

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

PRINTED: 11/09/2015
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345553	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 10/15/2015
NAME OF PROVIDER OR SUPPLIER AUTUMN CARE OF FAYETTEVILLE			STREET ADDRESS, CITY, STATE, ZIP CODE 1401 71ST SCHOOL ROAD FAYETTEVILLE, NC 28314		
(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 157 SS=D	<p>483.10(b)(11) NOTIFY OF CHANGES (INJURY/DECLINE/ROOM, ETC)</p> <p>A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is an accident involving the resident which results in injury and has the potential for requiring physician intervention; a significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life threatening conditions or clinical complications); a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or a decision to transfer or discharge the resident from the facility as specified in §483.12(a).</p> <p>The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is a change in room or roommate assignment as specified in §483.15(e)(2); or a change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.</p> <p>The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.</p> <p>This REQUIREMENT is not met as evidenced by: Based on observations, staff interviews, and record review, the facility failed to notify the physician of the difficulties in medication</p>	F 157	F 157 This plan of correction will serve as the facility's allegation of compliance with	11/12/15	

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

TITLE

(X6) DATE

Electronically Signed

10/30/2015

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 157	<p>Continued From page 1</p> <p>administration for Cymbalta via Gastrostomy tube (G Tube) for 1 of 3 sampled residents observed for medication administration via G Tube (Resident #139). Findings included:</p> <p>Resident #139 was admitted on 8/19/2014 with diagnoses that included depression, for which she was prescribed Cymbalta 60 mg daily via G tube. She was not interviewable as per the Minimum Data Set dated 08/19/15.</p> <p>Manufacture guidelines recommend that Cymbalta (duloxetine) "pellets accumulated in both the NG Tubes and G Tubes and few pellets passed through the tubes, (therefore) administration of duloxetine (Cymbalta) pellets through feeding tubes was shown not to be a dependable method for delivery to patients."</p> <p>Nurse #1 was observed to administer Cymbalta 60 mg dry granules via G Tube for Resident #139 at 10:30 AM on 10/13/15. She was observed to disassemble the Cymbalta capsule, put the granules into a medication administration cup, and pour a small amount of dry granules into the G Tube port. She then poked her gloved finger into the G Tube port several times to push the granules towards the bottom and then pushed 30 milliliters of water into the same G Tube port by using a syringe with a plunger to force the medication through the tubing. Large amounts of medication granule clusters were seen adhered to the entire inside length of the tubing of the G tube and discolored as black to light brown. The clusters were not able to be moved through the tube by palpating or 'milking' the tube.</p> <p>Nurse #1 was interviewed on 10/13/15 at 11:30 AM. She indicated that she administers the</p>	F 157	<p>requirements of 42 CFR, Part 483, Subpart B for long term care facilities. Preparation and submission of this plan of correction is in response to DHHS 2567 for the 10/15/2015 survey and does not constitute an agreement or admission of Autumn Care of Fayetteville of the truth of the facts alleged or the correctness of the conclusions stated on the statement of deficiencies. This plan of correction is prepared and submitted because of the requirements of 42 CFR, Part 483, Subpart B throughout the time period stated in the statement of deficiencies. In accordance with state and federal law, however, submits this plan of correction to address the statement of deficiencies and to serve as its allegation of compliance with the pertinent requirements as of the dates stated in the plan of correction and as fully completed as of November 12, 2015.</p> <p>For the Residents affected: Resident #139 was seen by the physician on 10-16-2015. The physician discontinued the Cymbalta. The physician also wrote an order for the resident's G-Tube to be replaced and an appointment has been scheduled for 12/15/2015.</p> <p>For the Residents with the potential to be affected: On 10/26/2015 all residents with G-tubes were assessed by Director of Nursing and RN Supervisor to ensure all other G-tubes did not have clusters adhered to the inside of the tubes. Physician was notified by RN supervisor for other resident taking Cymbalta via G-tube and orders were received to</p>		

