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

PRINTED: 10/30/2012
FORM APPROVED
OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 345113 | A. BUILDING _____ B. WING _____ | C 10/19/2012 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| WILLOW CREEK NURSING AND REHABILITATION CENTER | 2401 WAYNE MEMORIAL DRIVE GOLDSBORO, NC 27534 |

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| F 000 | INITIAL COMMENTS<br><br>The Division of Health Service Regulation (DHSR), Nursing Home Licensure and Certification Section began a complaint investigation survey on 10/17/12 through 10/19/12. During the complaint survey, it was determined the facility had provided substandard quality of care at the Immediate Jeopardy level. An extended survey was conducted on 10/19/12 and an exit conference was held with the facility on 10/19/12. The Immediate Jeopardy began on 10/01/12 and was removed on 10/19/12. | F 000 | Willow Creek acknowledges receipt of the Statement of Deficiencies and proposes this Plan of Correction to the extent that the summary of findings is factually correct and in order to maintain compliance with applicable rules and provisions of quality of care of residents. The Plan of Correction is submitted as a written allegation of compliance.<br><br>Willow Creek's response to this Statement of Deficiencies does not denote agreement with the Statement of Deficiencies nor does it constitute an admission that any deficiency is accurate. Further, Willow Creek reserves the right to refute any of the deficiencies on this Statement of Deficiencies through Informal Dispute Resolution, formal appeal procedure and/or any other Administrative or legal proceeding | |
| F 329 SS=J | 483.25(l) DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS<br><br>Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or any combinations of the reasons above.<br><br>Based on a comprehensive assessment of a resident, the facility must ensure that residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs. | F 329 | Resident #170 no longer resides in the Facility.<br><br>All orders for Residents prescribed Methotrexate were reviewed by the Director of Nursing for accuracy of transcription to the Medication Administration Record, blocking of the Medication Administration Record to reflect appropriate order schedule and to ensure the accuracy of the next scheduled dose of the medication on 10/11/12. Noted issues were corrected as identified on 10/11/12. | 11-1-12 |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Bill Mullinax | 11-1-12

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.



R.C. ✓

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| F 329 | Continued From page 1<br><br>This REQUIREMENT is not met as evidenced by:<br>Based on record review and staff interviews, the facility failed to ensure residents were free from an excessive dosage of methotrexate, an anti-neoplastic agent, for 1 of 3 sampled residents receiving methotrexate for the treatment of rheumatoid arthritis (resident #170). The resident was sent to the emergency room for evaluation on 10/11/12. She was determined to have methotrexate toxicity and was admitted to the intensive care unit of the hospital. The resident expired on 10/12/12 at 1:00AM.<br><br>The Immediate Jeopardy began on 10/1/12 at 10AM. The facility was informed of the Immediate Jeopardy on 10/18/12 at 5:55PM. Immediate Jeopardy was removed on 10/19/12 at 5:59PM, after the facility provided a credible allegation of compliance. The facility remained out of compliance at a scope and severity level D (no actual harm with the potential for more than minimal harm that is not immediate jeopardy) for the facility to complete employee training and to monitor its corrective action.<br><br>Findings include:<br><br>Resident #170 was admitted to the facility on 12/9/10 and readmitted on 5/14/12 with multiple diagnoses including rheumatoid arthritis, stage 3 chronic kidney disease, thrombocytopenia (low platelets), chronic unspecified hepatitis, anemia, and failure to thrive. | F 329 | Residents to include those receiving Methotrexate continue to receive medications as ordered and as deemed necessary by the Resident's Physician.<br><br>Physical Assessments and Labs were completed for All Residents receiving Methotrexate by licensed nurses by 10-13-12. Results of the assessment and labs were reviewed with the Resident's Physician and received follow up as indicated.<br><br>All Medication Administration Records were audited by licensed Nurses to include the Supervisors with oversight by the Director of Nursing on 10/11/12 to ensure medications that were ordered less than daily were being administered and were blocked off appropriately indicating days of administration. Noted issues were corrected as identified. Verification of corrections was completed on 10-16-12.<br><br>A second Medication Administration Record review was conducted by licensed nurses on 10-12-12 to include the MDS Nurses, QI Nurse, Treatment Nurses and ADON with assistance and oversight by Director of Nursing. This review included comparison of the Medication Administration Record to the current Physician Orders to ensure medications are being administered as ordered. This review also included ensuring that Medications used less than daily were | |

