STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED
	495342		06/08/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
YORK CONVALESCENT AND REHABILITATION CENTER	113 BATTLE ROAD YORKTOWN, VA 23692

(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	F 000		
	An unannounced Medicare/Medicaid standard survey was conducted on 6/6-6/8/2017. Corrections are required for compliance with 42 CFR Part 483 Federal Long Term Care requirements. The Life Safety Code survey/report will follow. The census in this 80 bed facility was 70 at the time of the survey. The survey sample consisted of 13 current resident reviews (Residents # 1-13) and 3 closed record reviews (Residents # 14-16)			
F 155 SS=E	RIGHT TO REFUSE; FORMULATE ADVANCE DIRECTIVES CFR(s): 483.10(c)(6)(8)(g)(12), 483.24(a)(3) 483.10 (c)(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive. c)(8) Nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate. (g)(12) The facility must comply with the requirements specified in 42 CFR part 489, subpart I (Advance Directives). (i) 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 resident's option, formulate an advance directive.	F 155		6/30/17

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Electronically Signed		06/22/2017

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.

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F 155	Continued From page 1 (ii) This includes a written description of the facility's policies to implement advance directives and applicable State law. (iii) Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. (iv) If an adult individual is incapacitated at the time of admission and is unable to receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State law. (v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time. 483.24 (a)(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to related physician orders and the resident's advance directives. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review, and clinical record review, the facility staff failed to ensure 4 Residents (Residents #3, #11, #10 and #2) were free from non-FDA (Food and Drug Administration) approved evaluation.	F 155	F 155 1. Residents # 3, 11, 10 and 2 were assessed and without negative outcome related to non FDA (Food and Drug Administration) approved evaluation. The facility will no longer participate in	

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F 155	Continued From page 2 www.mayoclinic.org defined CYP450 pathway testing: "Your doctor may use cytochrome P450 (CYP450) tests to help determine how your body processes (metabolizes) a drug. The human body contains P450 enzymes to process medications. Because of inherited (genetic) traits that cause variations in these enzymes, medications may affect each person differently. Drug-gene testing - also called pharmacogenomics or pharmacogenetics - is the study of how genes affect your body's response to medication. Tests look for changes or variations in these genes that determine whether a medication could be an effective treatment for you or whether you could have side effects from a specific medication. The P450 enzyme with the most variation in different people is the CYP2D6, which processes many antidepressants and antipsychotic medications. By checking your DNA [deoxyribonucleic acid] for certain gene variations, CYP450 tests can offer clues about how your body may respond to a particular antidepressant. Other CYP450 tests are available for other enzymes." The findings included: 1. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long	F 155	Pharmocogenetic testing for residents or any lab evaluations that have not been approved by the FDA or medical community as effective and conforming to accepted medical practice. 2. The Director of Nursing/designee will conduct medical record review on all residents to determine if non FDA approved lab evaluations were performed by physician. If further evaluation has been scheduled or ordered by physician, the facility will follow up with physician to terminate the arrangements. 3. The Director of Nursing Operations/designee will educate the Medical Director, Director of Nursing and Administrator on "Non FDA Approved Lab Evaluations". The inservice will include but is not limited to review of the State Operations Manual regulation regarding investigational therapy and treatment and the importance of ensuring any test ordered are approved by the FDA or medical community as effective and conforming to accepted medical practice. 4. The Director of Nursing/designee will audit 20% of lab orders weekly for six weeks to ensure all lab evaluations are approved by the FDA or medical community as effective and conforming to accepted medical practice. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 155	Continued From page 3 term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. Review of Resident #3's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: "To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #3's clinical record revealed no physician's order or informed consent from Resident #3's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it."	F 155		

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F 155	Continued From page 4 Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants) narcotics and antipsychotics. He denied the testing was experimental and that it was FDA [Federal Drug Administration] approved, and that was was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3. Employee D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care Residents were tested. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information for the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it."	F 155		

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F 155	Continued From page 5 She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility", and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2D6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings. 2. Resident #11 was tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA, none of the Residents had informed consent, nor education regarding the testing.	F 155		

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F 155	Continued From page 6 Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism. Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #11's clinical record revealed no physician's order or informed consent from	F 155		

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F 155	Continued From page 7 Resident #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. Results of the testing revealed recommending "continued Plavix use at the normal dosage. No therapy modification is needed." On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants), narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #11. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care Residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative from	F 155		

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F 155	Continued From page 8 the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2D6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug	F 155		

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F 155	Continued From page 9 sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. Review of the facility's policy on Resident Rights included: "7. The resident has the right to request, refuse and/or discontinue treatment, as well as to participate in or refuse to participate in experimental research". On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings.	F 155		
	3. For Resident #10, the facility failed to ensure the Resident was free from non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation. Resident #10 was admitted to the facility on 9-20-16. Diagnoses included: dementia, anxiety,			

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F 155	Continued From page 10 high blood pressure, chronic obstructive pulmonary disorder, emphysema, Lymphocytic leukemia, high cholesterol, right carotid occlusion, and glaucoma. Resident #10's most recent MDS (minimum data set) with an ARD (assessment reference date) of 3-24-17 was coded as a quarterly assessment. Resident #10 was coded as having no cognitive deficits, with a BIM's (brief interview for mental status) score of 15 of a possible 15 points scored, and required only set up help to perform her activities of daily living. Review of Resident #10's clinical record revealed a lab result for DNA testing. Review of Resident #3's clinical record revealed a physician's order on 2-2-17 for the testing, however, no informed consent from Resident #10, or their responsible party was obtained for the test to be completed. There was no record the resident or responsible party was informed of the testing. This Resident was included with Residents #3, #11 and #2, as a combined group of test subjects chosen for this testing. All deficient practices for this group was all inclusive of the group.	F 155		

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F 155	Continued From page 11 4. Resident #2 was an 87 year old who was admitted to the facility on 9/5/16. Resident #2's diagnoses included Generalized Muscle Weakness, Hypertension, and Major Depressive Disorder. The Minimum Data Set, which was a Quarterly Assessment with an Assessment Reference Date of 3/17/17 coded Resident #2 as having mildly impaired cognition. On 6/7/17 at 2:30 P.M. an observation was made of Resident #2 in her room. She was in bed while watching television. The head of her bed was elevated, and her feet were in protective boots made of a soft materials with her heels floated. On 6/17/17 a review was conducted of Resident #2's clinical record, revealing the following Physician Order signed by the Medical Director 1) "2/2/17. Pharmacogenetic DNA Testing 1 Time Daily for 1 Day." "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." The facility did not notify the resident's responsible party and explain that the test was not FDA Approved, and obtain written consent to	F 155		

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F 155	Continued From page 12 perform the test. There was no documented notification of the test results to the responsible party. On 10/8/17 at 11:30 A.M. the facility Administrator (Employee B), and Director of Nursing (Employee C) were informed of the findings. No further information was received.	F 155		
F 157 SS=E	NOTIFY OF CHANGES (INJURY/DECLINE/ROOM, ETC) CFR(s): 483.10(g)(14) (g)(14) Notification of Changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s) when there is- (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention; (B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications); (C) A need to alter treatment significantly (that is, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or (D) A decision to transfer or discharge the resident from the facility as specified in §483.15(c)(1)(ii).	F 157		6/30/17

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F 157	Continued From page 13 (ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that all pertinent information specified in §483.15(c)(2) is available and provided upon request to the physician. (iii) The facility must also promptly notify the resident and the resident representative, if any, when there is- (A) A change in room or roommate assignment as specified in §483.10(e)(6); or (B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section. (iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s). This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review, and clinical record review, the facility staff failed to ensure the responsible party/MD were informed of changes in condition and proposed non FDA (Food and Drug Administration) approved testing for 4 Residents (Residents' #3, #11, #10 and #2) in a survey sample of 16 Residents. Residents' #3, #11, #10 and #2 were tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA (Food and Drug Administration), no evidence was presented that responsible parties were notified of the proposed facility wide testing of a non FDA approved test.	F 157	F 157 1. The medical records for residents #3, 11, 10 and 2 were updated to reflect the notification to the resident representative and MD of the pharmocogenetic testing performed in March 2017. The resident representatives and MD have been notified of the cessation of non approved FDA testing by the facility. 2. The Director of Nursing/designee has reviewed the medical records of residents who participated in the non FDA approved testing and informed the resident representative and MD of changes in condition and cessation of non FDA approved testing by the facility.	