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F 157	Continued From page 2 Cymbalta as dry granules because the granules are difficult to dissolve. When asked if she has notified the physician or any member of administration of the difficulties in administration, she stated "No, because I feel that the resident is at least getting some of the medication. I feel that her behaviors have improved." She further revealed that the tubing has been discolored with palpable granules since she began working at the facility (July 2015). She indicated that she never thought to inform the physician of the condition of the tubing either. The Director of Nursing was interviewed on 10/14/15 at 1:45 PM. She indicated that she had not been notified of any medication administration issues with Cymbalta and that she had confirmed the same with the physician and the physician assistant assigned to take care of Resident #139. After seeing the G Tube, she stated "I am disgusted. I have never seen a tube like this. My expectation is that the nurse notify the physician if having issues with medication administration as soon as it happens."	F 157	discontinue the medication. Measures Put in Place/System Change: In-services began by Staff Development Nurse on 10/14/2015 until all nurses were in-serviced on contacting the physician if a resident's G-Tube condition has a change and notify the physician if there is an issue with administering any medication to a resident. Monitoring: Director of Nursing or Designee will observe 5 G-tube med passes per week for 4 weeks. Then 5 G-tube med passes monthly for 2 months to ensure if nurse is have any difficulty with administering medication via G-tube and if so physician is notified timely. A comprehensive review of the audits described above and the systems modifications we have made will be discussed and monitored through our quality assurance meeting at least quarterly. Any further omissions regarding physician notification will be addressed by the QA Committee to determine if further systems modifications and/or training are in order.		
F 322 SS=D	483.25(g)(2) NG TREATMENT/SERVICES - RESTORE EATING SKILLS Based on the comprehensive assessment of a resident, the facility must ensure that -- (1) A resident who has been able to eat enough alone or with assistance is not fed by naso gastric tube unless the resident 's clinical condition demonstrates that use of a naso gastric tube was unavoidable; and	F 322		11/12/15	

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F 322	<p>Continued From page 3</p> <p>(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.</p> <p>This REQUIREMENT is not met as evidenced by: Based on observations and staff interview, the facility failed to 1) push water into the Gastrostomy tube (G Tube) port prior to medication administration for 1 of 3 residents observed for G Tube medication administration (Resident #118) and 2) flush water in between individual medication administration for 2 of 3 residents observed for medication administration via G Tube (Resident #118 and #139). Findings included:</p> <p>Resident #118 was admitted on 1/3/13 with diagnoses that included diabetes mellitus, hypertension, dementia, reflux, rheumatoid arthritis, and calcium and vitamin D deficiency. The resident was prescribed the following medications to be administered via G Tube (a tube inserted through the abdomen that delivers nutrition and medicine directly to the stomach) for the above named diagnoses: Coreg 12.5 mg twice daily, Metformin 500 mg twice daily, Glipizide 5 mg twice daily, Namenda XR 28 mg daily, Zantac 150 mg daily, Norvasc 10 mg daily, Plaquenil 200 mg twice daily, Oyster calcium 500</p>	F 322	<p>F322 This plan of correction will serve as the facility's allegation of compliance with requirements of 42 CFR, Part 483, Subpart B for long term care facilities. Preparation and submission of this plan of correction is in response to DHHS 2567 for the 10/15/2015 survey and does not constitute an agreement or admission of Autumn Care of Fayetteville of the truth of the facts alleged or the correctness of the conclusions stated on the statement of deficiencies. This plan of correction is prepared and submitted because of the requirements of 42 CFR, Part 483, Subpart B throughout the time period stated in the statement of deficiencies. In accordance with state and federal law, however, submits this plan of correction to address the statement of deficiencies and to serve as it's allegation of compliance with the pertinent requirements as of the dates stated in the plan of correction and as fully completed as of November 12,</p>		