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| F 329 | Continued From page 2<br>Review of the resident's minimum data set (MDS) dated 8/8/12 revealed she was cognitively intact. The MDS revealed the resident had no signs or symptoms of a swallowing disorder.<br><br>Record review of laboratory results dated 9/18/12 revealed a complete blood count (CBC) with hemoglobin (Hg) 13 g/dl (grams/deciliter) (normal 12-15 g/dL), hematocrit 38.7% (normal 36-46%), and platelets 125 K/uL (thousand/microliter) (normal 150-400 K/uL). Results of a basic metabolic panel dated 9/18/12 revealed blood urea nitrogen (BUN) 92 mg/dL (milligram/deciliter) (normal 6-23 mg/dL), creatinine 2.43 mg/dL (normal 0.5-1.10 mg/dL), and estimated glomerular filtration rate (GFR) of 19 ml/min (milliliter/minute) (normal > 60 ml/min). BUN, creatinine, and GFR are indicators of renal function.<br><br>Record review of the rheumatologist's progress notes dated 9/18/12 revealed a diagnosis of erosive rheumatoid arthritis. Recommendations included "add methotrexate 4 tabs once a week - all tabs to be given with a meal at same time only one day a week."<br><br>Review of the resident's clinical record revealed physician orders dated 9/18/12 for Methotrexate 2.5mg (milligram) take four tablets every seven days. Methotrexate is an anti-neoplastic agent indicated for the treatment of certain neoplastic diseases, severe psoriasis, and adult rheumatoid arthritis.<br><br>The manufacturer's product information for methotrexate read in part:<br>"Warnings - Deaths have been reported with the | F 329 | blocked off indicating days for administration. Issues were corrected as identified during the review by the licensed<br><br>Nurse. Corrections for audits were completed on 10-17-12.<br><br>All staff involved in the Methotrexate Administration in question for Resident #170 were drug tested on 10/12/12 under the direction of the facility Administrator. All results were negative. The Nurse was re-educated, drug tested and suspended on 10/12/12 and remains suspended. The facility has suspended use of Medication Aides indefinitely effective 10-12-12. Prior to reimplementation of Medication Aides use in the facility, the Medication Aide will receive education related to Medication Administration to include having a Medication Pass Audit by the Pharmacy Consultant or an Administrative Nurse in order to verify competence. The retraining of certified Medication Aides will include, but will not be limited to:<br>• Six Rights of Medication Administration<br>• Importance of reading and understanding medication labels and orders | |

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| F 329 | Continued From page 3<br>use of methotrexate in the treatment of rheumatoid arthritis...methotrexate elimination is reduced in patients with impaired renal function. Such patients require especially careful monitoring for toxicity. Potentially fatal opportunistic infections may occur with methotrexate therapy.<br><br>Precautions - Methotrexate has the potential for serious toxicity. Toxic effects may be related in frequency and severity to dose or frequency of administration but have been seen at all doses. The clinical pharmacology of methotrexate has not been well studied in older individuals. Due to diminished hepatic and renal function, relatively low doses should be considered, and these patients should be closely monitored for early signs of toxicity.<br><br>Geriatric use - post-marketing experience suggests that the occurrence of bone marrow suppression, thrombocytopenia, and pneumonitis may increase with age.<br><br>Renal - methotrexate may cause renal damage that may lead to acute renal failure.<br><br>Overdosage - symptoms commonly reported following oral overdose include those symptoms and signs reported at pharmacologic doses, particularly hematologic and gastrointestinal reactions. For example, leucopenia (low white blood cells), thrombocytopenia, anemia, pancytopenia (low white blood cells, red blood cells, and platelets), bone marrow suppression, mucositis, stomatitis, oral ulceration, nausea, vomiting, and gastrointestinal bleeding. There have been reports of death following overdose. | F 329 | • Special instructions/alerts on packaging and MARs to include those for medications with unusual dosing schedules or those that could be potentially toxic, for example *****!!!!!!! or a stop sign.<br>• Infection Control measures related to the Medication Pass<br><br>Additional measure are being provided by the Dispensing Pharmacy in the dispensing and labeling process to minimize administration error potential for medications at high risk for medication error.<br><br>Examples of labeling currently in use are:<br><br>1) A "stop-sign shaped" red auxiliary label that reads "High Alert. Double-Check" affixed to the bottle dispensed to a resident or for the emergency drug kit<br>2) A mini-monograph with conversion grid dispensed with bottle. This handout is printed on bright pink/red paper.<br>3) Statements added to prescription labels and MAR, "Double-check dose. Use calibrated syringe."<br>4) Calibrated oral dosing syringe with the dispensed bottle. | |