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F 157	Continued From page 14 www.mayoclinic.org defined CYP450 pathway testing: "Your doctor may use cytochrome P450 (CYP450) tests to help determine how your body processes (metabolizes) a drug. The human body contains P450 enzymes to process medications. Because of inherited (genetic) traits that cause variations in these enzymes, medications may affect each person differently. Drug-gene testing - also called pharmacogenomics or pharmacogenetics - is the study of how genes affect your body's response to medication. Tests look for changes or variations in these genes that determine whether a medication could be an effective treatment for you or whether you could have side effects from a specific medication. The P450 enzyme with the most variation in different people is the CYP2D6, which processes many antidepressants and antipsychotic medications. By checking your DNA [deoxyribonucleic acid] for certain gene variations, CYP450 tests can offer clues about how your body may respond to a particular antidepressant. Other CYP450 tests are available for other enzymes." The findings included: 1. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long	F 157	3. The Director of Clinical Performance/designee will inservice RNs and LPNs on "Notification of Changes". The inservice will include but is not limited to the importance of notifying the resident representative and MD regarding any change in condition. The staff will also be educated on the facilities decision to cease non FDA approved pharmocogenetic testing. 4. The Director of Nursing/designee will audit 20% of lab orders weekly for six weeks to ensure resident representatives and MD have been notified of changes. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 157	Continued From page 15 term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. Review of Resident #3's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #3's clinical record revealed no physician's order or informed consent from Resident #3's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it."	F 157		

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F 157	Continued From page 16 Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants) narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that was was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care Residents were tested. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information for the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it."	F 157		

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F 157	Continued From page 17 She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility", and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2D6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings. 2. Resident #11 was tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA, none of the Residents had informed consent, nor education regarding the testing.	F 157		

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F 157	Continued From page 18 Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism. Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #11's clinical record revealed no physician's order or informed consent from	F 157		

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F 157	Continued From page 19 Resident #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants), narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #11. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care Residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental."	F 157		

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F 157	Continued From page 20 On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2D6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and	F 157		

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F 157	Continued From page 21 #11 did not show any billing to the resident. Review of the facility's policy on Resident Rights included: "7. The resident has the right to request, refuse and/or discontinue treatment, as well as to participate in or refuse to participate in experimental research". On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings.	F 157		
	3. For Resident #10, the facility failed to ensure the Resident, or their responsible party was notified of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation, and failed to obtain consent for such testing. Resident #10 was admitted to the facility on 9-20-16. Diagnoses included: dementia, anxiety, high blood pressure, chronic obstructive pulmonary disorder, emphysema, Lymphocytic leukemia, high cholesterol, right carotid occlusion, and glaucoma. Resident #10's most recent MDS (minimum data set) with an ARD (assessment reference date) of			

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F 157	Continued From page 22 3-24-17 was coded as a quarterly assessment. Resident #10 was coded as having no cognitive deficits, with a BIM's (brief interview for mental status) score of 15 of a possible 15 points scored, and required only set up help to perform her activities of daily living. Review of Resident #10's clinical record revealed a lab result for DNA testing resulted on 3-17-17. Review of Resident #3's clinical record revealed a physician's order on 2-2-17 for the testing, however, no informed consent from Resident #10, or their responsible party was obtained for the test to be completed. There was no record the resident or responsible party was informed of the testing. This Resident is included with Residents #3, #11, and #2, as a combined group of test subjects chosen for this testing. All deficient practices for this group was all inclusive of the group. 4. For Resident #2, the facility failed to ensure the Resident, or their responsible party was notified of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation, and failed to obtain consent for such testing. Resident #2 was an 87 year old who was admitted to the facility on 9/5/16. Resident #2's diagnoses included Generalized Muscle	F 157		

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F 157	Continued From page 23 Weakness, Hypertension, and Major Depressive Disorder. The Minimum Data Set, which was a Quarterly Assessment with an Assessment Reference Date of 3/17/17 coded Resident #2 as having mildly impaired cognition. On 6/7/17 at 2:30 P.M. an observation was made of Resident #2 in her room. She was in bed while watching television. The head of her bed was elevated, and her feet were in protective boots made of a soft materials with her heels floated. On 6/17/17 a review was conducted of Resident #2's clinical record, revealing the following Physician Order signed by the Medical Director 1) "2/2/17. Pharmacogenetic DNA Testing 1 Time Daily for 1 Day." "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." There was no documentation that Resident #2's Responsible Party was notified prior to the collection of her pharmacogenetic test being administered. In addition, there was no documentation that the test results were shared with Resident #2's Responsible Party.	F 157		

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F 157	Continued From page 24 On 10/8/17 at 11:30 A.M. the facility Administrator (Employee B), and Director of Nursing (Employee C) were informed of the findings. No further information was received.	F 157		
F 164 SS=E	PERSONAL PRIVACY/CONFIDENTIALITY OF RECORDS CFR(s): 483.10(h)(1)(3)(i); 483.70(i)(2) 483.10 (h)(l) Personal privacy includes 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. (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. §483.70 (i) Medical records. (2) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is- (i) To the individual, or their resident representative where permitted by applicable law; (ii) Required by Law; (iii) For treatment, payment, or health care	F 164		6/30/17

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F 164	Continued From page 25 operations, as permitted by and in compliance with 45 CFR 164.506; (iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review, and clinical record review, the facility staff failed to ensure private health and financial information was kept confidential for 4 Residents (Residents' #3, #11, #10 and #2) in a survey sample of 16 Residents. Residents' #3, #11, #10 and #2 were tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The facility was unaware of who obtained health, medical information (including medications), and financial information to bill for non FDA approved CYP450 pathway testing for 4 Residents (Residents' #3, #11, #10 and #2) in a survey sample of 16 Residents. www.mayoclinic.org defined CYP450 pathway testing: "Your doctor may use cytochrome P450 (CYP450) tests to help determine how your body processes (metabolizes) a drug. The human body contains P450 enzymes to process medications. Because of inherited (genetic) traits that cause variations in these enzymes, medications may	F 164	F 164 1. The residents/representative for residents # 3,11,10 and 2 were informed that resident insurance and protected health information was provided to outside lab vendor when pharmocogenetic testing was performed. The lab informed facility of their policy to maintain all resident protected health information in a HIPAA compliant manner. 2. All residents involved in non FDA approved lab testing and their representatives were informed that resident insurance and protected health information was provided to outside lab vendor when pharmocogenetic testing was performed. 3. The Director of Clinical Performance/designee will inservice RNs, LPNs and the Medical Director on "HIPAA Compliance". The inservice will include but is not limited a review of the facility HIPAA Privacy Policy and Procedures as well as the importance of maintaining all	

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F 164	Continued From page 26 affect each person differently. Drug-gene testing - also called pharmacogenomics or pharmacogenetics - is the study of how genes affect your body's response to medication. Tests look for changes or variations in these genes that determine whether a medication could be an effective treatment for you or whether you could have side effects from a specific medication. The P450 enzyme with the most variation in different people is the CYP2D6, which processes many antidepressants and antipsychotic medications. By checking your DNA for certain gene variations, CYP450 tests can offer clues about how your body may respond to a particular antidepressant. Other CYP450 tests are available for other enzymes." The findings included: 1. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. 2. Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism.	F 164	residents Protected Health information in a confidential manner. 4. The Administrator/designee will review 100% of outside vendors request for financial and/or protected health information weekly for six weeks to ensure resident authorization is obtained prior to dissemination of information. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 164	Continued From page 27 Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed a lab result for DNA testing. Review of Resident #3's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #3's and Resident #11's clinical record revealed no physician's order or informed consent from Resident #3's or Resident	F 164		