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F 322	<p>Continued From page 4</p> <p>mg twice daily, Aspirin 81 mg daily, and Calcitriol 2000 International Units daily.</p> <p>Resident #139 was admitted on 8/19/2014 with diagnoses that included hypertension, depression, reflux, iron deficiency anemia, and chronic back pain. The resident was prescribed the following medications to be administered via G Tube for the named diagnoses: Coreg 6.25 mg twice daily, Baclofen 5 mg twice daily, Cymbalta 60 mg daily, Cozaar 25 mg daily, Percocet 5/325 mg every 4 hours as needed, and Ferrous Sulfate liquid 1100 mg daily. Resident #139 was not interviewable per the Minimum Data Set dated 08/19/15.</p> <p>1) Medication administration observation was conducted on 10/13/15 at 10:30 AM. Nurse #1 was observed to remove all prescribed medications for Resident #118 from the punch cards and/or stock bottles. She then put all of the medications into 1 crush bag for the resident, crushed all of the medications together in the crush bag, and administered the medication mixture by G Tube. Nurse #1 did not push water into the G Tube prior to the medication administration. This important process is a verification step to check for any obstruction in the tube that is not perceived by observation alone.</p> <p>Nurse #1 was interviewed on 10/13/14 at 11:30 AM. She acknowledged that she did not flush the G Tube prior to administering the medications. She stated "I just missed it."</p> <p>The Director of Nursing was interviewed on 10/14/15 at 1:45 PM. She stated "My expectation is that the nurse flushes the G Tube</p>	F 322	<p>2015.</p> <p>For the Residents affected: Resident #139 was seen by the physician on 10-16-2015 to ensure resident's condition was stable. For the Residents with the potential to be affected: In-services began on 10/14/2015 by Staff Development Nurse until all nurses were in-serviced on the facilities policy of medication administration via G-tube. This policy includes Flushing tube with 30cc of water or as ordered prior to medication administration, and individually crushing medications in separate pouches, and flush tube with water after each medication is administered. Measures Put in Place/System Change: All nurses annually and upon hire will be observed by the Staff Development Coordinator or designee performing medication administration via peg tube per policy. Monitoring: Director of Nursing or Staff Development Nurse will observe 5 G-tube med passes per week for 4 weeks. Then 5 G-tube med passes monthly for 2 months to ensure nurses are flushing G-Tube prior to administering medication and flushing G-tube between each medication that is administered. A comprehensive review of the audits described above and the systems modifications we have made will be discussed and monitored through our quality assurance meeting at least quarterly. Any further omissions regarding physician notification will be addressed by the QA Committee to determine if further systems modifications</p>		

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F 322	Continued From page 5 with water prior to administering any medication each time as per our policy." 2) Nurse #1 was observed to remove all prescribed medications for Resident #118 from the punch cards and/or stock bottles, placed all of the medications into 1 crush bag, crushed all of the medications together in the crush bags, and administered the medication mixtures by G Tube. Nurse #1 replicated her procedure again for Resident #139. She did not administer the medications individually with 30 milliliters of water flushes in between medication administration to ensure that the full dose of the medication flows through the tube and reaches the gastric area of the residents. Nurse #1 was interviewed on 10/13/15 at 11:30 AM. She could not provide an answer to questions pertaining to what the facility policy is about flushing water in between individual medication G Tube administration. The Director of Nursing was interviewed on 10/14/2015 at 1:45 PM. She stated "Our policy does not say to combine all medications together to be administered by G tube. The nurses are instructed to administer one medication at a time with water flushes in between (administrations). My expectation is that the nurses do as our policy states."	F 322	and/or training are in order.		
F 332 SS=D	483.25(m)(1) FREE OF MEDICATION ERROR RATES OF 5% OR MORE The facility must ensure that it is free of medication error rates of five percent or greater.	F 332		11/12/15	