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| F 329 | Continued From page 4<br>In these cases, events such as sepsis or septic shock, renal failure, and aplastic anemia were also reported."<br><br>Review of the resident's September medication administration record (MAR) revealed a handwritten entry dated 9/19/12 for Methotrexate 2.5mg 4 tablets by mouth every 7 days. Review of the MAR revealed 4 tablets of methotrexate were given on Wednesday 9/19/12 and Wednesday 9/26/12 at 10AM.<br><br>Review of the provider pharmacy's delivery sheet revealed 16 methotrexate 2.5mg tablets were delivered to the facility for resident #170 on 9/19/12.<br><br>The resident's October MAR read "Methotrexate tab 2.5mg 4=10 mg by mouth every 7 days ***Note Dose and Frequency!!***" There was no blocking or other marking on the MAR that noted the weekly administration times. The medication was due to be given on Wednesday 10/3/12 and Wednesday 10/10/12. Review of the MAR revealed methotrexate was given at 10AM on 10/1/12, 10/2/12, 10/3/12, 10/4/12, 10/6/12, and 10/7/12, as indicated by the med aides' and nurse's initials. The entry for 10/5/12 was initialed and marked through with an "X" with no explanation on the back of the MAR. Entries for 10/8/12 and 10/9/12 were blank with no explanations on the back of the MAR. The entry for 10/10/12 was initialed and circled, indicating the medication was not given.<br><br>Review of the October MAR revealed the 8PM doses of Lotensin (antihypertensive) and Coreg (anti-arrhythmic) were held on 10/5/12, 10/8/12, | F 329 | 5) Exclamation points placed before the medication name on the MAR/product label<br><br>6) "Tall Man" letters will be used for sound alike and look alike drug names on the MAR/product label (per the ISMP – institute for safe medication practice – suggested list).<br><br>Beginning with the Medication delivery to the facility on 10-17-12 the following changes for dispensing Methotrexate were implemented:<br><br>-Package all Methotrexate orders in bingo packaging each time the drug is dispensed from the pharmacy<br>-Send only one week supply each time the drug is dispensed from the pharmacy.<br>-In addition to cautionary wording, **NOTE DOSE AND FREQUENCY!!!*** in sig (directions), place a *stop sign shaped caution auxiliary label* on the packaging that reads "HIGH ALERT CAUTION"<br>-Move Methotrexate to high risk station in pharmacy<br>-Have Registered Pharmacist double check final product in addition to initial review each time the drug is dispensed from the pharmacy. | |

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| F 329 | Continued From page 5<br>and 10/9/12 due to low blood pressure.<br><br>Review of nursing notes dated 10/8/12 at 9:49AM revealed the resident refused her scheduled medications due to swallowing issues. Her Lotensin and Coreg were held due to low blood pressure. The nurse assessed the resident and called the physician. The physician ordered Diflucan and Nystatin oral suspension (antifungal agents).<br><br>Review of nursing notes dated 10/9/12 at 7:26AM revealed the resident complained of sore mouth and throat. She refused all morning meds except one-half of a Lortab 5/500 (narcotic analgesic).<br><br>Review of nursing notes dated 10/10/12 at 4:41PM revealed the resident was found with dried frank red blood to her lips with complaints of pain. The dried blood was cleansed away which revealed several open areas to the bottom lip. Pressure was applied to stop the bleeding and a lip moisturizer was applied.<br><br>Record review revealed physician orders dated 10/10/12 to hold methotrexate until the resident was seen by her rheumatologist. The physician added Duragesic (narcotic analgesic) for the resident's ulcerative stomatitis, held her prednisone (corticosteroid) and Plaquenil (arthritis medication), and started ½ normal saline solution intravenously (IV) at 70 ml/hr (milliliter/hour).<br><br>Record review revealed an Incident Report dated 10/11/12 at 9:30AM for resident #170. The report read "resident has order for methotrexate 10mg every 7 days, on MAR signed for every day for 7 days. Predisposing factors - staff related. MD | F 329 | Previous supply of Methotrexate for all Residents receiving the medication was returned to the pharmacy on 10-17-12 upon receipt of the new supply of Methotrexate in the new packaging. New packaging remains in use for Resident's receiving Methotrexate.<br><br>In-services by the Staff Facilitator were initiated on 10/11/12 for all licensed Nurses and Medication Aides on the Six Rights of Medication Administration to include blocking the Medication Administration Record for medications given less than daily by the nurse that transcribed the medication to the Medication Administration Record or by the nurses co-signing the monthly orders to aide with ensuring that medications are administered as ordered as a deemed necessary by the Resident's Physician. In-servicing was completed on 10-31-12 Nurses hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator.<br><br>Additional in-servicing was initiated on 10/12/12 by the Staff Facilitator for licensed nurses and Medication Aides on signs and symptoms of Methotrexate Toxicity. In-servicing was completed on 10-31-12 Nurses hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator. | |