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F 164	Continued From page 28 #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants), narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3 and #11. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental."	F 164		

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F 164	Continued From page 29 On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2d6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's policy on Resident Rights	F 164		

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F 164	Continued From page 30 included: "7. The resident has the right to request, refuse and/or discontinue treatment, as well as to participate in or refuse to participate in experimental research" Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings. 3. For Resident #10, the facility failed to ensure the Resident's protected health, and financial information was not shared with sources unknown to the Resident and their responsible party for the purposes of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation. Resident #10 was admitted to the facility on 9-20-16. Diagnoses included: dementia, anxiety, high blood pressure, chronic obstructive pulmonary disorder, emphysema, Lymphocytic leukemia, high cholesterol, right carotid occlusion, and glaucoma. Resident #10's most recent MDS (minimum data	F 164		

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F 164	Continued From page 31 set) with an ARD (assessment reference date) of 3-24-17 was coded as a quarterly assessment. Resident #10 was coded as having no cognitive deficits, with a BIM's (brief interview for mental status) score of 15 of a possible 15 points scored, and required only set up help to perform her activities of daily living. Review of Resident #10's clinical record revealed a lab result for DNA testing resulted on 3-17-17. Review of Resident #3's clinical record revealed a physician's order on 2-2-17 for the testing, however, no informed consent from Resident #10, or their responsible party was obtained for the test to be completed. There was no record the resident or responsible party was informed of the testing. The testing was conducted by an outside source who had no consent to perform this evaluation from the Resident nor responsible party, and had no contract with the facility to perform laboratory testing on any resident. The facility provided the outside entity the Resident's financial, and protected health information without consent. This Resident is included with Residents #3, #11, and #2, as a combined group of test subjects chosen for this testing. All deficient practices for this group was all inclusive of the group. 4. For Resident #2, the facility failed to ensure the Resident's protected health, and financial	F 164		

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F 164	Continued From page 32 information was not shared with sources unknown to the Resident and their responsible party for the purposes of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation. Resident #2 was an 87 year old who was admitted to the facility on 9/5/16. Resident #2's diagnoses included Generalized Muscle Weakness, Hypertension, and Major Depressive Disorder. The Minimum Data Set, which was a Quarterly Assessment with an Assessment Reference Date of 3/17/17 coded Resident #2 as having mildly impaired cognition. On 6/7/17 at 2:30 P.M. an observation was made of Resident #2 in her room. She was in bed while watching television. The head of her bed was elevated, and her feet were in protective boots made of a soft materials with her heels floated. On 6/17/17 a review was conducted of Resident #2's clinical record, revealing the following Physician Order signed by the Medical Director 1) "2/2/17. Pharmacogenetic DNA Testing 1 Time Daily for 1 Day." "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others	F 164		

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F 164	Continued From page 33 have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." On 6/7/17 a review was conducted of facility documentation, revealing a Privacy Policy dated 10/21/13. "Protected Health Information (PHI) means information, in any format, that is created or received by (facility) and relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; and that identifies the patient or for which there is a reasonable basis to believe the information can be used to identify the patient. Protected Health Information included many common identifiers (e.g. name, address, birth date, Social Security Number). When (facility) uses a contractor or other non-workforce member to perform "Business Associate" functions or activities, the (facility) will require that individual or entity to enter into a Business Associate Agreement." On 6/7/17 an interview was conducted with the facility Administrator (Employee B). She stated that the facility did not have a contract with the lab that performed the procedure on Resident #2, and confirmed that the facility staff gave the lab representative Protected Health Information for billing purposes.	F 164		
F 323 SS=D	FREE OF ACCIDENT HAZARDS/SUPERVISION/DEVICES CFR(s): 483.25(d)(1)(2)(n)(1)-(3) (d) Accidents. The facility must ensure that -	F 323		6/30/17

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F 323	Continued From page 34 (1) The resident environment remains as free from accident hazards as is possible; and (2) Each resident receives adequate supervision and assistance devices to prevent accidents. (n) - Bed Rails. The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements. (1) Assess the resident for risk of entrapment from bed rails prior to installation. (2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation. (3) Ensure that the bed's dimensions are appropriate for the resident's size and weight. This REQUIREMENT is not met as evidenced by: Based on observation, staff interview, facility documentation review, and clinical record review, the facility staff failed to provide a safe environment on 1 of 2 units and for 1 resident (Resident #3) of 16 residents. 1. A medication cart was left unlocked and unattended on the Liberty unit. 2. Resident #3 did not have wheelchair pedals for use in transporting the resident to areas within the facility, resulting in the resident dragging her feet on the floor and possible injury. The findings included:	F 323	F323 # 1 There were no negative outcomes related to medication cart being left unlocked and unattended by medication nurse. The medication nurse was re-educated on the importance of keeping the medication cart locked at all times to include when nurse is away from medication cart or the cart is not clearly visible and under the control of the nurse. Resident #3 was without negative outcome related to being transported in wheelchair without pedals. The nurse was re-educated on the importance of	

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F 323	Continued From page 35 1. A medication cart was left unlocked and unattended on the Liberty unit. A medication pour and pass observation was conducted with Licensed Practical Nurse A (LPN A) on 6/6/17 at 4:42 p.m. Prior to beginning the observation, LPN A prepared a nutritional supplement with thickener. Approximately eight ounces of supplement was prepared. Upon entering the room, LPN A did not lock the medication cart. Once in the room, LPN A administered eye drops to both eyes. LPN A transferred part of the nutritional supplement from the larger cup to a smaller cup. She did this at least twice. LPN A held the cup to the resident's lips and spoke to the resident while the resident drank the supplement. The medication cart was in front of the resident's doorway. The medication cart was double sided, with medications stored in drawers on both sides. While in the room, the cart was not within eye sight of LPN A at all times. She was looking at the resident while administering eye drops and the nutritional supplement. LPN A could not see the back of the cart while in the room. One resident, who ambulated independently with a rollator, was seated on her rollator at the back side of the medication cart waiting for LPN A. LPN A exited the room at 3:51 p.m. LPN A spoke to the resident waiting at the medication cart, stating that she would prepare her medications. LPN A opened a drawer on the medication cart. At this time, this surveyor stopped LPN A. LPN A was shown the unlocked lock and it was reviewed that she did not use the key to open the drawer moments earlier. LPN A acknowledged that the	F 323	ensuring residents who do not self propel have wheelchair pedals to prevent feet from dragging on the floor and possible injury. #2 Nurses will be observed by the Director of Nursing/designee during medication pass to ensure medication carts are locked when nurses are away from the cart or when the cart is not clearly visible and under their control. Nurses will be responsible for ensuring the medication cart is locked at all times when it is not visible and under their control. All residents will be assessed to ensure residents who are unable to propel themselves in the wheelchair have wheelchair pedals in place to be used during transport. Nursing staff will be responsible for ensuring residents who are unable to self propel have wheelchair pedals in place while being transported. #3 RNs and LPNs were re-educated by Director of Clinical Performance/ designee on "Accident Hazards and Supervision-Medication Cart". The inservice will include but is not limited to a review of the medication administration guidelines of ensuring the medication cart is locked at all times when nurse is away from medication cart or when the cart is not clearly visible and under the control of the nurse. Facility staff were educated by Director of Clinical Performance/ designee on "Accident Hazards and Supervision-	