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F 332	<p>Continued From page 6</p> <p>This REQUIREMENT is not met as evidenced by: Based on observations, medical record review, and staff interview, the facility failed to maintain a medication administration error rate below an acceptable level of 5% for 26 opportunities observed (medication error rate 11.5%, Resident #118 and #139, 3 errors of 26 medication administration opportunities). Findings included:</p> <p>Medication administration observation was conducted on 10/13/15 at 10:30 AM.</p> <p>Resident #118 was admitted on 1/3/13 with diagnoses that included diabetes mellitus, hypertension, dementia, reflux, rheumatoid arthritis, and calcium and vitamin D deficiency. The resident was prescribed the following medications to be administered via gastrostomy tube (G Tube, a tube inserted through the abdomen that delivers nutrition and medicine directly to the stomach) for the above named diagnoses: Coreg 12.5 mg twice daily, Metformin 500 mg twice daily, Glipizide 5 mg twice daily, Namenda XR 28 mg daily, Zantac 150 mg daily, Norvasc 10 mg daily, Plaquenil 200 mg twice daily, Oyster calcium 500 mg twice daily, Aspirin 81 mg daily, and Calcitriol 2000 International Units daily.</p> <p>Resident #139 was admitted on 8/19/2014 with diagnoses that included hypertension, depression, reflux, iron deficiency anemia, and chronic back pain. The resident was prescribed the following medications to be administered via G Tube for the named diagnoses: Coreg 6.25 mg twice daily, Baclofen 5 mg twice daily, Cymbalta 60 mg daily, Cozaar 25 mg daily, Percocet 5/325</p>	F 332	<p>F332 This plan of correction will serve as the facility's allegation of compliance with requirements of 42 CFR, Part 483, Subpart B for long term care facilities. Preparation and submission of this plan of correction is in response to DHHS 2567 for the 10/15/2015 survey and does not constitute an agreement or admission of Autumn Care of Fayetteville of the truth of the facts alleged or the correctness of the conclusions stated on the statement of deficiencies. This plan of correction is prepared and submitted because of the requirements of 42 CFR, Part 483, Subpart B throughout the time period stated in the statement of deficiencies. In accordance with state and federal law, however, submits this plan of correction to address the statement of deficiencies and to serve as it's allegation of compliance with the pertinent requirements as of the dates stated in the plan of correction and as fully completed as of November 12, 2015.</p> <p>For the Residents affected: Nurse was provided one on one education by Staff Development Nurse regarding policy on g-tube medication administration with return demonstration on 10/19/2015 For the Residents with the potential to be affected and measures put in place/system change: In-services began on 10/14/2015 by Staff Development nurse until all nurses were in-serviced</p>		

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F 332	<p>Continued From page 7</p> <p>mg every 4 hours as needed, and Ferrous Sulfate liquid 1100 mg daily. Resident #139 was not interviewable per Minimum Data Set assessment dated 8/19/15.</p> <p>1). Nurse #1 was observed to remove all prescribed medications for Resident #118 from the punch cards and/or stock bottles, placed all of the medications into 1 crush bag, crushed all of the medications together in the crush bag, and administered the medication mixture by G Tube. Nurse #1 replicated the same procedure again for Resident #139.</p> <p>Nurse #1 was interviewed on 10/13/15 at 11:30 AM. She could not provide an answer to questions pertaining to what the facility policy is about combining medications for G Tube administration. She stated "The physician orders do not say that medications should or should not be crushed together and administered together by G Tube."</p> <p>The Director of Nursing was interviewed on 10/14/2015 at 1:45 PM. She stated "Our policy does not say to combine all medications together to be administered by G tube. The nurses are instructed to administer one medication at a time with water flushes in between (administrations). My expectation is that the nurses do as our policy states."</p> <p>2) Nurse #1 was also observed to administer Cymbalta (chemical name: duloxetine) 60 mg dry granules via G Tube for Resident #139. She was observed to disassemble the Cymbalta capsule, put the granules into a separate medication administration cup, and pour a small amount of dry granules into the G Tube medication port.</p>	F 332	<p>related to crushing all medications separately and administering them separately by G-Tube.</p> <p>Monitoring: Director of Nursing or Staff Development Nurse will observe 5 G-tube med passes per week for 4 weeks. Then 5 G-tube med passes monthly for 2 months to ensure nurses are crushing all medications to be administered via G-tube separately and giving them separately with water flushes between each medication.</p> <p>A comprehensive review of the audits described above and the systems modifications we have made will be discussed and monitored through our quality assurance meeting at least quarterly. Any further omissions regarding physician notification will be addressed by the QA Committee to determine if further systems modifications and/or training are in order.</p>		