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| F 329 | Continued From page 6<br>notified."<br><br>Record review revealed physician orders dated 10/11/12 for a stat (immediate) methotrexate level, CBC, hepatic panel, and renal function tests. When the staff was unable to obtain an adequate blood sample for the labs, the physician sent the resident to the emergency room for evaluation.<br><br>Nursing notes dated 10/11/12 at 10:20AM revealed the resident was sent to the emergency room with hypotension and bleeding mouth sores.<br><br>Record review of the hospital Emergency Room (ER) record revealed the resident presented with hypotension and altered mental status. The physician noted some dried blood on her lips and was told she was being treated for mouth pain. The resident communicated but not clearly. The physician note read "she seems to understand my questions and will nod her head yes or no to appropriate questions. When she initially arrives, as mentioned, seems to be alert certainly to her name and to where she is, i.e. the hospital." When the physician asked if she hurt, the resident said "my mouth hurts."<br>The physical examination in the ER revealed pulse of 70, respirations 16, blood pressure initially 110/41, temperature 95.4, and oxygen saturation of 90% on nasal cannula. A cardiac monitor, urinary catheter, occult blood test, and laboratory monitoring were ordered. Hematology results revealed a white blood count (WBC) of 2.1 K/mm3 (thousand/cubic millimeter) (normal 4.5 - 13.5 M/mm3), Hg 7.5 g/dL (normal 12-15 g/dL), hematocrit 22.8% (normal 36-46%), and platelet count of 11 K/uL (normal 150-400 K/uL). | F 329 | An Interview Tool was developed and implemented on 10-18-12 to aide with validating the comprehension of the information provided. All nurses were interviewed by an Administrative Nurse prior to the beginning of their scheduled shift. Interviews were completed on 10-31-12 and will continue to be completed by the Staff Facilitator or an Administrative 1 per shift for 4 weeks, then one daily for a minimum of 4 weeks.<br><br>Medication Administration audits began on 10-12-12 for all licensed Nurses and were completed on 10/19/12 by a Supervisor or Administrative Nurse to include MDS Nurses, QI Nurse, and the ADON. The medication audits consist of the use of a Medication Pass Audit Form developed by the pharmacy which consists of observation of multiple medications and requiring a less than 5% error rate to pass. The audit includes observing to ensure the medications are given as ordered aiding with the elimination of unnecessary medications. Concerns were addressed at the time of the observation. Nurses with a Med Pass error rate of 5% or greater received a second Med Pass Audit by an Administrative Nurse. Nurses hired after 10-19-12 will receive a Med Pass audit within 2 weeks of completion of the | |

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| F 329 | Continued From page 7<br>Chemistry results revealed a BUN of 120mg/dL (normal 6-23 mg/dL), creatinine 2.5 mg/dL (normal 0.5-1.10 mg/dL), and GFR of 20 ml/min (normal > 60ml/min). A stool hemoccult, a test for gastro-intestinal (GI) bleeding, was positive. The resident received two units of IV fluids and her blood pressure dropped. She received two units of blood and her blood pressure stabilized. She was admitted to the Intensive Care Unit for anemia and hypotension. The ER report read "I think that she has a very poor prognosis and death would not be surprising based on the poor presentation here in the Emergency Department."<br><br>Record review revealed the resident was admitted to the Intensive Care Unit (ICU) on 10/11/12 at 5PM. Orders included laboratory monitoring, oxygen, chest X-ray, blood cultures, urinalysis, IV fluids, and medications including folate, thiamine (supplements), solu-medrol (corticosteroid), Diflucan, acyclovir (anti-viral), Nexium (GI bleeding, reflux), morphine (narcotic analgesic), and Invanz (antibiotic). Blood cultures were positive for pseudomonas aeruginosa (bacterial infection).<br><br>The Summary of Hospital Course revealed physician notes which read in part "patient is profoundly cachectic, chronically ill appearing white female who presented from the nursing home with hypotension and decreased level of consciousness with evidence of mouth pain and dried blood on her lips. She complains of severe mouth pain. Shortly after arrival she became progressively hypotensive and unresponsive...She was noted to be markedly anemic, thrombocytopenic, and neutropenic (low white blood cells)." | F 329 | Orientation process. Med Pass audits will continue to be completed by an Administrative Nurse 1 per shift for 3 days a week for 4 weeks, then 1 per shift for 2 days a week for 4 weeks then 1 per shift for 1 day for a minimum of 4 weeks.<br>Beginning 11-1-12<br><br>Beginning 10/12/12 Medication Administration Records to include for those Residents receiving Methotrexate will be reviewed by an Administrative Nurse using a current census to ensure medications given less than daily are blocked off on the MAR and are being administered as ordered. This audit will be completed daily x 14 days then 3 x weekly for a minimum of 6 weeks.<br><br>Beginning with the November 2012, the Medication Administration Record change over will incorporate a third check by two licensed Nurses to ensure accuracy of the MAR according to current Physician Orders and to ensure all medications given less than daily have been blocked off on the MAR. A Resident Census will be used as the audit tool to show completion of the audit. Audit will be completed by the end of the first day of the new MAR implementation and will occur for a minimum of 3 months. | |

