

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/06/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 185358	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 12/29/2014
NAME OF PROVIDER OR SUPPLIER SIGNATURE HEALTHCARE OF TRIMBLE COUNTY			STREET ADDRESS, CITY, STATE, ZIP CODE 50 SHEPHERD LANE BEDFORD, KY 40006		
(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) COMPLETION DATE	
F 000	INITIAL COMMENTS An Abbreviated Survey was initiated on 12/29/14 and concluded on 12/29/14 to investigate KY22612. The Division of Health Care substantiated the allegation with related deficiencies cited.	F 000	The Facilities submission of this plan of correction, which constitutes our credible allegation of compliance, is for the purpose of meeting licensure and certification requirement. It is not an admission or agreement to the deficiency cited by the regulatory agency of the Commonwealth of Kentucky.		
F 155 SS=E	483.10(b)(4) RIGHT TO REFUSE; FORMULATE ADVANCE DIRECTIVES The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section. The facility must comply with the requirements specified in subpart I of part 489 of this chapter related to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. This REQUIREMENT is not met as evidenced by: Based on interview and record review, it was determined the facility failed to ensure informed consent was obtained prior to performing DNA (DeoxyriboNucleic Acid) testing via cheek swab	F 155	F 155 Completion Date 2/9/15 1. On 12/12/2014 the Administrator and/or Social Service Director contacted the responsible parties of the following residents #1, #2, #3, #4, #5, #6, #7 and #8 to inform them of the DNA testing that was performed on the resident the day prior (12/11/2014). The responsible parties were explained that the testing was for DNA testing related to identifying how the residents body is absorbing their medications and if the resident is getting the full benefits of the medications they are receiving. The responsible parties were informed that the information would be going to their primary care physician and that he would		

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

X Elissa [Signature]

TITLE

X N/A

(X6) DATE

X 1/22/15

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

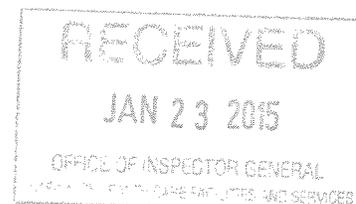
JAN 23 2015

OFFICE OF INSPECTOR GENERAL
DIVISION OF HEALTH CARE FACILITIES AND SERVICES

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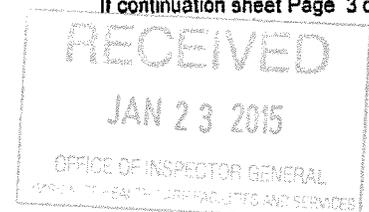
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F 155	<p>Continued From page 1</p> <p>samples on eight (8) of eight (8) sampled residents.</p> <p>The findings include:</p> <p>Review of the facility's policy and procedure for Federal Resident Rights, dated July 2014, revealed the resident had the following rights: to be fully informed in advance about care and treatment that affected his/her well-being; to make choices about aspects of his/her life in the facility that were significant to the resident; to be informed of his/her rights to accept or refuse medical care; to make advance directives regarding care; and, not to have his/her care conditioned upon; or to be discriminated against based upon whether or not he/she had executed an advance directive regarding care.</p> <p>Review of the medical records for Residents #1, #2, #3, #4, #5, #6, #7, and #8 revealed there were written physician orders in each medical record, dated 12/11/14, that stated the facility may perform DNA testing via cheek swabs for therapeutic response to medications. However, there were no signed consents in the medical records to reflect informed consent was obtained from the resident, family or Power of Attorney (POA), prior to performing the cheek swabbing. Further review of the physician orders, revealed each resident's family was notified of the testing on 12/12/14, the day after the DNA testing was performed.</p> <p>Interview with Resident #1's POA, on 12/29/14 at</p>	F 155	<p>review the results. All responsible parties voiced understanding and did not have any concerns with their resident receiving the testing. At that time the Administrator and/or Social Service Director apologized to the responsible parties for not contacting them prior to having the test performed. On 12/12/2014 the administrator and/or Social Service Director went to residents #1, #2, #3, #8, all with a BIMS of 8 or above, to ask if they had DNA testing performed on them the day before. #1, #2, and #3 recalled having the testing performed on them the day prior. The three residents were asked if the nurse collecting the swab asked permission and explained the procedure prior to the testing being conducted. Each resident stated that the nurses asked for permission to perform the test and explained what the test swab was for. All stated they did not have any issue with having the testing to be completed.</p>	