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F 332	<p>Continued From page 8</p> <p>She then attempted to poke her gloved finger into the G Tube medication entrance port to push the granules towards the bottom of the port and then pushed 30 milliliters of water into the medication port. Large amounts of granule clusters were seen adhered to the entire length of the tubing and discolored as black to light brown.</p> <p>The physicians order dated 4/27/15 stated "Cymbalta 60 mg by G Tube daily." However, information from Eli Lilly, the manufacturer of Cymbalta, stated "A laboratory study was conducted to determine whether the pellets from a 60 mg duloxetine (Cymbalta) capsule would visually adhere to or obstruct G Tubes of NG (naso-gastric) Tubes when mixed with either apple juice or water. Based on the results, in which the pellets accumulated in both the NG Tubes and G Tubes and few pellets passed through the tubes, administration of duloxetine pellets through feeding tubes was shown not to be a dependable method for delivery to patients."</p> <p>Nurse #1 was interviewed on 10/13/15 at 11:30 AM. She stated "This is the only way that I can get some of the Cymbalta into the resident. It doesn't dissolve in water so I administer it as dry granules. I feel that (Resident #139's) behaviors have improved since I have been doing this." Nurse #1 further stated "No one taught me to do it this way. This is what I think works best for me and the resident. The tube has been like this since I started working at the facility which was in July (of 2015)." Nurse #1 indicated that she did not know that Cymbalta could not be administered via G Tube, had not informed the pharmacy or the physician of the difficulties in medication administration, and did not give consideration to questioning the largely</p>	F 332			

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F 332	Continued From page 9 discolored tube with palpable clusters of medication adhered throughout the entire tube. The Director of Nursing was interviewed on 10/14/2015 at 1:45 PM. After seeing the tube, she stated "I am disgusted. I would expect the nurse to have alerted me or the physician of the difficulties of administering Cymbalta by G Tube. I would also expect pharmacy to review our orders and recommend the best way to administer medications."	F 332			
F 333 SS=D	483.25(m)(2) RESIDENTS FREE OF SIGNIFICANT MED ERRORS The facility must ensure that residents are free of any significant medication errors. This REQUIREMENT is not met as evidenced by: Based on observations, record review, and staff interview, the facility failed to prevent the repeated occurrence of a significant medication error by administering Cymbalta by Gastrostomy tube (G Tube) since July 2015 for 1 of 1 residents prescribed Cymbalta via G tube (Resident #139). Findings included: Resident #139 was admitted on 8/19/2014 with diagnoses that included depression with behaviors, for which she was prescribed Cymbalta (chemical name: duloxetine) 60 mg daily via G Tube. She was not interviewable as per Minimum Data Set assessment done on 8/19/15. Manufacture guidelines recommend that Cymbalta "pellets accumulated in both the NG	F 333	F333 This plan of correction will serve as the facility's allegation of compliance with requirements of 42 CFR, Part 483, Subpart B for long term care facilities. Preparation and submission of this plan of correction is in response to DHHS 2567 for the 10/15/2015 survey and does not constitute an agreement or admission of Autumn Care of Fayetteville of the truth of the facts alleged or the correctness of the conclusions stated on the statement of deficiencies. This plan of correction is prepared and submitted because of the requirements of 42 CFR, Part 483, Subpart B throughout the time period stated in the statement of deficiencies. In	11/12/15	

