body temperature) to develop for 1 of 3 residents reviewed for accidents (Resident #4).

The findings included:

Resident #4 admitted to the facility on 10/02/20 with diagnoses that included Alzheimer's disease with behavioral disturbance.

The Minimum Data Set (MDS) dated 10/08/20 assessed Resident #4 with severe impairment in cognition for daily decision making. He required limited assistance with locomotion on and off the unit, had no wandering episodes during the MDS assessment period and used a walker and wheelchair for mobility.

A care plan initiated 10/22/20 noted Resident #4 was at risk for elopement due to confusion, wandering and exit-seeking behaviors. The goal was he would not leave the facility unattended through the next review. Interventions included: place elopement device on resident, re-orient to person and family while redirecting as needed, distract resident from wandering by offering pleasant diversion, structured activities, food, conversation, television, and books.

Review of the staff progress notes related to Resident #4's wandering revealed the following entries:
12/16/20 3:27 PM read in part, "resident does talk about leaving the building, reoriented and encouraged not to leave the building unassisted. Wears elopement device."
12/19/20 3:43 PM read in part, "resident found in back service hall at the back door. Redirected to room without difficulty, resident wearing elopement device that is working properly."

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12/22/20 1:09 AM read in part, "resident stated he wanted to go home. Redirected him to understand that he needed to stay in the building. No acute behaviors noted. Continue to monitor." 12/22/20 8:39 PM read in part, "resident was exit seeking all afternoon. Was redirected back to his room several times. Will continue to monitor."

A staff progress note dated 12/25/20 at 11:01 PM written by Nurse #1, read in part, "Resident #4 found outside building behind C Hall corridor at 8:15 PM. Resident unable to get back into building. Resident brought back in and assessed. Covered resident with heated blankets and administered warm beverage. Resident refused pain meds. Skin warm, dry and fragile, no discoloration to upper and lower extremities."

A staff progress note dated 12/26/20 at 3:07 AM written by Nurse #1, read in part, "found nurse at end of C-Hall outside pounding on door with Resident #4 standing beside her with walker. At 8:10 PM, Resident #4 was assessed and swaddled in heated blankets and towels. Vitals were as follows: temperature 97.7 degrees, pulse 72, respiration 16, oxygen saturation 97 percent on room air, and blood pressure 117/59. Skin warm, dry and fragile. Staff have checked on Resident #4 every hour this shift, resting in bed in room with eyes closed."

Review of the December 2020 Secure Care Nightly Checklist for elopement device functioning noted Resident #4's was checked nightly with no concerns identified. Resident #4's elopement device was initialed as checked and functioning on 12/24/20 with no time noted when the check was completed.

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An online website named Custom Weather was used to obtain the outside weather in the Asheville area on 12/25/20 and noted at 6:54 PM the temperature was 15 degrees Fahrenheit with wind speeds of 6 miles per hour (mph). At 7:54 PM the temperature was 14 degrees Fahrenheit with wind speeds of 6 mph.

A physician's progress note dated 12/26/20 read in part, "left building last night in two coats and a hat at about 8:00 PM. He was out for more than 20 minutes but less than 40 minutes. He did have his wanderguard on. When Nurse #2 found him, he had no evidence of hypothermia. There were no ramifications from his going outside. He did have some confusion above his baseline last night and this AM."

During a telephone interview on 04/01/21 at 1:25 PM, Nurse #2 confirmed she was working 6:00 PM to 6:00 AM on 12/25/20 when she found Resident #4 standing at the exit door, outside the building. Nurse #2 was unable to recall the exact time she found Resident #4 but stated it would have been between 8:00 PM and 9:00 PM when Pharmacy usually delivered. She explained when she went to the front entrance to meet Pharmacy, she forgot her badge and wasn't able to get back into the building. Nurse #2 added she rang the buzzer for several minutes and then decided to walk around the outside of the building to see if she could get Nurse #1's attention on C-Hall. As she rounded the corner of the building at the bottom of the parking lot, Nurse #2 stated she saw someone standing at the C-Hall exit door and the closer she got, she realized it was Resident #4. Nurse #2 recalled Resident #4 stating he couldn't get back in and when she started pounding on the door, Nurse #1

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responded quickly and let them both back in the facility. She added Nurse #1 assisted Resident #4 back to his room for assessment and wrapped him with warm blankets. Nurse #2 explained the alarm to the exit door normally sounded when the door was opened; however, it had not sounded that evening when opened by Resident #4.