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F 323	Continued From page 36 cart was unlocked. The issue was reviewed with the Administrator, Corporate Nurse and Director of Nursing at the end of day meeting on 6/7/17. 2. Resident #3 did not have wheelchair pedals for use in transporting the resident to areas within the facility, resulting in the resident dragging her feet on the floor and possible injury. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. Resident #3 was coded as requiring total assistance in the wheelchair to mobilize around the unit. On 6/7/17 at 1:50 PM, Resident #3 was transported by wheelchair to the resident's room by LPN (licensed practical nurse) C. LPN (C) attempted to push the wheelchair forward, but was unable to as the resident's feet remained on the floor, stopping the forward motion of the wheelchair. LPN (C) then transported the resident backwards through the hall way to the resident's room.	F 323	Wheelchair Pedals". The inservice will include but is not limited to the importance of ensuring all resident who are unable to propel themselves in a wheelchair are to have wheelchair pedals in place when resident is being transported by staff. #4 The Director of Nursing/designee will conduct five random observations weekly for six weeks during medication pass to ensure medication carts are locked when not clearly visible by nurse or when the cart is not under control of the nurse. The Director of Nursing/designee will review 20% of residents who are unable to propel themselves weekly for six weeks to ensure wheelchair pedals are in place while resident are being transported. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 323	Continued From page 37 On 6/17/17 at 1:55 PM, CNA (certified nursing assistant) B (currently caring for Resident #3) was asked if the resident had wheelchair pedals for her wheelchair. CNA (B) stated, "I don't believe she does" and "She won't move by herself." Review of the current care plan for Resident #3 included the following: "Requires extensive to total assistance and has beginning contractures to bilateral knees." On 6/8/17, the facility presented a Rehabilitation screening form dated 6/8/17, which contained the following: "Calf board placed onto leg rests to improve positioning and safety while in wheelchair." On 6/17/17 at the end of the day meeting, the DON (director of nursing) and Administrator were notified of above findings.	F 323		
F 441 SS=D	INFECTION CONTROL, PREVENT SPREAD, LINENS CFR(s): 483.80(a)(1)(2)(4)(e)(f) (a) Infection prevention and control program. The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements: (1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment	F 441		6/30/17

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F 441	Continued From page 38 conducted according to §483.70(e) and following accepted national standards (facility assessment implementation is Phase 2); (2) Written standards, policies, and procedures for the program, which must include, but are not limited to: (i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility; (ii) When and to whom possible incidents of communicable disease or infections should be reported; (iii) Standard and transmission-based precautions to be followed to prevent spread of infections; (iv) When and how isolation should be used for a resident; including but not limited to: (A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and (B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances. (v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and (vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.	F 441		

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F 441	Continued From page 39 (4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility. (e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection. (f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary. This REQUIREMENT is not met as evidenced by: Based on observation, staff interview, and clinical record review, the facility staff failed to ensure an effective infection control program for two resident (Resident #10 and #11) of 16 residents in the survey sample. Resident #10's bottle of Flonase nasal spray was stored in Resident #11's Flonase nasal spray box. Upon identification of the mix up, the bottles were switched back to their corresponding boxes. Resident #10 was administered medication from the bottle that had been in Resident #11's box. The findings included: On 6/6/17 at approximately 3:55 p.m., a medication pour and pass observation was conducted with Licensed Practical Nurse A (LPN A) for Resident #10. At this time, LPN A removed a box of Flonase from the cart. She looked at the box and the bottle inside the box then handed both to this surveyor. The box was labeled with Resident #10's name. The bottle inside the box did not belong to Resident #10. It was labeled with Resident #11's name.	F 441	F441 #1 Resident #10 and #11 were without negative outcome related to resident #11's nasal spray being stored in Resident #10's box. Nasal sprays from both residents were replaced. The nurse was re-educated on the importance of ensuring medications are stored in corresponding resident box to ensure infection control standards are followed. #2 The Director of Nursing/designee will perform a 100% audit of all multi-dose medications to ensure all multi-dose medications are in their corresponding boxes. Any variances have been corrected. The medication nurses will be responsible for ensuring multi-dose medication are in correct boxes on a daily basis. #3 RNs and LPNs were re-educated by the Director of Clinical Performance/ designee on "Infection Control-Medication Administration". The in-service will include	

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F 441	Continued From page 40 LPN A asked if everything was ok with the Flonase. The box and the bottle were handed back to her. LPN A looked at the medication again and realized that the bottle did not belong to Resident #10. She removed Resident #11's box of Flonase from the cart. Resident #11's box contained Resident #10's bottle. LPN A switched the bottles so that the resident name on the box matched the resident name on the bottle. LPN A administered the Flonase to Resident #10 from the bottle labeled with her name. This is the bottle that had been in Resident #11's Flonase box. While not observed, this bottle could have been used to administer Resident #11's Flonase on previous dates. Resident #10, a 73 year old, was admitted to the facility on 9/20/16. Her diagnoses included dementia, anxiety, cancer, high blood pressure, asthma, and allergies. The most recent minimum data set assessment was a quarterly assessment with assessment reference date of 3/24/17. Resident #10 coded with a Brief Interview of Mental Status score of 15 indicating no cognitive impairment. She was coded as needing limited assistance to perform her activities of daily living. Resident #10 had a physician order dated 1/4/17 for Flonase 2 sprays both nostrils daily. According to the June 2017 Medication Administration Record, Resident #10 had received the Flonase daily. Resident #10, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia, hypothyroidism, and allergies. The most recent minimum data set assessment was a	F 441	but is not limited to a review of the medication administration policy focusing on the importance of ensuring multi-dose medication is being stored in the appropriate container and any multi- dose medication container is checked for the right resident name prior to administration. #4 The Director of Nursing/ designee will conduct five random observations during medication pass weekly for the next 6 weeks to ensure multi- dose medication labels are being checked prior to administration and the multi dose medication is in its corresponding box. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 441	Continued From page 41 quarterly assessment with assessment reference date of 5/9/17. Resident #10 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Resident #10 had a physician order dated 10/4/16 for Flonase 2 sprays both nostrils daily. According to the June 2017 Medication Administration Record, Resident #11 had received the Flonase daily. On 6/7/17 at 10:50 a.m. (the morning after the observation), the Flonase nasal spray for Resident #10 and #11 was removed from the medication cart by LPN D and given to this surveyor upon request. The Flonase was available for use for both residents. The Flonase boxes and bottles were dated as follows: Resident #10: box 3/28/17 bottle 3/22/17 Resident #11 (box 1): box 3/22/17 bottle 3/28/17 Resident #11 (box 2) box 3/1/17 bottle 3/1/17 LPN D was asked why Resident #11 would have two bottles of Flonase. She stated that a nurse probably opened a second box not knowing that a	F 441		

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F 441	Continued From page 42 box was already open. When asked if both bottles had been used, LPN D stated yes, or else there would be a green clip on bottle cap indicating that the bottle had not been opened. On 6/7/17 at 11:00 a.m., the issue was reviewed with the Corporate Nurse. It was reviewed that LPN A had administered nasal spray for Resident #10 that had been stored in Resident #11's box and most likely administered to Resident #11 previously. The dates on the boxes and bottles of nasal spray were reviewed. It was reviewed that the Flonase was still available for administration the morning after the mix up was identified, and it was likely that Resident #11 would be administered nasal spray from a bottle that had been used to administer Flonase to Resident #10. The Corporate Nurse stated that the Flonase mix up was an infection control issue and she took all three boxes of Flonase to discard. An interview regarding the facility's infection control program was conducted on 6/8/17 at 10:25 a.m. with the Director of Nursing. The Administrator, Director of Nursing and Corporate Nurse were notified of the issue at the end of day meeting on 6/7/17.	F 441		
F 500 SS=E	OUTSIDE PROFESSIONAL RESOURCES-ARRANGE/AGRMNT CFR(s): 483.70(g)(1)(2)(i)(ii) (g) Use of outside resources. (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the	F 500		6/30/17