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F 333	<p>Continued From page 10</p> <p>Tubes and G Tubes and few pellets passed through the tubes, (therefore) administration of duloxetine pellets through feeding tubes was shown not to be a dependable method for delivery to patients."</p> <p>Nurse #1 was also observed to administer Cymbalta 60 mg dry granules via G Tube for Resident #139 at 10:30 AM on 10/13/15. She was observed to disassemble the Cymbalta capsule, put the granules into a medication administration cup, and pour a small amount of dry granules into the G tube medication port. She then poked her gloved finger into the G Tube port to push the granules towards the bottom and then pushed 30 milliliters of water into the G Tube medication port. Large amounts of granule clusters were seen adhered to the entire length of the tubing of the G tube and discolored from black to light brown.</p> <p>Nurse #1 was interviewed on 10/13/15 at 11:30 AM. She indicated that the granule clusters adhering to the tubing did look like Cymbalta granules. When questioned about her thoughts on the full dose of Cymbalta not reaching the resident with her method of administration, she stated "I had not thought about it. This is the only way that I can get some of the Cymbalta into the resident. It doesn ' t dissolve in water so I administer it as dry granules. I feel that (Resident #139 ' s) behaviors have improved since I have been doing this. " Nurse #1 further stated " No one taught me to do it this way. This is what I think works best for me and the resident. The tube has been like this since I started working at the facility which was in July (of 2015). " Nurse #1 indicated that she did not know that Cymbalta could not be administered via G Tube, had not</p>	F 333	<p>accordance with state and federal law, however, submits this plan of correction to address the statement of deficiencies and to serve as it¿s allegation of compliance with the pertinent requirements as of the dates stated in the plan of correction and as fully completed as of November 12, 2015.</p> <p>For the resident found to be affected, the nurse observed during the medication administration was in-serviced on the rights of medication administration and the importance of triple check procedures to prevent any further medication error by Staff Development Nurse. Resident #139¿s physician was informed of the medication error 10/14/2015 and states the medication error was not significant and did not place the resident at risk of complications.</p> <p>To ensure other residents are not affected in a similar manner, the nursing staff was in-serviced by Staff Development Nurse on 10/14/2015 until all nurses were in-serviced on making sure all medication is given to a resident.</p> <p>To ensure on-going compliance, the pharmacy¿s quality assurance nurse conducted unannounced med pass audits on 10/29/2015 to ensure proper dosage is administered per physician¿s orders. The nurse observed during survey was also observed during these audits. She was found to be proficient during the medication pass and was able to verbalize the information gained during the in-service.</p>		

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F 333	Continued From page 11 informed the pharmacy or the physician of the difficulties in medication administration, and did not give consideration to questioning the largely discolored tube with palpable clusters of medication adhered throughout the entire tube. She further indicated that the tube has had large globules of black granules adhered to the tubing since she began working at the facility which was in July 2015. She also revealed that she had never brought this issue to the attention of the physician, nor had the pharmacy ever instructed her that Cymbalta could not be administered by G Tube. The Director of Nursing was interviewed on 10/14/15 at 1:45 PM. She indicated that she was not aware of any issues with medication administration of Cymbalta for Resident #139. After seeing the tube, she stated " I am disgusted. I would expect the nurse to have alerted me or the physician of the difficulties of administering Cymbalta by G Tube. I would also expect pharmacy to review our orders and recommend the best way to administer medications. "	F 333	Monitoring: Director of Nursing or Staff Development Nurse will observe 5 G-tube med passes per week for 4 weeks. Then 5 G-tube med passes monthly for 2 months to ensure that there is timely notification of physician if any difficulty occurs with administering medication via G-tube The results of these audits intended to ensure on-going compliance will be discussed and monitored through our next quality assurance meeting for the next two quarters.		
F 428 SS=D	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.	F 428		11/12/15	