During a telephone interview on 03/31/21 at 10:09 AM, Nurse #1 confirmed she was the nurse assigned to provide care to Resident #4 during the hours of 6:00 PM to 6:00 AM on 12/25/20. Nurse #1 recalled at around 8:00 PM, she in a room assisting another resident when she heard "pounding" on the exit door at the end of the C-Hall and when she stepped out to investigate, she noticed Nurse #2 and Resident #4 standing outside the exit door. Nurse #1 was unaware that Resident #4 had gotten out of the building and stated the best she could recall, she had last seen him when she went to his room at approximately 6:40 PM. Nurse #2 stated they assisted him back to his room, wrapped him in warm blankets and completed a skin assessment which revealed his skin was "pinkish red" and vitals were stable. Nurse #1 stated Resident #4 had an elopement device in place on his ankle that was checked each shift and functioning but when he opened the exit door, the alarm never went off. She added normally they would also receive an automated phone call alerting them the name of the resident and their location but they never received a phone call. Nurse #1 notified the Director of Nursing and the on-call physician of the elopement. She did not recall any interventions put into place that evening other than conducting safety checks on Resident #4 every hour the remainder of the night.

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During a follow-up telephone interview on 03/31/21 at 7:01 PM, Nurse #1 confirmed Resident #4 was wearing his elopement device, 2 coats, socks and shoes when he exited the building on 12/25/20. Nurse #1 explained elopement devices were checked "diligently" every night; however, there was no set time as to when the check was to be completed, some nurses checked them during medication pass while others might check the functioning later in the shift after finishing their charting. Nurse #1 added Resident #4's elopement device was last checked on 12/24/20 before he exited the facility on 12/25/20 and she checked it again after they had found him outside the building and it was functioning. She could not recall Resident #4 exhibiting any behavior out of the ordinary that evening and stated he had a history of wandering into other resident rooms but she had not known him to attempt to open the exit doors of the facility.

During a telephone interview on 03/31/21 at 1:24 PM, Nurse Aide (NA) #1 confirmed she worked 6:00 PM to 6:00 AM on 12/25/20 and was assigned to provide care to Resident #4. NA #1 recalled being notified by Nurse #1 that Resident #4 was found outside the building. NA #1 stated she was not aware he had gotten out of the building and explained typically the alarm would sound to alert staff but it had not gone off that evening when Resident #4 opened the exit door. NA #1 added Resident #4 had the tendency to wander out into the hall but had never tried to exit the building before. She recalled seeing Resident #4 in his room during first rounds but could not recall the exact time.

During an interview on 03/31/21 at 10:55 AM, the

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Director of Nursing (DON) recalled being notified by Nurse #1 that Resident #4 exited the building on 12/25/20. The DON explained Nurse #2 had gone to the front door of the facility to meet Pharmacy but forgot her badge and couldn't get back into the building, so she walked around the building to the C-Hall exit door to get the attention of Nurse #1 to let her back in when she found Resident #4 standing outside on the sidewalk just a few feet to the right of the exit door and brought him back into the building. The DON instructed Nurse #1 to assess Resident #4 for hypothermia and the physician assessed him on 12/26/20.

During interviews on 03/31/21 at 12:03 PM and 3:36 PM, the Administrator stated he was notified on 12/25/20 that Resident #4 was found outside the building at approximately 8:00 or 9:00 PM. The Administrator stated when he reviewed the video footage from 12/25/20, Resident #4 went to the exit door at the end of C-Hall at 7:23 PM, pushed the door handle and walked outside the door to the sidewalk. The video footage also showed Resident #4 immediately turned back around to go back in the facility but couldn't get in the door and was later found by Nurse #2 by the exit door, brought back into the building at 8:15 PM and assessed by Nurse #1. The Administrator stated Resident #4 was placed on 30 minute visual checks throughout the remainder of the evening and the next day, 12/26/20, he was evaluated by the physician with no adverse effects identified. The Administrator stated staff were also instructed to visually check the hallway exit door throughout the remainder of the evening on 12/25/20 to ensure it was functioning and recalled seeing the log where staff had checked but he was unable to locate the documentation. A root cause analysis was