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F 500	Continued From page 43 Act or an agreement described in paragraph (g)(2) of this section. (2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for- (i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and (ii) The timeliness of the services. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review and clinical record review, the facility staff failed to ensure a contractual agreement was established to provide Pharmacogenetic testing for 4 Residents (Residents' #3, #11, #10 and #2) in a survey sample of 16 Residents. For Residents' #3, #11, #10 and #2, the facility staff allowed an independent contractor to obtain buccal swabs for CYP450 pathway testing and submit the swabs to an outside laboratory with whom the facility had no contractual agreement. The findings included: www.mayoclinic.org defined CYP450 pathway testing: "Your doctor may use cytochrome P450 (CYP450) tests to help determine how your body processes (metabolizes) a drug. The human body	F 500	F 500 1. The facility will not pursue establishing a contract with outside labs conducting pharmocogenetic testing as the facility has decided to cease all pharmocogenetic testing for residents. The facility will not allow independent contractors to obtain lab specimens and submit to outside lab with whom no contractual agreement has been established. The Medical Director has been reeducated on ensuring contractual agreements have been established prior to pursuing services from outside lab vendors. 2. The Administrator/designee will review all arrangements with outside lab vendors to ensure contractual agreements have been established. The Administrator/designee will be responsible	

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F 500	Continued From page 44 contains P450 enzymes to process medications. Because of inherited (genetic) traits that cause variations in these enzymes, medications may affect each person differently. Drug-gene testing - also called pharmacogenomics or pharmacogenetics - is the study of how genes affect your body's response to medication. Tests look for changes or variations in these genes that determine whether a medication could be an effective treatment for you or whether you could have side effects from a specific medication. The P450 enzyme with the most variation in different people is the CYP2D6, which processes many antidepressants and antipsychotic medications. By checking your DNA for certain gene variations, CYP450 tests can offer clues about how your body may respond to a particular antidepressant. Other CYP450 tests are available for other enzymes." The findings included: 1. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. 2. Resident #11 was tested through a buccal	F 500	for ensuring any service provided to resident from an outside vendor are in accordance with established contractual agreement. 3. The Senior Vice President of Operations/designee will inservice the Administrator, Director of Nursing and Medical Director on "Contractual Agreements". The in-service will include but is not limited to a review of the regulation regarding outside professional resources, arrangements and agreements. 4. The Administrator/designee will review 100% of proposed services from outside vendors weekly for six weeks to ensure a contractual agreement has been established prior to services rendered. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 500	Continued From page 45 (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA, none of the Residents had informed consent, nor education regarding the testing. Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism. Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed a lab result for DNA testing. Review of Resident #3's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level	F 500		

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F 500	Continued From page 46 and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #3's and Resident #11's clinical record revealed no physician's order or informed consent from Resident #3's or Resident #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants), narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3 and #11. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term	F 500		

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F 500	Continued From page 47 care Residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2d6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational."	F 500		

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F 500	Continued From page 48 Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings.	F 500		
	3. For Resident #10, the facility failed to ensure the Resident's protected health, and financial information was not shared with sources who had no contractual agreement to provide testing services, for the purposes of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation. Resident #10 was admitted to the facility on 9-20-16. Diagnoses included: dementia, anxiety, high blood pressure, chronic obstructive pulmonary disorder, emphysema, Lymphocytic leukemia, high cholesterol, right carotid occlusion, and glaucoma. Resident #10's most recent MDS (minimum data set) with an ARD (assessment reference date) of			

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F 500	Continued From page 49 3-24-17 was coded as a quarterly assessment. Resident #10 was coded as having no cognitive deficits, with a BIM's (brief interview for mental status) score of 15 of a possible 15 points scored, and required only set up help to perform her activities of daily living. Review of Resident #10's clinical record revealed a lab result for DNA testing dated 3-17-17. Review of Resident #3's clinical record revealed a physician's order on 2-2-17 for the testing, however, no informed consent from Resident #10, or their responsible party was obtained for the test to be completed. There was no record the resident or responsible party was informed of the testing. The testing was conducted by an outside source who had no consent to perform this evaluation from the Resident nor responsible party, and had no contract with the facility to perform laboratory testing on any resident. The facility provided the outside entity the Resident's financial, and protected health information without consent. This Resident was included with Residents #3, #11, and #2, as a combined group of test subjects chosen for this testing. All deficient practices for this group was all inclusive of the group. 4. Resident #2 was an 87 year old who was admitted to the facility on 9/5/16. Resident #2's diagnoses included Generalized Muscle Weakness, Hypertension, and Major Depressive	F 500		

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F 500	Continued From page 50 Disorder. The Minimum Data Set, which was a Quarterly Assessment with an Assessment Reference Date of 3/17/17 coded Resident #2 as having mildly impaired cognition. On 6/7/17 at 2:30 P.M. an observation was made of Resident #2 in her room. She was in bed while watching television. The head of her bed was elevated, and her feet were in protective boots made of a soft materials with her heels floated. On 6/17/17 a review was conducted of Resident #2's clinical record, revealing the following Physician Order signed by the Medical Director 1) "2/2/17. Pharmacogenetic DNA Testing 1 Time Daily for 1 Day." "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." On 6/7/17 a review was conducted of facility documentation, revealing a Privacy Policy dated 10/21/13. "Protected Health Information (PHI) means information, in any format, that is created or received by (facility) and relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; and that identifies the patient or for	F 500		

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F 500	Continued From page 51 which there is a reasonable basis to believe the information can be used to identify the patient. Protected Health Information included many common identifiers (e.g. name, address, birth date, Social Security Number). When (facility) uses a contractor or other non-workforce member to perform "Business Associate" functions or activities, the (facility) will require that individual or entity to enter into a Business Associate Agreement." On 6/7/17 an interview was conducted with the facility Administrator (Employee B). She stated that the facility did not have a contract with the lab that performed the procedure on Resident #2, and confirmed that the facility staff gave the lab representative Protected Health Information for billing purposes.	F 500		
F 501 SS=E	RESPONSIBILITIES OF MEDICAL DIRECTOR CFR(s): 483.70(h)(1)(2) (h) Medical director. (1) The facility must designate a physician to serve as medical director. (2) The medical director is responsible for- (i) Implementation of resident care policies; and (ii) The coordination of medical care in the facility. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review, and clinical record review, the medical director failed to implement appropriate Resident care policies and coordinate Resident care for 4	F 501	F 501 1. The Medical Director has reviewed the records of Residents # 2, 3, 10 and 11 to ensure care has been coordinated and	6/30/17

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(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 501	Continued From page 52 Residents (Residents #3, #11, #10 and #2) in a survey sample of 16 Residents. Residents' #3, #11, #10 and #2 were tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The decision to do the testing was made by the medical director. The test is not approved by the FDA, none of the Residents had informed consent, education regarding the testing, assurance of confidentiality of financial and health information. www.mayoclinic.org defined CYP450 pathway testing: "Your doctor may use cytochrome P450 (CYP450) tests to help determine how your body processes (metabolizes) a drug. The human body contains P450 enzymes to process medications. Because of inherited (genetic) traits that cause variations in these enzymes, medications may affect each person differently. Drug-gene testing - also called pharmacogenomics or pharmacogenetics - is the study of how genes affect your body's response to medication. Tests look for changes or variations in these genes that determine whether a medication could be an effective treatment for you or whether you could have side effects from a specific medication. The P450 enzyme with the most variation in different people is the CYP2D6, which processes many antidepressants and antipsychotic medications. By checking your DNA for certain gene variations, CYP450 tests can offer clues about how your body may respond to a particular antidepressant. Other CYP450 tests are available for other enzymes."	F 501	provided to resident. FDA non approved lab evaluations will no longer be provided at the facility therefore any related care policies will not be implemented. 2. The medical records of current residents who received pharmocogenetic testing will be reviewed by provider to ensure care has been coordinated. The Medical Director will not request further non FDA approved evaluations to be obtained. 3. The Director of Nursing Operations/designee will inservice the Medical Director on "Responsibilities of the Medical Director". The inservice will include but is not limited to a review of the regulations related to implementation of resident care policies and coordination of medical care in the facility focusing on regulations pertaining to experimental testing and laboratory services agreements. The Medical Director does not intend to order any further testing that is not approved by the FDA. 4. The Director of Nursing/designee will review 100% of new lab services from outside vendors weekly for six weeks to ensure the Medical Director has implemented appropriate resident care policies and coordinated resident care. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 501	Continued From page 53 The findings included: 1. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. 2. Resident #11 was tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA, none of the Residents had informed consent, nor education regarding the testing. Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism. Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed	F 501		

