

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HAL034062	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/02/2017
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NAME OF PROVIDER OR SUPPLIER

STREET ADDRESS, CITY, STATE, ZIP CODE

CLEMMONS VILLAGE II

6441 HOLDER ROAD
CLEMMONS, NC 27012

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
D 000	Initial Comments The Adult Care Licensure Section conducted an annual survey on November 1-2, 2017.	D 000	Response Preface The provider submits this Plan of Action (POA) in accordance with specific regulatory requirements. The Provider does not denote agreement with the Statement of Deficiencies nor does it constitute an admission that the stated deficiencies are accurate.	
D 358	10A NCAC 13F .1004(a) Medication Administration 10A NCAC 13F .1004 Medication Administration (a) An adult care home shall assure that the preparation and administration of medications, prescription and non-prescription, and treatments by staff are in accordance with: (1) orders by a licensed prescribing practitioner which are maintained in the resident's record; and (2) rules in this Section and the facility's policies and procedures. This Rule is not met as evidenced by: Based on observations, record reviews, and interviews, the facility failed to ensure medications were administered as ordered by a licensed prescribing practitioner for 1 of 5 sampled residents (Resident #2), who was ordered a thyroid medication. The findings are: Review of Resident #2's current FL2 dated 02/13/17 revealed: -Diagnoses included hypothyroidism, hyperlipidemia, diabetes mellitus and hypertension. -A physician's order for levothyroxine 125 mcg 1 tablet daily (a medication used to treat hypothyroidism, an underactive thyroid). Review of Resident #2's signed physician's orders dated 09/20/17 revealed an order to	D 358	The Provider submits this POA with the intention that it be inadmissible by any third party in any civil or criminal action against the Provider or any employee, agent, officer, director, or shareholder of the Provider. The Provider hereby reserves the right to challenge the findings if at any time the Provider determines that the findings: (1) are relied upon to adversely influence or serve as a basis, in any way, for the selection and/or imposition of future remedies, or for any increase in future remedies, whether such remedies are imposed by the State of North Carolina or any other entity; or (2) serve, in any way, to facilitate	

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X8) DATE

STATE FORM

6889

P3CG11

Continuation sheet 1 of 7

Renewed + accepted. AJS 12/14/17

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: HAL034082	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 11/02/2017
NAME OF PROVIDER OR SUPPLIER CLEMMONS VILLAGE II		STREET ADDRESS, CITY, STATE, ZIP CODE 6441 HOLDER ROAD CLEMMONS, NC 27012		
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D 358	Continued From page 1 discontinue levothyroxine 125 mcg and start levothyroxine 100 mcg 1 tablet daily. Review of Resident #2's September 2017 medication administration record (MAR) revealed: -An entry for levothyroxine 125 mcg 1 tablet daily was documented as administered from 09/01/17 to 09/20/17. -An entry for levothyroxine 100 mcg 1 tablet daily was documented as administered from 09/21/17 to 09/30/17. Review of Resident #2's October 2017 MAR revealed: -An entry for levothyroxine 100 mcg 1 tablet daily was documented as administered from 10/01/17 to 10/16/17. -There was a handwritten note documenting levothyroxine 100 mcg had been discontinued on 10/16/17. Review of Resident #2's October 2017 electronic medication administration record (eMAR) revealed: -An entry for levothyroxine 100 mcg 1 tablet daily was documented as being administered on 10/20/17. -There was no documentation of levothyroxine 100 mcg administered from 10/17/17 to 10/19/17 and 10/21/17 to 10/31/17. -There was an electronic note documenting levothyroxine 100 mcg had been discontinued with a stop date of 10/20/17. Review of Resident #2's November 2017 eMAR revealed there was no entry for levothyroxine 100 mcg. Review of Resident #2's physician's orders revealed there was no physician's order to	D 358	or promote action by any third party against the Provider. Any changes to Provider's policy or procedures should be considered to be subsequent remedial measures as that concept is employed in Rule 407 of the Federal Rules of Evidence and should be inadmissible in any proceeding on that basis. D 358 It is the community's policy and normal practice to assure that the administration of medications are in accordance with the prescribing physician's orders utilizing the guidelines as outlined in 10A NCAC 13F.1004 (a). The community has policies and procedures designed to maintain these goals. Routine chart and cart audits, RN and pharmacy consultant audits, and Quality Assurance audits are all examples of the many components utilized.	

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D 358	Continued From page 2 discontinue levothyroxine 100 mcg 1 tablet daily. Interview on 11/02/17 at 9:43 am with the campus facility's Registered Nurse (RN) and the Resident Care Coordinator (RCC) revealed: -They were unable to locate a physician's order to discontinue levothyroxine 100 mcg 1 tablet daily for Resident #2. -They had contacted Resident #2's Primary Care Provider (PCP) on 11/01/17. -On 11/02/17, Resident #2's PCP had re-ordered levothyroxine 100 mcg 1 tablet daily for Resident #2 and ordered the facility to obtain a thyroid-stimulating hormone (TSH) level. -The facility had converted from using paper MARs to eMARs on 10/19/17. -The facility's contracted pharmacy had been responsible for entering the residents' medication orders into the eMAR computer system during the conversion from paper MARs to eMARs. -The contracted pharmacy had mistakenly entered a stop date of 10/20/17 for Resident #2's levothyroxine. -Medication Aides (MA) would not administer medications beyond the stop date. -The night shift MA was responsible for auditing residents' eMARs one time per month to ensure they were accurate. -If the MA found an entry that was inaccurate, she would notify the RCC. -It was the RCC's responsibility to review the audit log to ensure the audits had been completed. -The RCC was unsure if an audit had been completed for Resident #2 since the conversion from paper MARs to eMARs. Telephone interview on 11/02/17 at 10:13 am with the Director of Operations for the facility's contracted pharmacy revealed:	D 358	Action Plan Measures to Correct On 11/1/17, Resident #2's physician was contacted regarding clarification of the Levothyroxine order. Upon clarification, Resident #2 received the medication as prescribed. Resident #2's TSH was also checked as ordered by the physician. Resident #2 continues to receive Levothyroxine as prescribed by the physician. Resident #2's TSH level was checked on 11/02/2017 and 11/14/2017. Measures to Prevent The community's RN programmed the eMAR software to require a second medication technician or member of management to validate any discontinued, newly added, or edited medication order that is manually entered, by facility staff into eMAR.	