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| F 329 | Continued From page 8<br><br>An addendum dated 10/11/12 read "patient medical list was reviewed and currently is apparently taking methotrexate on a daily basis as well as Plaquenil. Not on folic acid. Indication for therapy unclear at this point. Will administer IV folate and followup level. Certainly may be contributing to the mucositis and severe pancytopenia present on admission."<br><br>The Assessment/Plan read in part "acute renal failure, hypotension/sepsis - blood pressure low. Leukopenic. Etiology of sepsis unclear at present ...thrombocytopenia - question if related to medication effect...oral lesions/sores, metabolic acidosis, anemia, cachexia, chronic hepatitis, deconditioning."<br><br>The hospital Death Summary read "Preliminary Cause of Death: sepsis syndrome secondary to leukopenia/pancytopenia secondary to methotrexate." The Final Diagnoses read: "sepsis syndrome secondary to leukopenia/immunosuppression contributed to by methotrexate, acute renal failure secondary to acute tubular necrosis, thrombocytopenia, anemia, and metabolic acidosis secondary to acute renal failure." The resident expired on 10/12/12 at 1:00AM.<br><br>In an interview on 10/18/12 at 3:16PM, medication aide #1 stated the procedure for giving oral medications was to first check the MAR, check the medication in the cart, remove the medication from the cart, then double check the medication against the MAR to be sure the right medication and dose were given. After the medication was given, she initialed the entry on | F 329 | Results of the audits will be reviewed and addressed weekly as completed by the Director of Nursing, Quality Improvement Nurse or the designee. The results of the audits will be compiled and forwarded to the Quality Improvement Committee for weekly review of identification of trends, development of action plans and to determine the need and /or frequency of continuing QI monitoring. | |

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| F 329 | Continued From page 9 | F 329 | | |

the MAR. If a medication was not given for any reason, she initialed the MAR, and circled her initials. For medications ordered weekly, a square box was made around the day on the MAR that the medication was due or the days it was not given were "X'd" out. The med aide reviewed the methotrexate order on resident 170's MAR. She acknowledged she had initialed it as given on 10/3/12 but stated "I don' remember if I gave it or not." Her initials were circled on 10/10/12 indicating the medication was not given. She had noticed the methotrexate was not supposed to be given but every seven days and reported it to the nurse. She also reported the resident's complaint of mouth pain at that time.

In an interview on 10/18/12 at 3:43PM, nurse #1 stated the procedure for giving medication was to check the order on the MAR, check the medication label versus the MAR, pour and give the medication, and then sign the MAR. For medication ordered weekly, the MAR was marked with a square box on the day it was due and X'd out the other days. The nurse that took the original order was responsible for marking the current MAR. Two nurses checked the new MARS for accuracy before the first of the month and were responsible for marking the boxes and X's for medications not given daily. Nurse #1 reviewed the methotrexate order on resident 170's MAR. The nurse acknowledged she had initialed it on 10/5/12 but then crossed it out. She had also worked on 10/8/12 and left the entry for methotrexate blank. The nurse stated there was no methotrexate in the cart and she did not give it. The nurse stated she should have circled her initials and indicated a reason on the back of the

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| F 329 | Continued From page 10<br>MAR. She did not realize the methotrexate was ordered only every seven days. She did not report the resident was out of medication or call the pharmacy. The nurse stated she knew methotrexate was given for arthritis but was not aware that it was usually given only once weekly.<br><br>In an interview on 10/18/12 at 4:07PM, medication aide #2 stated when she gave medications, she checked the MAR for accuracy, then checked the drug label, and then checked the drug label against the MAR again. For medications not ordered daily, the MAR was marked with an X on the days it was not given and marked with a box on the day it was given. The nurse was responsible for marking the appropriate days on the MAR. The nurses also checked the new MARS twice against the old MARS and new orders. The med aide reviewed the methotrexate order on resident 170's MAR and acknowledged she had given it on 10/1/12, 10/2/12, and 10/4/12. She stated "it was an oversight."<br><br>In an interview on 10/18/12 at 4:29PM, medication aide #3 stated she was trained to read the MAR, check the dose, route, and patient name versus the medication label. She removed the medication from the cart and checked it again versus the MAR before administering the medication. For medication not ordered daily, the MARS were usually X'd out on the days it was not given. The nurses marked the X's on the MARS and also checked them monthly for accuracy. The med aide reviewed the methotrexate order on resident 170's MAR and acknowledged she had given it on 10/6/12 and 10/7/12. The med aide offered no explanation why she gave it daily. | F 329 | | |