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F 501	Continued From page 54 a lab result for DNA testing. Review of Resident #3's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #3's and Resident #11's clinical record revealed no physician's order or informed consent from Resident #3's or Resident #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated	F 501		

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F 501	Continued From page 55 on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3 and #11. Employee. D said that his PA (physician's assistant created the list of what Residents would be tested. He stated only the long term care Residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it."	F 501		

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F 501	Continued From page 56 She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2d6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's policy on Resident Rights included: "7. The resident has the right to request, refuse and/or discontinue treatment, as well as to participate in or refuse to participate in experimental research" On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings.	F 501		

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3. For Resident #10, the facility Medical Director failed to ensure that conducting research in the facility was guided by current professional standards of practice. Further, the Medical Director failed to ensure that the Resident's protected health, and financial information was not shared with sources who had no contractual agreement to provide testing services, for the purposes of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation, and that consent was obtained for such testing.

Resident #10 was admitted to the facility on 9-20-16. Diagnoses included: dementia, anxiety, high blood pressure, chronic obstructive pulmonary disorder, emphysema, Lymphocytic leukemia, high cholesterol, right carotid occlusion, and glaucoma.

Resident #10's most recent MDS (minimum data set) with an ARD (assessment reference date) of 3-24-17 was coded as a quarterly assessment. Resident #10 was coded as having no cognitive deficits, with a BIM's (brief interview for mental status) score of 15 of a possible 15 points scored, and required only set up help to perform her activities of daily living.

Review of Resident #10's clinical record revealed a lab result for DNA testing dated 3-17-17.

Review of Resident #3's clinical record revealed a

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F 501	Continued From page 58 physician's order on 2-2-17 for the testing, however, no informed consent from Resident #10, or their responsible party was obtained for the test to be completed. There was no record the resident or responsible party was informed of the testing. The testing was conducted by an outside source who had no consent to perform this evaluation from the Resident nor responsible party, and had no contract with the facility to perform laboratory testing on any resident. The facility provided the outside entity the Resident's financial, and protected health information without consent. This Resident is included with Residents #3, #11, and #2, as a combined group of test subjects chosen for this testing. All deficient practices for this group was all inclusive of the group. 4. Resident #2 was an 87 year old who was admitted to the facility on 9/5/16. Resident #2's diagnoses included Generalized Muscle Weakness, Hypertension, and Major Depressive Disorder. The Minimum Data Set, which was a Quarterly Assessment with an Assessment Reference Date of 3/17/17 coded Resident #2 as having mildly impaired cognition. On 6/7/17 at 2:30 P.M. an observation was made of Resident #2 in her room. She was in bed while watching television. The head of her bed was elevated, and her feet were in protective boots made of a soft materials	F 501		

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F 501	Continued From page 59 with her heels floated. On 6/17/17 a review was conducted of Resident #2's clinical record, revealing the following Physician Order signed by the Medical Director 1) "2/2/17. Pharmacogenetic DNA Testing 1 Time Daily for 1 Day." "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." The facility did not notify the resident's responsible party and explain that the test was not FDA Approved, and obtain written consent to perform the test. There was no documented notification of the test results to the responsible party. On 6/8/17 at approximately 9:30 A.M. an interview was conducted with the facility Medical Director in the conference room. He stated that there was no documentation of him making any adjustments to the resident's medication regime as a result of test results. He was unable to state how he coordinated Resident #2's care and services and implemented policies to protect the resident. On 6/8/17 at 10:00 A.M. the facility Administrator (Employee A), and Director of Nursing (Employee	F 501		

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F 501	Continued From page 60 B) were informed of the findings. No further information was provided.	F 501		
F 503 SS=E	LAB SVCS - FAC PROVIDED, REFERRED, AGREEMENT CFR(s): 483.50(a)(i)-(iv) (a) Laboratory Services (i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter. (ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter. (iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter. (iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review and clinical record review, the facility staff failed to ensure a contractual agreement was established with a referral laboratory prior to Pharmacogenetic testing being performed for 4 Residents (Residents' #3, #11, #10 and #2) in a	F 503	F 503 1. Pharmocogenetic testing will no longer be conducted at the facility therefore a contractual agreement will not be established with the referral laboratory.	6/30/17

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F 503	Continued From page 61 survey sample of 16 Residents. For Residents' #3, #11, #10, and #2, the facility staff allowed an independent contractor to obtain buccal swabs for CYP450 pathway testing and submit the swabs to an outside laboratory with whom the facility had no contractual agreement. The findings included: 1. Resident #3, a female, was admitted to the facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. Review of Resident #3's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: "To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects	F 503	2. The Administrator/designee will review current laboratory services arrangements to ensure contractual agreements have been established. The Administrator/designee will review any proposed referral laboratory services to ensure a contractual agreement has been established prior to services being rendered. 3. The Senior Vice President of Operations/designee will inservice the Administrator, Director of Nursing and Medical Director on "Contractual Agreements". The in-service will include but is not limited to a review of the regulation regarding outside professional resources, arrangements and agreements. Also discussed was importance of ensuring a contractual agreement has been established for any referral laboratory services. 4. The Administrator/designee will review 100% of proposed services from outside vendors weekly for six weeks to ensure a contractual agreement has been established prior to services rendered. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 503	Continued From page 62 are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen" . Review of Resident #3's clinical record revealed no physician's order or informed consent from Resident #3's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants) narcotics and antipsychotics. He denied the testing was experimental and that it was FDA approved, and that was was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3. Employee. D said that his PA (physician's assistant) created	F 503		

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F 503	Continued From page 63 the list of what Residents would be tested. He stated only the long term care Residents were tested. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information for the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor. A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility", and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2D6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational."	F 503		

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F 503	Continued From page 64 Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings. 2. Resident #11 was tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA, none of the Residents had informed consent, nor education regarding the testing. Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism. Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed a lab result for DNA testing. A laboratory requisition was filled out for the	F 503		

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F 503	Continued From page 65 following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #11's clinical record revealed no physician's order or informed consent from Resident #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. Results of the testing revealed recommending "continued Plavix use at the normal dosage. No therapy modification is needed." On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of	F 503		

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F 503	Continued From page 66 medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants), narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #11. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care Residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor.	F 503		

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F 503	Continued From page 67 A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2D6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. Review of the facility's policy on Resident Rights included: "7. The resident has the right to request, refuse and/or discontinue treatment, as well as to participate in or refuse to participate in experimental research". On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings.	F 503		

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F 503	Continued From page 68	F 503		
	3. For Resident #10, the facility failed to ensure that a contractual agreement was secured prior to conducting research in the facility, and that the Resident's protected health, and financial information was not shared with sources who had no contractual agreement to provide testing services, for the purposes of non-FDA (Food and Drug Administration) approved investigational DNA testing & evaluation. Resident #10 was admitted to the facility on 9-20-16. Diagnoses included: dementia, anxiety, high blood pressure, chronic obstructive pulmonary disorder, emphysema, Lymphocytic leukemia, high cholesterol, right carotid occlusion, and glaucoma. Resident #10's most recent MDS (minimum data set) with an ARD (assessment reference date) of 3-24-17 was coded as a quarterly assessment. Resident #10 was coded as having no cognitive deficits, with a BIM's (brief interview for mental status) score of 15 of a possible 15 points scored, and required only set up help to perform her activities of daily living.			