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completed and determined somehow the exit door had been put in override mode for the exit door to open freely without alarming, which the Administrator stated should have not happened, and was immediately fixed. The Administrator explained they put a Performance Improvement Plan (PIP) in place on 12/26/20 for elopement prevention which included staff education, an added sensor placed on the exit door so when the door handle was pushed and the delayed egress (locking system to prevent a door from opening immediately) opened the door lock, he and the Facilities Maintenance Director (FMD) now receive a call within 10 seconds to let them know the door was opened, and the panel to the exit door was reprogrammed with a new override code that only the Administrator and FMD have. The Administrator verified education was provided to staff the end of December 2020 and stated he knew they had discussed elopement but it was right in the midst of a facility-wide COVID outbreak and he couldn't locate any documentation of the staff training provided. Since then, the Administrator reported there had not been any issues with the alarm on the C-Hall exit door not working.

During an interview on 04/01/21 at 2:50 PM, the Facilities Maintenance Director (FMD) reported he conducted weekly checks of the 4 facility exit doors with delayed egress to ensure they were functioning properly which included holding the door handle for 15 seconds to make sure the alarm sounded when opened and when the door was reset, it was secure. The FMD stated he was not at the facility on 12/26/20 but was told about the incident that happened on 12/25/20 with Resident #4 and they could not determine how the exit door was placed into override mode

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allowing the exit door to open without alarming. He added the C-Hall exit door was the only one in the facility that had both delayed egress and elopement device locking systems. The FMD explained the facility had since installed an audible strobe light alarm system at the nurses' station to alert them when the door was opened. He added the egress panel was set at 15 seconds that started counting down when the door handle was pushed and when it reached 12 seconds, the audible alarm at the nurses' station would sound, giving staff a head start to reach the door before the panel reached zero and the exit door opened.

During a telephone interview on 04/01/21 at 4:46 PM, the Physician confirmed she evaluated Resident #4 on 12/26/20 and upon exam, determined he had no negative outcome as a result of his elopement on 12/25/20.

Observations of each of the 4 exit doors with delayed egress were conducted with the FMD on 04/01/21 at 2:50 PM. When the FMD held the door handle down, the egress panel started beeping and after 15 seconds, the alarm sounded. On the C-Hall, once the exit door handle was pushed and the panel reached 12 seconds, an alarm sounded at the nurses' station along with a blue flashing light. After the alarms were tested on each exit door, the FMD reset the panel and made sure the doors were locked and secure.

The facility provided the following Corrective Action Plan with the correction date of 12/28/20:

1. On the evening of 12/25/2020 Resident #4 eloped from facility at 7:23 PM and was

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subsequently observed by Nurse #2 who was in the parking lot, and at 8:10 PM saw the resident standing outside the door he had exited previously. Resident was outside the facility for 47 Minutes, as confirmed by the Administrator after reviewing video footage early on 12/26/20. When the nurse #2 came upon him, he was directly outside of the door he had exited, fully dressed, with shoes and socks and wearing two coats. Nurse #2 brought him back into facility. He was made comfortable by team members and was immediately assessed by the Nurse #1. The resident's vital signs were stable, and his assessment revealed no negative outcome. This was documented in the medical record that evening. The doctor on call was notified the same evening, 12/25/20. Further, as noted in the medical record, the resident was visualized at least hourly throughout the night to ensure there was no further elopement attempt or adverse impact from the elopement. The Medical Director / Attending Physician was notified and assessed the resident on 12/26 and noted in the medical record that the resident had no adverse effects from the elopement. His Elopement device was checked and noted to be operational on 12-24-20 and at the time of event on 12-25-20. The Director of Nursing (DON), Administrator, and Medical Director notified the family on 12/26/20 of the elopement and that no adverse impact had resulted from the elopement.

2. In order to protect other residents from the potential for elopement, at the DON's direction a head count of residents within the facility was performed that evening to ensure all residents were accounted for. Further, the specific egress door alarm and mechanical locking system that the resident walked through was identified by

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reviewing common area video and was inspected on the morning of 12/26/20. Facilities Maintenance staff and the Administrator assessed the exit door and discovered it was in a bypass mode, disabling the elopement alarm. This was corrected immediately and monitored frequently over the following two days to ensure it continued to properly function. This panel is unique from all other panels in the facility, and on 12/26/20, maintenance team members and the Asst. Facilities Director for Maintenance verified that all other exterior doors in the facility did not have the ability to bypass or override the alarm systems, which were designed, in part, to prevent elopement.