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| F 329 | Continued From page 11<br><br>In a telephone interview on 10/18/12 at 5:15PM, the attending physician stated the resident was referred to a rheumatologist due to her severe rheumatoid arthritis. The rheumatologist ordered methotrexate once weekly. The physician stated he observed one sore on the resident's lateral tongue on 10/9/12. When he assessed her two days later, her whole mouth was affected and he sent her to the emergency room for evaluation. The physician stated the facility had notified him of the medication error. The resident was supposed to get methotrexate once weekly but he was unsure how much she had actually received.<br><br>An interview was conducted on 10/19/12 at 10:11AM with one of the nurses (nurse #2) responsible for checking resident 170's October MAR. Nurse #2 stated the new MARS came to the facility on the 21st of each month. Two nurses checked for new orders daily and added them to the new MARS. The MARS were checked again on the last day of the month to ensure all new orders had been added and the MARS were correct. For unusual dosages such as weekly administration, the MARS were X'd out on the days the medication was not to be given. The nurse stated she checked the resident's October MAR to be sure it was correct but did not mark or X out the days methotrexate was not to be given. She stated the nurse giving the medication was responsible for marking the MAR.<br><br>In an interview on 10/19/12 at 11:44AM, nurse #3 stated a nursing assistant had asked her to look at resident #170 on 10/10/12. The resident complained of mouth pain and had blood on her lower lip. The nurse applied a cool washcloth to | F 329 | | |

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| F 329 | Continued From page 12<br>the resident's lip. The physician was notified, the methotrexate was held, and an IV fluid was started. On 10/11/12, nurse #3 noted documentation that the resident hadn't been eating or drinking well. She thought it could be due to the medication. She checked the resident's MAR and discovered that the methotrexate was signed as given daily instead of weekly. The nurse checked the resident ' s vital signs and called the physician. The physician ordered stat labs and then sent the resident to the hospital. Nurse #3 stated the MARS and physicians' orders were checked at the end of the month to be sure they matched. For medication ordered weekly, the nurse doing the first MAR check was supposed to mark the next month's MAR with a box on the days the medication was to be given. The nurse was supposed to X out or draw a line through the other days on the MAR.<br><br>In an interview on 10/19/12 at 4:33PM, the Director of Nursing (DON) stated the staff was trained to thoroughly read the MARS and confirm the accurate medication, dose, time, and route. The DON stated two nurses checked the MAR for accuracy at the end of the month. For weekly medications, the nurses marked the MARS with an X or drew a line through the days it was not to be given. The nurses that checked the new MARS at the end of the month were responsible for marking them. If a new order was started after the first of the month, the nurse taking the order was responsible for marking the MAR. The DON stated she expected the staff to observe the five rights of medication administration. She expected them to check the MAR versus the label and the medication. If staff was unfamiliar with the indication, dosage, or side effects of a | F 329 | | |

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| F 329 | Continued From page 13<br>medication, she expected them to research the information from one of the available references, or ask other nursing staff and/or the pharmacy. Her expectation was for the nurses that checked the monthly MARS to mark them to ensure that medications ordered less than daily were given correctly.<br><br>In a telephone interview on 10/25/12 at 4:05PM, the physician that treated resident 170 in the ICU stated she had multiple contributing factors, including her age, chronic diseases, and debility. The physician stated the methotrexate may have contributed to the resident's pancytopenia. He stated adverse reactions to methotrexate were possible at usual doses and it would take days for the medication to clear after it was stopped. The physician stated he wasn't sure the amount of methotrexate the resident received would be considered an overdose but that it certainly contributed to her condition and death.<br><br>The Administrator was notified of the Immediate Jeopardy on 10/18/12 at 5:55PM. The facility provided a credible allegation of compliance on 10/19/12 at 4:30PM. The allegation of compliance indicated:<br><br>On 9/18/12 Resident # 6758 received an order for Methotrexate 2.5mg 4=10mg po Q 7 days by the Physician. Resident #6758 was administered Methotrexate per Physician's order on 9/19/12 and 9/26/12 by the Medication Aidee. Resident #6758 was assessed by the licensed Nurse on 10/8/12 and was noted to have a blood pressure of 90/50 and difficulty swallowing in which all 8pm blood pressure medications were held and the MD was notified in person of Resident's change | F 329 | | |

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| F 329 | Continued From page 14<br>in condition by the licensed Nurse. On 10/8/12 the MD assessed the Resident and wrote an order for Nystatin suspension 5ml swish and spit TID and Diflucan 100mg daily x 10days. Resident #6758 was reassessed on 10/9/12 by the licensed Nurse and complained of sore mouth and sore throat, ½ Lortab 5/500 was administered by the license Nurse. On 10/10/12 Resident # 6758 lips were assessed by the licensed Nurse and the MD, new orders were received to hold Prednisone and Plaquenil, hold/stop Methotrexate, Duragesic 25mcg patch change Q 72 hours, and IV ½ normal saline @ 70 cc per hour. On 10/11/12 resident #6758 blood pressure, mouth, and mental status was assessed by the licensed Nurse and the MD and the RP was notified of Resident's change in condition, new order was received to send to ER for evaluation. On 10/11/12 at 1023 am Resident was sent to the ER for evaluation. The Director of Nursing was informed the morning of 10/12/12 the resident was deceased.<br><br>All staff involved were drug tested 10/12/12. All results came back negative. The nurse was re-educated, drug tested and suspended on 10/12/12 and remains suspended at this time. The medication aides were re-educated. The facility has suspended use of medication aides. All medication aides are working as certified nursing assistants giving direct patient care.<br><br>All other Residents prescribed Methotrexate initial orders were reviewed by the Director of Nursing for accuracy of transcription on to the MAR, blocking of the MAR for every seven day administration and to ensure the accuracy of the next scheduled dose of the medication on | F 329 | | |