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F 428	Continued From page 12 This REQUIREMENT is not met as evidenced by: Based on record review, staff interviews, and observations, the facility's consulting pharmacist failed to identify and recommend solutions to issues dealing with inappropriate medication administration of Cymbalta via Gastrostomy tube (G Tube, a tube inserted directly into the stomach to provide nourishment and medications) for 1 of 1 residents (Resident #139). Findings included: Resident #139 was admitted on 8/19/2014 with diagnoses that included depression. The resident was prescribed the Cymbalta 60 mg daily to be administered via G Tube. Resident #139 was not interviewable as per information from the Minimum Data Set dated 8/19/15. Medication administration observations were done on 10/13/15 at 10:30 AM. Nurse #1 was observed to administer Cymbalta (chemical name: duloxetine) 60 mg dry granules via G Tube for Resident #139. She was observed to disassemble the Cymbalta capsule, put the granules into a medication administration cup, and pour a small amount of dry granules into the G Tube medication port at a time. She then poked her gloved finger into the G Tube medication entrance port to push the granules towards the bottom of the port and then pushed 30 milliliters of water into the medication port. Large amounts of granule clusters were seen adhered to the entire length of the tubing and discolored as black to light brown. A review of the medical record revealed a physician order dated 4/27/15 which stated "Cymbalta 60 mg by G Tube daily." Information from Eli Lilly, the manufacturer of Cymbalta, stated "A laboratory study was	F 428	F428 This plan of correction will serve as the facility's allegation of compliance with requirements of 42 CFR, Part 483, Subpart B for long term care facilities. Preparation and submission of this plan of correction is in response to DHHS 2567 for the 10/15/2015 survey and does not constitute an agreement or admission of Autumn Care of Fayetteville of the truth of the facts alleged or the correctness of the conclusions stated on the statement of deficiencies. This plan of correction is prepared and submitted because of the requirements of 42 CFR, Part 483, Subpart B throughout the time period stated in the statement of deficiencies. In accordance with state and federal law, however, submits this plan of correction to address the statement of deficiencies and to serve as its allegation of compliance with the pertinent requirements as of the dates stated in the plan of correction and as fully completed as of November 12, 2015. For the Residents affected: Resident #139 was seen by the physician on 10-16-2015. The physician discontinued the Cymbalta. For the Residents with the potential to be affected and measures put in place/system change: The Consultant Pharmacist was in-serviced by Director of Nursing on 10/15/2015 on the manufactures recommendation not to		

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F 428	Continued From page 13 conducted to determine whether the pellets from a 60 mg duloxetine (Cymbalta) capsule would visually adhere to or obstruct G Tubes or NG (nasogastric) Tubes when mixed with either apple juice or water. Based on the results, in which the pellets accumulated in both the NG Tubes and G Tubes and few pellets passed through the tubes, administration of duloxetine pellets through feeding tubes was shown not to be a dependable method for delivery to patients." Nurse #1 was interviewed on 10/13/15 at 11:30 AM. She stated "This is the only way that I can get some of the Cymbalta into the resident. It doesn't dissolve in water so I administer it as dry granules" Nurse #1 further stated "No one taught me to do it this way." Nurse #1 indicated that she did not know that Cymbalta could not be administered via G Tube per manufacturer recommendations and had not informed the pharmacy of the difficulties in medication administration. She also confirmed that the consulting pharmacist, who reviews medications for all residents on a monthly basis, never indicated to her that Cymbalta could not be administered by G Tube. The Pharmacist was interviewed on 10/15/15 at 12:00 PM. He confirmed that he was aware that Resident #139 was being administered Cymbalta by G Tube, but had not brought up the issue of Cymbalta insolubility by G Tube and had not ever made a recommendation that the facility refrain from such administrative practice. He provided information from The Society of Health Systems Pharmacist of Australia that stated "Open capsule content and disperse in apple juice for enteral feeding tubes." He did not respond to a question regarding the applicability of using information from Australia in the United States. He, next, provided information from an abstract of	F 428	administer Cymbalta via G-tube. The Director of Nursing notified physician on 10/16/2015 of one other resident in facility receiving Cymbalta by G-Tube and orders were received to discontinue the Cymbalta Monitoring: Director of Nursing or RN Supervisor will monitor all new medication orders for residents receiving medications by G-Tube weekly ongoing to ensure any resident does not receive the Cymbalta via G-tube. A comprehensive review of the audits described above and the systems modifications we have made will be discussed and monitored through our quality assurance meeting at least quarterly. Any further omissions regarding physician notification will be addressed by the QA Committee to determine if further systems modifications and/or training are in order.		

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

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F 428	Continued From page 14 a clinical trial suggesting the dissolution of Cymbalta pellets in various methods including applesauce, apple juice, and chocolate pudding for administration in patients with swallowing difficulties. He confirmed that this abstract did not provide specific information about G Tube administration and stated "If it is stable in applesauce and apple juice, I believe it would be stable by G Tube administration." The physician's order did not state to administer the Cymbalta with applesauce or apple juice to Resident #139, nor did the pharmacist ever recommend it, nor did Nurse #1 attempt to administer the granules in applesauce. He did not provide an answer to questions regarding his awareness of the vast information available on the internet dissuading the practice of G Tube administration of Cymbalta, including information from reputable sources in the United States including the Federal Drug Administration (FDA) and the manufacturer, Eli Lilly. The Director of Nursing was interviewed on 10/14/2015 at 1:45 PM. After seeing the tube, she stated "I am disgusted. I would expect the nurse to have alerted me or the physician of the difficulties of administering Cymbalta by G Tube. I would also expect pharmacy to review our orders and recommend the best way to administer medications from reputable sources in the United States."	F 428			
F 520 SS=D	483.75(o)(1) QAA COMMITTEE-MEMBERS/MEET QUARTERLY/PLANS A facility must maintain a quality assessment and assurance committee consisting of the director of nursing services; a physician designated by the	F 520		11/12/15	

