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

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	345342	A. BUILDING _____ B. WING _____	C 03/17/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BIG ELM RETIREMENT AND NURSING CENTERS	1285 WEST A STREET KANNAPOLIS, NC 28081

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F 428 SS=G	483.60(c) DRUG REGIMEN REVIEW, REPORT IRREGULAR, ACT ON The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon. This REQUIREMENT is not met as evidenced by: Based on record review, pharmacist interview, physician interview and staff interview, the facility failed to ensure the consultant pharmacist requested a Digoxin blood level for one (1) of four (4) sampled residents who received Digoxin (Resident # 1). Findings include: Resident #1 was admitted to the facility on 01/07/2011 with multiple diagnoses that included: atrial fibrillation (abnormal heart rhythm), congestive heart failure, cerebrovascular accident 12/03/2010 and renal insufficiency. Record review of the resident's clinical chart revealed Resident #1 received Digoxin 250 micrograms (mcg) daily. There was not a physician's order for a Digoxin blood level on the admission orders. There were no standing orders for laboratory blood draws. Lexi-Comp's Geriatric Drug Dosage Handbook 12th edition stated, in part,"Digoxin is used in the treatment of atrial fibrillation. Warnings/	F 428	Preparation and/or execution of this plan of correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. The Plan of Correction is prepared and/or executed solely because it is required by the provisions of Federal and State law. The facility ensures that the consultant pharmacist reports any irregularities to the attending physician and the director of nursing to be acted upon. **F428 483.60(c)** 1) Resident #1 was discharged to the hospital on 2/18/2011. 2) All residents in the facility who are medicated with digoxin have the potential to be affected by the same alleged deficient practice. The consultant pharmacist completed an audit on 4/6/11 of other residents who are being treated with digoxin therapy. The pharmacist made recommendations to the attending physician and nursing manager to ensure that each resident affected has a current lab completed with digoxin results within therapeutic range. Special attention	**4/14/2011**

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Ann Clennis — TITLE: Administrator — (X6) DATE: 4/8/2011

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 428	Continued From page 1 Precautions included adjustment of dose in residents with renal impairment and aged patients; older adults may develop exaggerated serum/tissue concentrations due to decreased lean body mass, total body water and age-related reduction in renal function. Symptoms of acute overdosage/ toxicity included vomiting and hyperkalemia (excess potassium)." Medical record, hospital discharge summary dated /01/07/2011 and laboratory reports were reviewed. Resident #1 was admitted to the hospital with a diagnosis of shortness of breath and hypoxemia related to pulmonary edema for rapid atrial fibrillation. A list of hospital medications included Digoxin 250 micrograms (mcg). A Digoxin level was not noted in Resident #1's facility record. On 02/03/2011, Resident #1 had a potassium level of 5.5 (normal 3.5-5.1). Her physician ordered Kayexalate 30 Grams (GM) given for hyperkalemia (elevated potassium). Physician's progress note dated 01/10/2011 indicated Resident #1 had a diagnosis of atrial fibrillation and was on Digoxin for heart rate control. Consultant pharmacist note dated 01/19/2011 indicated there were no labs. Risk medications included Digoxin. No recommendations were noted. On 02/08/2011, consultant pharmacist note indicated Resident #1 had received Kayexalate 30 GM. Labs noted did not include a Digoxin level. Risk meds included Digoxin. No recommendations were noted.	F 428	was paid to residents with renal insufficiency. Any resident's results found to be outside the therapeutic range for digoxin therapy was referred to the physician who ordered the necessary steps to be taken to correct the situation. 3) The facility does not feel that system changes are necessary because the consultant pharmacist should have identified that the facility did not have a current digoxin level on resident #1. The consultant pharmacist was counseled by Marybeth Terry, pharmacy owner on 4/7/11 regarding the need to look at other diagnoses that may affect the level of digoxin for any resident receiving digoxin therapy. All other pharmacy consultants with Southern Pharmacy were educated by Joel Noped, Director of Pharmacy Operations-West on 4/7/11 regarding the need to look at other diagnoses that may affect the level of digoxin for residents receiving digoxin therapy. Additionally, for any newly admitted resident on digoxin therapy who does not have a current digoxin level in the record, the consultant pharmacist is to request one immediately.	

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F 428	Continued From page 2 History and Physical from (name) hospital dated 02/18/2011 revealed Resident #1 was admitted to the hospital with a diagnosis of Digoxin toxicity. Digoxin level, at time of admission, was 4.1 (normal 0.8-2.1). Resident #1 was admitted to (name) hospital with nausea, vomiting and confusion. She had evidence of acute renal insufficiency and Digoxin toxicity. She was evaluated by Cardiology and treated with intravenous fluids. During a telephone conversation on 3/21/2011 at 11:05 AM., the consultant pharmacist stated Digoxin is noted as a Risk medication. That would have alerted her to make sure labs (Digoxin blood level) would be drawn every six months and Resident #1 was admitted in January 2011. When asked if the elevated potassium, use of Kayexalate, weight loss and diagnosis of renal failure with elevated creatinine would have alerted her to obtain a Digoxin level, she indicated she could not remember if she had made any recommendations for a Digoxin blood level for Resident #1. During a telephone conversation on 3/21/2011 at 7:35 PM., Resident #1's physician (MD) stated resident #1 was very sick during her stay in the facility. She had multiple diagnoses and was on multiple medications. When asked regarding a Digoxin level, he stated Digoxin blood levels are usually performed every six months per protocol. He had not ordered a Digoxin blood level and did not receive a recommendation for a Digoxin blood level from the pharmacy consultant. On 3/28/2011 at 8:22 AM., the Director of Nursing stated the consulting pharmacist reviews residents' medications once a month. She stated	F 428	4) The consultant pharmacist will audit, on a monthly basis for 3 months, each resident receiving digoxin therapy and will document results. Any problem found during regular audits will be reported to the attending physician, director of nursing, and administrator immediately for corrective action steps to be taken. A pharmacy report will be presented to the quality assurance committee monthly for continued monitoring and appropriate action. Nursing management will monitor pharmacy compliance and report monthly to the quality assurance committee. The administrator is responsible for overall compliance.	

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F 428	Continued From page 3 the pharmacist consultant did not make any recommendations to obtain a Digoxin level for Resident #1 and stated Digoxin levels are obtained every six months per protocol. She expected the pharmacist consultant to monitor medications and report to her and the physician any need for laboratory monitoring of medications.	F 428		