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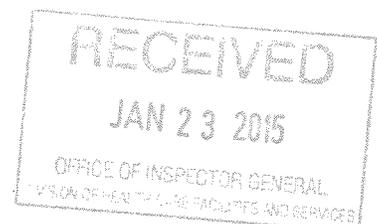
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F 155	<p>Continued From page 2</p> <p>12:09 PM, revealed Licensed Practical Nurse (LPN) #1 contacted him on 12/12/14 regarding the DNA testing. He stated LPN #1 apologized to him for not obtaining his consent prior to the genetics company performing the DNA testing on Resident #1. He said LPN #1 informed him the test was done to determine if the resident's medicine was doing what it was supposed to do. He stated he was not provided any written information regarding the company that conducted the testing or if the results would be provided to him, only that the physician would receive the results.</p> <p>Interview with LPN #1, on 12/29/14 at 2:00 PM, revealed the Administrator contacted each of the facility's physicians and one of them agreed to conduct DNA testing on the twelve residents they treated. She stated on 12/11/14 the Administrator asked her to obtained the verbal orders to perform the DNA testing on the twelve residents. She stated she was not asked to obtain informed consent from the residents or their POA/family member prior to the test being done.</p> <p>Further interview with LPN #1 revealed the facility did not have any other consent forms available for use other than the Consent to Treat form that was signed upon admission. She stated the facility would obtain signed consents for procedures, but the forms were usually provided by the physician or another facility. She stated two representatives from the DNA testing company came to the facility on 12/11/12 and went to Resident #1, #2, #3, #4, #5, #6, #7 and #8's rooms, unaccompanied by facility staff, and performed the cheek swabs.</p>	F 155	<p>2. The testing was completed on 12 residents in the facility. On 12/12/2014 the administrator and/or Social Service Director went to residents with a BIM of 8 or greater that had the swabs completed, to ask if they had DNA testing performed on them the day before. All but one resident recalled having the testing preformed on them the day prior. The residents were asked if the nurse collecting the swab asked permission and explained the procedure prior to the testing being conducted. Each resident stated that the nurse asked for permission to perform the test and explained what the test swab was for. All stated they did not have any issue with having the testing to be completed. All could recall and verbalize what the test was for. On 12/12/2014 the Administrator and/or Chaplin interviewed all residents of the facility that have a BIMS of 8 or greater to ask: Have your resident's rights been violated and Do you feel the facility provides you care against your will. No resident stated that they did not have their resident rights violated</p>	



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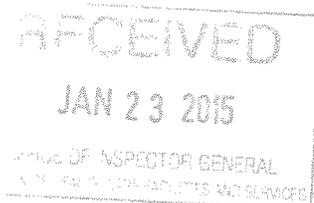
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F 155	Continued From page 3 Interview with the Physician for Resident #1, #2, #3, #4, #5, #6, #7, and #8, on 12/29/14 at 2:35 PM, revealed the facility Administrator had contacted him, via telephone, and requested his permission to conduct DNA testing on the twelve residents he treated at the facility. He stated he agreed to the testing because it would help with the residents' medication regimen. He stated the Administrator promised him she would obtain each resident's consent prior to the testing. He stated since he was not at the facility he could not obtain the informed consent and was depending on the Administrator to do this. He stated he was informed by Resident #1's family member, who was very upset, that informed consent was not obtained prior to testing. He stated he called the facility and the facility's corporate office to ensure the situation was rectified. Interview with the Administrator, on 12/29/14 at 3:00 PM, revealed she had recently attended a corporate meeting of Administrators, where she was informed the corporation had contracted with a genetics company to do DNA testing on residents. She stated each Administrator was directed to contact their facility's physicians about performing DNA testing on their residents for medication absorption. She stated she contacted the facility's six physicians and only one agreed to have the DNA testing performed on their residents. She stated the facility did not have a policy on DNA testing to direct them; however, the facility process was to obtain written informed consent prior to any procedure being conducted on residents. She also stated the physician of Resident #1, #2, #3, #4, #5, #6, #7, and #8 did	F 155	nor do they feel they receive care against their will. On 1/13/15 the Social Service Director and Chaplin contacted the responsible parties of the resident that have a BIM of 7 or less to ask them the following questions: Do you feel the facility has violated your loved ones residents rights and Has your loved one received care that you wish that they would have not received. None of the residents responsible party's felt that their loved ones rights had been violated nor had they received care that they did not wish for them to receive. 12/12/2014 thru 12/14/2014 (three days) the facility conducted psychosocial intervention and documentation on the 12 residents that were subjected to the DNA testing. No signs or symptoms of psychosocial harm were noted. 3. On 12/12/2014 the Administrator was in-serviced by the Nurse Consultant on the facilities policy regarding notifying families and physician when there is a change in a resident's status and the facilities policy on notifying families regarding a new physician order or new treatment order prior to the treatment being cared out. Starting		