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STATE FORM

6409

P3CG11

If continuation sheet, 3 of 7

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D 358	Continued From page 3 -The pharmacy had been responsible for the electronic conversion of residents' medication orders into the eMAR computer system when the facility had converted from using paper MARs to eMARs on 10/19/17. -A team of individuals at the pharmacy had conducted an "edit" of the residents' medication orders to ensure they had been transferred correctly. -The pharmacy's computer system indicated that Resident #2 still had an active order for levothyroxine 100 mcg 1 tablet daily. -The facility had the capability to mark a medication as being discontinued in the facility's eMAR system. -In order for the pharmacy to know that a resident's medication had been discontinued, the facility had to fax a physician's order to the pharmacy. -He did not have a physician's order indicating that Resident #2's levothyroxine had been discontinued. -The "change log" in the eMAR system indicated that the facility's campus RN had performed an "override" of the system on 10/20/17 and had discontinued Resident #2's levothyroxine. Telephone interview on 11/02/17 at 10:49 am with Resident #2's PCP revealed: -She was notified on 11/01/17 that Resident #2 was not administered levothyroxine 100 mcg 1 tablet daily for a total of 15 days. -She had not ordered for the facility to discontinue Resident #2's levothyroxine. -She wanted the facility to continue administering levothyroxine 100 mcg 1 tablet daily to Resident #2. -Resident #2 had to take levothyroxine to treat hypothyroidism. -Resident #2's TSH level had been "around 1.0 in	D 358	All medication technicians were educated on the extra precautionary step that is required when discontinuing, adding, or changing an order manually. Monitoring The eMAR software was programmed to generate an email to the RCC, RN, and Executive Director for any medications that were manually entered into eMAR by a facility staff member as being discontinued, newly added, or edited. The RCC or designee will be responsible for also reviewing these manual changes.	12/2/2017

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D 358	Continued From page 4 September 2017 which was too low" so she had lowered his dose of levothyroxine from 125 mcg to 100 mcg daily. -She had ordered the facility to check Resident #2's TSH level 6 weeks after changing the dose which was 10/31/17. -Resident #2's TSH level on 10/31/17 was 115 which was "significantly elevated from the level in September" so she ordered for the lab to check the level again on the same blood sample on 11/01/17. -Resident #2's TSH level on 11/01/17 was 109 which was "still higher than she expected" so she ordered for the facility to obtain an "urgent" TSH again on 11/02/17. -Resident #2's TSH level had likely risen due to him missing doses of levothyroxine. -She wanted Resident #2's TSH level to be less than 10. -Typical symptoms in someone with an elevated TSH level would be fatigue and difficulty sleeping but Resident #2 had not complained of these symptoms. -The long term effects of someone with hypothyroidism not taking levothyroxine would be damage to their heart. Interview on 11/02/17 at 11:26 am with Resident #2 revealed: -The MA had administered his levothyroxine earlier that morning. -He was unaware that he had missed doses of levothyroxine. -He had not felt any differently over the past 15 days. -He had not experienced any increase in fatigue or difficulty sleeping. Observation on 11/02/17 at 12:00 pm of Resident #2's medications on hand for administration	D 358			

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D 358	Continued From page 5 revealed 1 blister pack containing levothyroxine 100 mcg dispensed on 11/01/17 with 29 of 30 tablets remaining. Attempted phone interviews with 2 night shift MAs on 11/02/17 at 12:34 pm and again at 2:49 pm were unsuccessful. Interview on 11/02/17 at 1:10 pm with the lead MA on day shift revealed: -She was unaware of any process for auditing resident's eMARs to ensure they were accurate. -If there was a medication marked as being discontinued on the eMAR, she would typically check the binder located on the medication cart to find the physician's order for discontinuing the medication. -If she located a physician's order in the binder to discontinue the medication, she would then have to "approve" the order in the computer system. -If she was unable to locate a physician's order in the binder, she would contact the pharmacy for clarification. -She had not administered levothyroxine to Resident #2 because it was scheduled to be administered by the night shift MA in the mornings prior to the start of her shift. -She was unaware that Resident #2 had not been administered levothyroxine because she could only see in the computer the medications that were due for administration during her shift. A second interview on 11/02/17 at 2:55 pm with the RCC revealed: -The night shift MA would randomly select 6 residents to audit each month and would compare their previous month's eMAR to the current month's eMAR to ensure all medications were accurate. -The MA had not performed an audit of Resident	D 358		

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STATE FORM

5490

P3CG11

If continuation sheet 6 of 7

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D 358	Continued From page 6 #2's eMAR since the facility's conversion from paper MARs to eMARS on 10/20/17. -She had been informed by the facility's contracted lab that they could not perform urgent TSH levels and that Resident #2's TSH level would not be resulted until 11/03/17. A second interview on 11/02/17 at 5:00 pm with the campus facility's RN revealed: -She was unaware that she had performed an "override" of the computer system on 10/20/17 and discontinued Resident #2's levothyroxine. -She recalled assisting one of the MAs to delete an order on 10/20/17 and must have discontinued Resident #2's levothyroxine by mistake.	D 358		