Systems were in existence and utilized for team members to identify those residents at risk for elopement. All residents are consistently assessed for elopement risk upon admission to the facility, and these assessments are updated on quarterly basis, and upon any significant change of condition. Each resident assessed to be at risk for elopement had an elopement device in place. This device automatically engages the elopement prevention systems on exterior doors. In addition, the devices serve to identify any resident who is an elopement risk to team members. These devices are monitored daily to ensure they are operational, identifying the residents at risk for elopement and protecting these residents from elopement. In addition, residents at risk for elopement had further interventions in place including, monitoring for anxiety, monitoring exit-seeking behavior, offering reassurance as indicated, monitoring for wandering behaviors, provision of one-on-one diversional activities, and medication reviews. These interventions and the elopement devices

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are noted on each resident's individualized care plan and are made readily available to Nurses and CNAs to inform them in caring for their assigned residents. Further, nurses inform nursing assistants of the care needs, including elopement risk, of each resident at shift change and as changes occur. Further, the elopement devices serve as a visual cue to all team members indicating the resident's assessed to be at risk for wandering or exit seeking behaviors.

3. To prevent further elopements, team members were re-trained regarding elopement prevention and response protocols during 12/26/20 - 12/28/20, regarding the need to closely monitor residents wearing elopement devices, as they had been assessed as having an elopement risk. They were also re-in-serviced on elopement protocols regarding responding to door alarms, routine monitoring of residents, monitoring residents for increased agitation and exit seeking behaviors, and performing nightly checks on elopement devices. These nightly device checks continue to be provided to the DON to monitor checks are performed and to ensure the system continues to work as designed.

Team members were instructed to immediately notify a supervisor or nurse when any resident had an acute episode of high anxiety and/or exit seeking behaviors for reassessment of their elopement risk. Each resident at risk for elopement is identified on the daily device testing log, and this same log is used by nurses for daily testing of the devices for proper operation.

Staffing levels were good the evening the incident occurred and the entire Christmas Holiday weekend. We did not document the training

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thoroughly as is our usual practice. However, our leadership has attested to the fact that training was done and multiple team members have acknowledged the fact that training occurred at the time, and that training was helpful to their understanding. Further, ongoing compliance monitoring detailed below, and documented through QAPI, demonstrates that the re-in-service training provided to all staff not only occurred, but was effective.

4. To ensure sustained compliance, a Performance Improvement Plan (PIP) was developed on 12/26/20 noting the interventions that were put in place to address the root cause of the elopement on 12/25/20.

A Root Cause Analysis was initiated on 12/26/20, analyzing the resident, staff, and mechanical systems involved.

Root cause analysis indicates that Resident #4, was noted on MDS 10/08/20 to have Alzheimer's Disease with Behavioral disturbances and noted severe impairment in cognition for daily decision making and had no wandering episodes during the MDS assessment period. However, on 10/22/20 the resident was noted to be at risk for wandering and to have wandering behaviors with a Care Plan was initiated due to wandering, confusion, and exit seeking behavior. An elopement device was put in place at that time and checked nightly thereafter to ensure operationality. Other interventions included reorientation to person and family, redirecting as needed, distract resident while wandering by offering pleasant diversion, structured activities, food, conversation, television, and books. On the evening of 12/25/20 the resident was visualized to

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be in his room by nursing team members prior to his elopement and did not show any indication of exit seeking behavior. The resident was known to be sociable and enjoyed being outside on nice days. It appears the confused resident was simply intending to go for an evening stroll, as he dressed himself with two coats, but did not take any possessions with him. He chose to walk into the hallway to the outside door nearest his room, however, it is apparent from the video that the moment he stepped outside he changed his mind and attempted to reenter the building. The resident's behaviors previous to his elopement on 12/25/20 were consistent with his previous behaviors he demonstrated and that had been previously assessed by facility staff and were well known and communicated to facility staff.

Root Cause analysis of team member actions on 12/25/20, noted that staffing was at acceptable levels, and team members interviewed by surveyors, noted that the resident was visualized by Nurse #1 at 6:40, and NA noted visualizing the resident on her first round after 6:00 pm. On interview by DON, both staff members noted the resident to be in his room, showing no agitation, active wandering or indication of exit seeking behaviors. NA #1 was providing pm care for her assigned residents at the time of the elopement, and Nurse #1 had begun her nighttime medication pass as was around the corner of the hallway, and out of sight of the door the resident exited. It is determined our analysis that the facility was properly staffed for the evening of the incident, and that the team members were appropriately performed visual round on each resident including Resident #4 throughout the night and were providing resident care to other residents at the time of the incident.