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F 503	Continued From page 69 Review of Resident #10's clinical record revealed a lab result for DNA testing dated 3-17-17. There was no contractual agreement between the testing laboratory, and the facility. There was also no contractual agreement, nor consent for the testing between the Resident, their Responsible Party, and the testing laboratory. Review of Resident #10's clinical record revealed a physician's order on 2-2-17 for the testing, however, no informed consent from Resident #10, or their responsible party was obtained for the test to be completed. There was no record the resident or responsible party was informed of the testing. The testing was conducted by an outside source who had no consent to perform this evaluation from the Resident nor responsible party, and had no contract with the facility to perform laboratory testing on any resident. The facility provided the outside entity the Resident's financial, and protected health information without consent. This Resident is included with Residents #3, #11, and #2, as a combined group of test subjects chosen for this testing. All deficient practices for this group was all inclusive of the group. 4. Resident #2 was an 87 year old who was admitted to the facility on 9/5/16. Resident #2's diagnoses included Generalized Muscle Weakness, Hypertension, and Major Depressive Disorder.	F 503		

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F 503	Continued From page 70 The Minimum Data Set, which was a Quarterly Assessment with an Assessment Reference Date of 3/17/17 coded Resident #2 as having mildly impaired cognition. On 6/7/17 at 2:30 P.M. an observation was made of Resident #2 in her room. She was in bed while watching television. The head of her bed was elevated, and her feet were in protective boots made of a soft materials with her heels floated. On 6/17/17 a review was conducted of Resident #2's clinical record, revealing the following Physician Order signed by the Medical Director 1) "2/2/17. Pharmacogenetic DNA Testing 1 Time Daily for 1 Day." "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." On 6/7/17 a review was conducted of facility documentation, revealing a Privacy Policy dated 10/21/13. "Protected Health Information (PHI) means information, in any format, that is created or received by (facility) and relates to the past, present, or future physical or mental health or condition of a patient; the provision of health care to a patient; and that identifies the patient or for which there is a reasonable basis to believe the information can be used to identify the patient.	F 503		

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F 503	Continued From page 71 Protected Health Information included many common identifiers (e.g. name, address, birth date, Social Security Number). When (facility) uses a contractor or other non-workforce member to perform "Business Associate" functions or activities, the (facility) will require that individual or entity to enter into a Business Associate Agreement." On 6/7/17 an interview was conducted with the facility Administrator (Employee B). She stated that the facility did not have a contract with the lab that performed the procedure on Resident #2, and confirmed that the facility staff gave the lab representative Protected Health Information for billing purposes.	F 503		
F 504 SS=D	LAB SVCS ONLY WHEN ORDERED BY PHYSICIAN CFR(s): 483.50(a)(2)(i) (a) Laboratory Services (2) The facility must- (i) Provide or obtain laboratory services only when ordered by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws. This REQUIREMENT is not met as evidenced by: Based on staff interview, facility documentation review and clinical record review, the facility staff failed to ensure a physician's order was obtained prior to Pharmacogenetic testing being performed for 2 Residents (Residents' #3 and #11) in a survey sample of 16 Residents.	F 504	F 504 1. The medical records for Residents # 3 and 11 were updated by the provider to reflect the order for pharmocogenetic testing. The resident/representatives have been notified regarding the order for prior	6/30/17

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F 504	Continued From page 72 For Residents' #3,#11 and #10 the facility staff failed to obtain a physician's order prior to CYP450 Pharmacogentic pathway testing being performed. The findings included: www.mayoclinic.org defined CYP450 pathway testing: "Your doctor may use cytochrome P450 (CYP450) tests to help determine how your body processes (metabolizes) a drug. The human body contains P450 enzymes to process medications. Because of inherited (genetic) traits that cause variations in these enzymes, medications may affect each person differently. Drug-gene testing - also called pharmacogenomics or pharmacogenetics - is the study of how genes affect your body's response to medication. Tests look for changes or variations in these genes that determine whether a medication could be an effective treatment for you or whether you could have side effects from a specific medication. The P450 enzyme with the most variation in different people is the CYP2D6, which processes many antidepressants and antipsychotic medications. By checking your DNA for certain gene variations, CYP450 tests can offer clues about how your body may respond to a particular antidepressant. Other CYP450 tests are available for other enzymes." The findings included: 1. Resident #3, a female, was admitted to the	F 504	testing. 2. The medical records of current residents who participated in pharmocogenetic testing have been reviewed and updated by the provider to reflect the physician□s order. The charge nurse will ensure any labs obtained have a corresponding physician□s order. 3. The Director of Clinical Performance/designee will inservice RNs and LPNs on "Lab Services". The inservice included but was not limited to the importance of verifying a physician□s order is in place prior to obtaining labs. 4. The Director of Nursing/designee will review 20% of labs obtained weekly for six weeks to ensure a physician□s order is in place prior to obtaining lab services. Any trends or patterns will be reported to the Quality Assurance Performance Improvement Committee on at least a quarterly basis.	

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F 504	Continued From page 73 facility 10/31/11. Her diagnoses included dementia, high blood pressure and hypothyroidism. Resident #3's most recent MDS (minimum data set) with an ARD (assessment reference date) of 4/20/17 was coded as a quarterly assessment. Resident #3 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing total assistance of one staff member to perform her activities of daily living. 2. Resident #11 was tested through a buccal (interior lining of the cheek) swab test for CYP450 pathway testing. The test is not approved by the FDA, none of the Residents had informed consent, nor education regarding the testing. Resident #11, a female, was admitted to the facility 9/1/16. Her diagnoses included high blood pressure, dementia and hypothyroidism. Resident #11's most recent MDS (minimum data set) with an ARD (assessment reference date) of 5/9/17 was coded as a quarterly assessment. Resident #11 was coded as having short and long term memory deficits and required total assistance with making daily life decisions. She was also coded as needing extensive to total assistance of one staff member to perform her activities of daily living. Review of Resident #11's clinical record revealed a lab result for DNA testing. Review of Resident #3's clinical record revealed a	F 504		

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F 504	Continued From page 74 lab result for DNA testing. A laboratory requisition was filled out for the following reasons for the tests: To evaluate the patient's metabolic uptake due to multiple diseases and the use of multiple medications, to determine if the the patient's symptoms are because of a potential intolerance to their current medication regime, to determine the patient's best tolerance to a new prescription and how it will interact with their current medications, to determine proper individualized drug combinations and dosing so that desired effects are achieved, to safely reduce the number and type of medication to the patient's optimal level and to prevent or reduce medication interaction and adverse drug effects." The lab requisition was signed by the Medical Director and the RN (registered nurse from the outside vendor) collecting the specimen. Review of Resident #3's and Resident #11's clinical record revealed no physician's order or informed consent from Resident #3's or Resident #11's responsible party for the test to be completed. There was no record the resident or responsible party was informed of the testing. On 6/8/17, at 8:40 AM, the DON (director of nursing) was questioned about the testing. The DON stated she was not the DON at the time of the testing and the Medical Director was "handling it." Employee. D, the facility's medical director, stated on 6/8/17 at 9:20 AM, that he had attended a conference on this testing and had called in the representative to learn more. The lab would test for enzymes that affect the metabolism of	F 504		