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F 520	<p>Continued From page 15 facility; and at least 3 other members of the facility's staff.</p> <p>The quality assessment and assurance committee meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and develops and implements appropriate plans of action to correct identified quality deficiencies.</p> <p>A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.</p> <p>Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.</p> <p>This REQUIREMENT is not met as evidenced by: Based on record reviews and staff interviews the facility ' s Quality Assessment and Assurance Committee (QA Committee) failed to maintain implemented procedures and monitor these interventions that the committee put into place on 01/08/2015. This was for one recited deficiency which was originally cited on 12/11/2014 during a recertification survey, and again on the current recertification survey. The deficiency was in the area of notifying the physician of changes in a timely manner. The continued failure of the facility during the two federal surveys of record shows a pattern of the facility ' s inability to sustain an effective Quality Assurance Program. Findings included:</p>	F 520	<p>F520 This plan of correction will serve as the facility's allegation of compliance with requirements of 42 CFR, Part 483, Subpart B for long term care facilities. Preparation and submission of this plan of correction is in response to DHHS 2567 for the 10/15/2015 survey and does not constitute an agreement or admission of Autumn Care of Fayetteville of the truth of the facts alleged or the correctness of the conclusions stated on the statement of deficiencies. This plan of correction is prepared and submitted because of the requirements of 42 CFR, Part 483, Subpart B throughout the time period</p>		

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F 520	<p>Continued From page 16</p> <p>This tag is cross referred to:</p> <p>F 157: Based on observations, staff interviews, and record review, the facility failed to notify the physician of the difficulties in medication administration for Cymbalta via Gastrostomy tube (G Tube, a tube inserted directly into the stomach for facilitation of nutrition and medication administration) for 1 of 3 sampled residents observed for medication administration via G Tube (Resident #139).</p> <p>The facility was recited for F157 when they failed to develop and implement procedures and monitor these interventions to ensure the physician is notified in a timely manner as it relates in the current situation to administering Cymbalta by G Tube.</p> <p>During an interview with the Administrator on 10/15/15 at 12:00 PM, he indicated that the facility's QA Committee consisted of himself, the Director of Nursing, the Medical Director, the pharmacist, and 9 department heads. The Administrator indicated that the QA Committee met on a quarterly basis. For the citation dated 12/11/14, the Administrator stated that the committee "focused on inservicing, monitoring, and reporting changes to the physician in relation to wound care only."</p>	F 520	<p>stated in the statement of deficiencies. In accordance with state and federal law, however, submits this plan of correction to address the statement of deficiencies and to serve as its allegation of compliance with the pertinent requirements as of the dates stated in the plan of correction and as fully completed as of November 12, 2015.</p> <p>For the Residents affected and for those with the potential to be affected: A QA meeting consisting of Medical Director, Pharmacist, Dietician, Director of Nursing, Administrator, both Unit Managers is scheduled for 11/2/2015 to review the survey findings.</p> <p>Measures put in place/system change: 5 days a week the Director of Nursing or Administrator will conduct a meeting with the unit manager, MDS Coordinator, and Staff Development Coordinator. This meeting is intended to review incidents from the previous days, critical issues, and all orders written from previous days to ensure follow-up on any area of identified concern.</p> <p>Monitoring: Director of Nursing or Administrator will review the notes from the weekly meeting to ensure any areas that are currently being followed by the QA committee are followed up on a weekly basis. The QA committee will review these reviews quarterly to evaluate for effectiveness.</p>		