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Root Cause Analysis of the mechanical systems designed to prevent elopement indicates that the elopement was clearly a failure in the mechanical elopement prevention systems which allowed a properly assessed and supervised resident to open a door to the outside of the facility despite wearing a functional elopement prevention device. The analysis noted that the doors were inspected and noted to be functioning properly days earlier on the routine weekly audit, and that the resident's elopement device was noted to be functional when checked the night before, and upon return to the facility. The door the resident exited was an emergency exit, not regularly used by residents, visitors, or staff. When inspected the following morning by maintenance staff and the Administrator, the door was found to be in a bypass mode which disabled the secure locking mechanism as well as disabling the elopement prevention systems and alarms. This Bypass mode is easily identifiable and is indicated by dashes the LED panel.

Further root cause analysis noted that this door was unique to all other doors in the facility, having a keypad panel that was a different brand and style from all others in the facility. Further, it was unique from other panels in that it had a bypass feature that could disable not only the locking mechanisms, but also the elopement prevention system alarms. It was further determined that there were two possible causes of the alarm panel being in by-pass mode. One of these possible causes was a ground fault, electrical short, or power surge that reset the panel into the by-pass mode. This could not be replicated on testing. The Other possible cause was a person with knowledge of the bypass code, manually

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entered the code placing the system into bypass. No one other than maintenance staff had knowledge of the bypass / override code. Further, as part of the root cause analysis the Administrator reviewed video from the previous week, noting no one who had exited during this time period. The Facility immediately addressed both of these possible causes. The door was reset to operational mode, and the door was extensively tested on 12/26/20. Further, the Maintenance team member and the Administrator visualized the operational mode of the door panel multiple times throughout day 12/26 and 12/27/20. The Administrator also personally in-serviced the evening nurse who monitored it for proper operation throughout the night.

On 12/28/20, maintenance team members installed a redundant door sensor alarm on this door, which alerts the Administrator and Maintenance director any time the door is opened for any reason. This system was tested extensively on 12/28/20 and weekly thereafter. Each time it is tested it has been noted to be functional and has no ability to be overridden at any time. This system is separate from and in addition to the elopement system. Every time this redundant alarm has been activated, it has been verified by the administrator that the elopement systems were operational as well. In addition, further upgrades to the system were contracted to further strengthen the system and are noted in the PIP initiated in 12/26/20.
Ongoing monitoring of the resident's elopement prevention devices continues to be performed on a nightly basis, and all elopement systems on exterior doors continue to be tested weekly to ensure proper operation with results documented. The documents with monitoring results are

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reviewed regularly by maintenance and the Administrator to ensure compliance.

These Weekly audits of proper door alarm operation and daily audits of elopement devices continue to be conducted and are provided to The Administrator who, in turn, reports the results of these monitoring activities to the QAPI committee on a monthly basis to ensure ongoing oversight occurs.

The interventions put in place on 12/25/20-12/28/20 effectively addressed the root cause of the elopement, preventing further elopement.

In addition, as part of the QAPI process at Givens Estates Health Center, the Performance Improvement Plan initiated on 12/26/20 has continued to be updated as new interventions were put in place to strengthen the elopement prevention systems and reported in the monthly QAPI meetings.

The facility alleges compliance on 12/28/2020

The Corrective Action Plan was validated on 04/06/21 and concluded the facility implemented an acceptable corrective action plan on 12/28/20 once the alarm was reset on the C-Hall exit door and the door contactor was put in place to immediately send notifications to the Administrator and FMD when the exit door was opened. The Corrective Action Plan was reviewed during QAPI meetings held on 01/14/21 and 02/11/21.