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F 504	Continued From page 75 medications and may indicate medication reactions. Classic categories of medications would include SSRI's (selective serotonin reuptake inhibitors, such as antidepressants), narcotics and antipsychotics. He denied the testing was experimental and that is was FDA approved, and that is was paid for by Medicare and Medicaid. He went on to state the facility provided the billing information (face sheets). He also stated there was no contract, and that he "didn't do that." The medical director was the attending physician for Resident #3 and #11. Employee. D said that his PA (physician's assistant) created the list of what Residents would be tested. He stated only the long term care Residents were tested. Additionally he stated that the consent used was the consent for routine laboratory testing signed on admission. On 6/8/17 at 10:35 AM, the representative form the outside lab vendor was contacted. He stated, "It is not an FDA product, that the test was paid for by Medicare part B and that it was not experimental." On 6/8/17 at 10:50 AM, the Director of Operations for the outside lab vendor was contacted. She stated, "Medicare B is billed for the testing." The outside vendor refused to provide billing information on the residents listed as having received the testing. On 6/8/17 at 1:15 PM, the facility Administrator was questioned about the pharmacogenetics testing. She stated, "I don't know much about it." She denied notifying corporate about the testing and did not establish a contract with the outside vendor.	F 504		

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F 504	Continued From page 76 A LCD (local coverage determination) was provided by the vendor representative. It contained the following for Plavix (antiplatelet medication), antidepressant treatment, proton pump inhibitors (such as Prilosec) as "there is insufficient evidence of clinical utility, and non covered indications included Amitriptyline, Plavix, proton pump inhibitors, SSRI's and Coumadin. "Genetic testing for CYP2C19 is considered investigational at this time" for the mentioned medications. In addition, genetic testing for the CYP2d6 gene for Amitriptyline, antidepressants, antipsychotics, codeine, Aricept, Galantamine and Tamoxifen is considered investigational." Genelex is a pioneer in comprehensive medication management, pharmacogenetic testing and analysis. The company stated, "On June 22, 2015, Medicare will begin denying coverage for the majority of genetic drug sensitivity (pharmacogenetic) testing that it has reimbursed since 2009." Review of the facility's billing for Resident #3 and #11 did not show any billing to the resident. On 6/8/17 at 11:30 AM, the Administrator, DON, clinical nurse consultant, and Medical Director, were notified of above findings.	F 504		
F 518 SS=D	TRAIN ALL STAFF-EMERGENCY PROCEDURES/DRILLS CFR(s): 483.75(m)(2) The facility must train all employees in emergency procedures when they begin to work in the facility; periodically review the procedures with existing staff; and carry out unannounced staff drills using those procedures.	F 518		6/30/17

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F 518	Continued From page 77 This REQUIREMENT is not met as evidenced by: Based on staff interview, the facility staff failed to ensure staff were trained in emergency procedures. Licensed Practical Nurse B (LPN B), Supervisor, stated she did not know how to use a fire extinguisher. The findings included: LPN B was interviewed by phone on 6/6/17 at 11:48 p.m. LPN B identified herself as the supervisor. LPN B was asked to describe how to use a fire extinguisher. She stated to aim at the base. LPN B was asked to describe the specific steps to be implemented prior to aiming at the base. At this time, LPN B stated that she did not know how to use a fire extinguisher. She was advised to check with the person in charge of the fire drills for instructions on how to use the fire extinguisher. The issue was reviewed with the Administrator, Director of Nursing and Corporate Nurse at the end of day meeting on 6/7/17.	F 518	F518 1. LPN B was re-educated on Fire Drills, how to use a fire extinguisher, disaster drills and emergency preparedness. 2. Facility employees will be educated on emergency preparedness including how to use a fire extinguisher on hire and at least annually. Drills will be conducted at least quarterly per shift to ensure that all staff demonstrate proper knowledge as well as ensuring and promoting safety to all residents. 3. The Education and Training Coordinator/Designee inserviced facility staff on emergency preparedness specifically fire safety and proper use of a fire extinguisher. 4. The Administrator/Designee will review the in-service records at least quarterly to ensure that facility staff is receiving adequate education on emergency preparedness including use of a fire extinguisher. The Administrator/Designee will identify and report any trends quarterly to the Quality Assurance Performance Improvement Committee.	
F 520 SS=E	QAA COMMITTEE-MEMBERS/MEET QUARTERLY/PLANS CFR(s): 483.75(g)(1)(i)-(iii)(2)(i)(ii)(h)(i) (g) Quality assessment and assurance.	F 520		6/30/17

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F 520	Continued From page 78 (1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of: (i) The director of nursing services; (ii) The Medical Director or his/her designee; (iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and (g)(2) The quality assessment and assurance committee must : (i) Meet at least quarterly and as needed to coordinate and evaluate activities such as identifying issues with respect to which quality assessment and assurance activities are necessary; and (ii) Develop and implement appropriate plans of action to correct identified quality deficiencies; (h) Disclosure of information. A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section. (i) Sanctions. Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions. This REQUIREMENT is not met as evidenced by: Based on staff interview and facility	F 520	F 520	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING ____ B. WING ____	(X3) DATE SURVEY COMPLETED
	495342		06/08/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
YORK CONVALESCENT AND REHABILITATION CENTER	113 BATTLE ROAD YORKTOWN, VA 23692

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F 520	Continued From page 79 documentation review, the facility staff failed to ensure that the Quality Assurance Committee provided oversight and coordination for pharmacogenetic testing. The facility staff failed for 4 residents (Resident #3, #11, #10, #2) of the survey sample of 16 residents, to ensure that the Quality Assurance Committee provided oversight and coordination for pharmacogenetic testing. The Findings included: On 6/8/17, at 9:30 A.M. an interview was conducted with the facility Administrator (Employee B) to review the Quality Assurance Committee's function. She stated that she was aware that an outside lab had conducted pharmacogenetic testing on approximately 20 residents during February, 2017. She stated that the testing was done by persons unknown to the facility, and that the credentials of the person who had collected the samples from the residents had not been verified. The facility did not have a contract with the lab. The facility did not notify the residents involved, or their Responsible party's of the nature of the testing. She stated that Medical Director had "arranged for the lab to do everything, and facility staff weren't involved in the process., In addition, the Administrator stated that the testing had never been addressed by the Quality Assurance Committee. "According to the Mayo Clinic (www.mayo.edu), "Pharmacogenetics researchers in the Developmental Therapeutics Program focus on the role of genetic inheritance in drug response. They study two aspects of a patient's response to	F 520	1. The Quality Assurance Performance Improvement Committee met and discussed the pharmocogenetic testing performed on four residents. The committee decided to abstain from further testing for the facility residents. No further coordination or oversight is needed. 2. The Quality Assurance Performance Improvement Committee will provide oversight and coordination of services when new lab arrangements are implemented. The Administrator, Director of Nursing and Medical Director will be responsible for presenting any newly proposed services to the Quality Assurance Performance Improvement Committee for review and oversight prior to implementation of services. 3. The Senior Vice President of Operations/designee will inservice the Quality Assurance Performance Improvement Committee on "Continuous Quality Improvement". The inservice will include but is not limited to a review of the Continuous Quality Improvement policy addressing methods to provide oversight and coordination of resident services. 4. The Administrator/designee will ensure any newly proposed resident services will be brought to the Quality Assurance Performance Improvement Committee prior to implementing in facility to ensure oversight and coordination of care are provided. . Any trends or patterns will be reported to the Quality Assurance	

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F 520	Continued From page 80 drugs: drug response and adverse drug reaction. For example, some patients don't get the desired response from a therapeutic drug, while others have a strong negative reaction to it. Several factors may contribute to these reactions, such as age, sex and underlying disease." On 6/7/17 a review was conducted of facility documentation, revealing an Administration Policy. It read, "This facility is governed by an organized Board of Directors. The above are legally responsible for establishing and implementing policies regarding the management and operation of the facility." On 6/8/17 at approximately 11:30 A.M. the Administrator (Employee B) was informed of the findings. No further information was received.	F 520	Performance Improvement Committee on at least a quarterly basis.	