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| F 329 | Continued From page 15<br>10/11/12. There were no doses scheduled to be given at the time of the audit. Noted issues were corrected as identified on 10/11/12. Physical Assessments were completed on Residents on Methotrexate by licensed nurses and labs obtained by 10/12/12.<br><br>The determination was made by the Director of Nursing after review of the medication administration record (MAR) that the orders were transcribed correctly to the MAR. The medication error was the direct result of the licensed/certified staff not following the six rights of medication administration (right resident, right medication, right dose, right route, right method, right time) resulting in the medication being administered incorrectly. The medication administration record not being blocked off for medication to be given every seven days was a contributing factor to the medication error.<br><br>The dispensing pharmacy has identified the following medications as being at high risk for medication errors and has taken steps in the dispensing and labeling process to minimize administration error potential:<br><br>1. Methotrexate- Effective 10-17-12 the following changes for dispensing Methotrexate will be implemented. Beginning with the medication delivery on 10-17-12:<br><br>-Package all Methotrexate orders in bingo packaging each time the drug is dispensed from the pharmacy<br>-Send only one week supply each time the drug is dispensed from the pharmacy.<br>-In addition to cautionary wording, **NOTE DOSE | F 329 | | |

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| F 329 | Continued From page 16<br>AND FREQUENCY!!!*** in sig (directions), place a<br>stop sign shaped caution auxiliary label on the packaging that reads "HIGH ALERT CAUTION"<br>-Move Methotrexate to high risk station in pharmacy<br>-Have Registered Pharmacist double check final product in addition to initial review each time the drug is dispensed from the pharmacy.<br><br>2. Concentrated liquid morphine and oxycodone:<br>1) A "stop-sign shaped" red auxiliary label that reads "High Alert. Double-Check" affixed to each bottle dispensed to a resident or for the emergency drug kit<br>2) A mini-monograph with conversion grid dispensed with each bottle. This handout is printed on bright pink/red paper.<br>3) The following statement is added to each concentrated morphine and oxycodone prescription label and MAR, "Double-check dose. Use calibrated syringe."<br>4) Calibrated oral dosing syringe is dispensed bottle.<br><br>3. For Warfarin products exclamation points are placed before the medication name on the MAR/product label<br><br>4. "Tall Man" letters are used for sound alike and look alike drug names on the MAR/product label (per the ISMP - institute for safe medication practice - suggested list).<br><br>Methotrexate, for the Residents continuing to receive the medication have been returned to the pharmacy upon receipt of the 10-17-12 delivery. Validating of Methotrexate doses occurred by 2 | F 329 | | |

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| F 329 | Continued From page 17<br>licensed Nurses prior to Administration until new packaging was available. Signage to alert staff of Residents receiving Methotrexate and the need to verify dose with a second Nurse was inserted in the Resident' Medication Record. The new packaging arrived in the facility on 10/17/12. Medications in the old packaging have been returned to the pharmacy.<br><br>As a precautionary measure on 10/12/12 the facility temporarily suspended the use of Medication Aides pending medication administration retraining and a medication pass audit by the Pharmacy Consultant or an Administrative Nurse. The retraining of certified medication aidees will include, but will not be limited to:<br>· the six rights of medication administration<br>· the importance of reading and understanding medication labels and orders<br>· being aware of special instructions/alerts on packaging and MARs to include those for medications with unusual dosing schedules or those that could be potentially toxic, for example *****!!!!!! or a stop sign.<br>· infection control<br><br>All Medication Administration Records were audited by licensed Nurses to include the Supervisors with oversight by the Director of Nursing on 10/11/12 to ensure medications that were ordered less than daily were blocked off on the MAR and are being administered as ordered. Noted issues were corrected as identified. Verification of corrections was completed on 10-16-12.<br><br>In-services were started by the Staff Facilitator, | F 329 | | |