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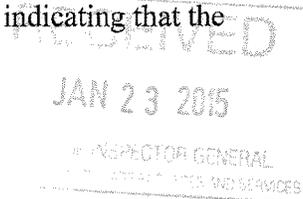
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F 155	Continued From page 4 ask her to obtain the residents' consent prior to conducting the DNA testing. However, she was not in the building on 12/11/14, when the testing was done, and she failed to direct the staff to obtain the informed consent prior to the testing.	F 155	on 1/20/2015 the Administrator, Director of Nursing or Assistant Director of Nursing will in-service staff regarding a resident who has the capacity to make a health care decision or the resident representative has the right to refuse prior to a treatment occurring. That a resident may not be treated against his/her wishes. The resident or resident representative must give informed		



consent prior to the treatment occurring. Staff was in-serviced starting 12/12/2014 by the Administrator and/or Director of Nursing regarding residents rights and the facilities abuse policy. On 12/20/2015 the Administrator and/or Director of Nursing started in-servicing facility nurses and department managers regarding residents participating in clinical research. The facility will obtain a signed consent from each resident and/or resident representative prior to the clinical research occurring. A resident being considered for participation in experimental research will be fully informed of the nature of the experiment and will verbalize understanding of the possible consequences of participating. If the resident is unable to make a health care decision, the facility will educate the resident's surrogate or representative and receive consent prior to treatment. The consent will consist of the residents rights and the right to refuse prior to the clinical research occurring. Prior to formulating or changing an advanced directive, the resident will be informed and verbalize understanding of the possible consequences of this choice. This will be documented by the facility on a care plan meeting note by the SSD, MDS Nurse, Administrator, Director of Nursing or Assistant Director of Nursing.

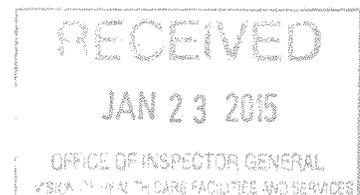
4. During the daily clinical meeting, the Director of Nursing, Assistant Director of Nursing or Social Service Director will check the nurse's notes and/or physicians telephone order indicating that the



resident or resident representative was informed and gave consent prior to an order, treatment or other action taking place. If no informed consent was obtained prior to the action taking place, treatment or physician order the resident and/or resident representative will be notified immediately upon identification by the Director of Nursing, Assistant Director of Nursing, Charge Nurse or Administrator and documentation will be made. The nurse responsible will be re-educated by the Director of Nursing, Assistant Director of Nursing or Administrator to follow the facility policy regarding informed consent prior to an order, treatment or other action taking place.

Beginning on 1/21/15, the Director of Nursing, Assistant Director of Nursing or Administrator will audit 5 residents that received physician telephone orders for a treatment or other action to take place to ensure that the resident and/or resident representative received informed consent prior to the event occurring. The physician telephone orders will be compared to that resident's medical chart to ensure documentation is present supporting informed consent prior to the event occurring and that the resident and or resident representative either refused or consented. This will occur daily Monday – Friday, for four weeks, then three days a week for 4 weeks and lastly once a week for 4 weeks.

All results will be taken to the QAPI committee and the audits will be increased if needed.



Beginning on 1/21/15, the Social Service Director, Chaplain or Administrator will interview 5 residents per day, Monday – Friday for 4 weeks, then 5 residents three days a week for 4 weeks, then 5 residents once a week for 4 weeks to ensure that they do not feel that their resident's rights have been violated, that they feel the facility does not provide care against their will, and that they received education and consent prior to having a physician's order, treatment, experimental research or an order for or change to an advanced directive. All results will be taken to the QAPI committee monthly for review. Any concerns will be reported to the Administrator immediately and will be addressed at that time.

Beginning on 1/21/15, the Administrator, Director of Nursing or Social Service Director will audit all advanced directive changes weekly on Friday to ensure that the resident or resident surrogate or representative was fully informed in the decision making process and were aware of the possible consequences of their choice. This audit will continue weekly on Friday for 3 months and all results will be taken to the QAPI committee monthly for review.