The weekly monitoring logs of the facility exit doors for January 2021 to March 2021 were

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F 689	Continued From page 27 reviewed with no concerns identified. Observations of the egress exit doors conducted with the FMD on 04/01/21 revealed the alarms on the doors were functioning properly and when the panel was reset, the doors were locked and secure. Review of the Secure Care Nightly Checklists for January 2020 to March 2020 revealed resident elopement devices were initialed as checked daily and functioning. The Administrator was unable to locate documentation of the staff training conducted on 12/26/20 to 12/28/20; however, multiple staff on various shifts were interviewed and verified they received re-education related to elopement in December 2020 and were able to describe facility processes for: what to do when a resident demonstrated elopement/exit seeking behaviors, monitoring of residents identified as high risk for elopement, responding to door alarms, and what to do in the event of an elopement.	F 689		
F 761 SS=D	Label/Store Drugs and Biologicals CFR(s): 483.45(g)(h)(1)(2) §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	F 761		4/23/21

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F 761	Continued From page 28 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 observations and staff interviews, the facility failed to secure an unattended medication cart for 1 of 3 medication carts (Hall A/B/C). The findings include: A continuous observation on 3/31/2021 from 12:30 PM to 12:33 PM revealed an unattended medication cart found in the hallway by the Hall A/B/C nursing station. Further observations revealed the locking mechanism for the medication cart was not engaged and, therefore, the unlocked medication draws storing the resident's medications, refill packages of resident medications and as needed (PRN)/stored over the counter medications, including a locked narcotics box, were easily opened and contents were visible upon inspection. This medication cart was observed unattended for 3:00 minutes before the Medication Aide #1 (MA#1) exited a resident's room and returned to the medication cart. An interview was conducted on 3/31/21 at 12:33 PM, with MA#1 when he returned to the medication cart, confirmed he left the medication	F 761	Plan of Correction for Tag F791 During the Survey, the surveyor noted that Med Aid 1 (MA#1) failed to properly secure his medication cart, leaving it unsecured and unsupervised. No medications were tampered with or displaced during this incident as witnessed by the surveyor. The Employee immediately corrected the issue when informed of it by the surveyor. When the Director of Nursing was informed of the above situation, she directed the floor supervisor to immediately review facility protocol for medication storage and security with the MA#1. MA#1 was monitored closely by supervisor for the remainder of the shift to ensure no further medication security / storage issues occurred. In order to ensure no other residents were affected in a similar manner, as soon as the DON was made aware of the issue, MA#1 was provided re-education by the charge nurse regarding the importance of	

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F 761	Continued From page 29 cart unlocked while he administered medications to a resident in their room. MA#1 revealed he should had locked the medication cart when leaving it unattended. He stated that was the facility's policy. An interview with the Medication Aide Educator #1 (MAE#1), revealed MA#1 was a nurse aide who completed his education and course work for Medication Aide and was under supervised training from 1/26/21 through 2/4/2021 and signed off as competent to pass medications. MAE#1 revealed the facility training components included locking the cart when away from it and keep keys on person. Interview with the Administrator and Director of Nursing (DON) revealed MA#1 received his certification as a Medication Aide from formal training and facility competency provided by their education department. The DON expected the Med Aide to secure his medication cart while it was unattended by locking the medication cart.	F 761	and facility policy requiring proper securing of medications at all times. The DON personally reinforced this training again on 4/1/21, and again on April 14, 2021, restating facility policies related to medication storage and security. Further, nurses and medication aids were in-serviced on medication storage and security by the Director of Nursing and nursing supervisors 4/21-4/23/21. In these one on one trainings, all team members with access to resident medications were clearly retrained regarding maintaining chain of custody at all times, including locking of medication carts when not in direct use, utilization of the rights of administration of medications, and proper documentation of administration. In order to prevent reoccurrence of this type of error in the future, each nurse and medication aid will undergo an annual medication pass observation by a Licensed Nurse or Pharmacist, to ensure compliance with facility policies for medication storage and security. Daily monitoring of all nurses and Medications Aids by Director of Nursing and nursing supervisors for compliance to proper medication storage and security is documented until 5/01/21. Nursing Supervisors will continue to monitor and address any observed non-compliance immediately with staff involved and document any noted non-compliance to be reported in the monthly QAPI meetings. Ongoing compliance will be monitored as	

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F 761	Continued From page 30	F 761	noted in the Performance Improvement Plan (PIP) that was initiated 4/1/21. This PIP addresses medication security and storage and directs the DON to report her Audits and surveillance to the QAPI Committee on a monthly basis for ongoing monitoring and oversight until 6/1/ 2021 or until the QAPI Committee determines that ongoing, consistent compliance has been achieved. The completion date is 4/23/21.	