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| F 329 | Continued From page 18<br>RN on 10/11/12 for all licensed Nurses and Medication Aides on the six rights of medication administration, blocking the MAR for medications given less than daily by the nurse that takes off the telephone order to the MAR or by the nurses co-signing the monthly orders, notification of MD and RP of significant change in condition. Staff will be in-serviced prior to beginning their shift, to include staff on vacation and those that only work weekends by an Administrative Nurse.<br><br>In-service was started on 10/12/12 by Staff Facilitator for licensed nurses and Medication Aides on signs and symptoms of Methotrexate Toxicity. Staff will be in-serviced prior to beginning their shift, to include staff on vacation and those that only work weekends.<br><br>Nurses hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator related to the Six Rights of Medication Administration, Blocking the MAR for Medications given less than daily, Notification of MD and RP of significant change in condition and the Signs and Symptoms of Methotrexate toxicity.<br><br>In-service was started on 10/12/12 by the Staff Facilitator for the certified Nursing Assistants on change in Resident conditions that need to be reported to the Nurse. Staff will be in-serviced prior to beginning their shift, to include staff on vacation and those that only work weekends.<br><br>Nursing Assistants hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator related to the Changes in Resident conditions that need to be reported to the Nurse. | F 329 | | |

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| F 329 | Continued From page 19<br><br>An Interview Tool has been developed related to in-servicing material covered with Nurses and Medication Aides related to the Six Rights of Medication Administration, Blocking the MAR for Medications given less than daily, Notification of MD and RP of significant change in condition and the Signs and Symptoms of Methotrexate toxicity. Implementation of the interview tool will occur on 10-18-12. All nurses will be interviewed by an Administrative Nurse prior to the beginning of their scheduled shift. The Staff Facilitator or Administrative nurse will use the interview tool on one nurse per shift for 4 weeks, then one nurse daily for 4 weeks. Results of interviews will be reviewed weekly by the Quality Improvement Committee.<br><br>On 10/12/12 a review of all current MARS was initiated by licensed nurses to include MDS Nurses, QI Nurse, Treatment Nurses and ADON with assistance and oversight by Director of Nursing to include comparison of October MAR to the September MAR and telephone orders to ensure medications are being administered as ordered. Medication used less than daily were reviewed to ensure the MAR was blocked off. Issues were corrected as identified during the review by the licensed Nurse. Corrections were completed on 10-17-12.<br><br>Beginning 10/12/12 the licensed Nurses reviewed nurse notes on all Residents from 9/11/12 to 10/12/12 ensure there are no acute issues that have not been addressed. A general assessment was completed on each Resident by a licensed Nurse to ensure Residents did not have a change in condition that warranted the notification of the | F 329 | | |

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| F 329 | Continued From page 20<br>MD and/or RP. Identified issues were addressed as indicated by the licensed Nurse.<br><br>On 10/12/12 Medication Administration audits were started for all licensed Nurses and were completed by 10/19/12. The medication audits consist of the use of a Medication Pass Audit Form developed by the pharmacy which consists of observation of multiple medications and requiring a less than 5% error rate to pass. Concerns were addressed by the auditing Nurse at the time of the observation. Nurses with a Med Pass error rate of 5% or greater received a second Med Pass Audit by an Administrative Nurse. Nurses hired after 10-19-12 will receive a Med Pass audit within 2 weeks of completion of the Orientation process. The Med Pass audit will be completed by an Administrative Nurse.<br><br>Beginning 10/12/12, all telephone orders will be reviewed by the Administrative Nurse to ensure accurate transcription and blocking of the MARS for medications given less than daily on the medication administration record using copies of the telephone orders daily x 14 days, 3 x weekly x 6 weeks and then as determined necessary by the QI team.<br><br>Beginning 10/12/12 MARS will be reviewed by the Administrative Nurse using a current census to ensure medications that ware given less than daily are blocked off on the MAR and are being administered as ordered daily x 14 days, 3 x weekly 6 weeks and then as determined necessary by the QI team<br><br>Beginning 10/12/12 the MARS of residents taking Methotrexate will be reviewed by the | F 329 | | |

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| F 329 | Continued From page 21<br>Administrative Nurses using a current census to ensure accurate administration of the medication daily x 14 days, 3 x weekly x 6 weeks and then as determined necessary by the QI team.<br><br>Beginning with the November MAR, the MAR change over will incorporate a third check by two licensed Nurses on the first day of the month to ensure accuracy of the November MAR and to ensure all medications given less than daily have been blocked off on the MAR. MARs will continue to be signed off by two Nurses, the first Nurse will do the initial check when MARs arrive and the second check will be on the last day of the month prior to change over. Two licensed Nurses will audit 100% of MARs monthly x 3 months by performing a check of the hard copy MAR from the previous month and comparing it to the hard copy MAR for the current month and also incorporating the telephone orders in the third check. The two Nurses completing the third check will sign off on each hard copy and use a current census as the audit tool to show completion of the audit. Audit will be completed by the end of the first day of the new month.<br><br>Results of the audit will be reviewed and addressed weekly by the Director of Nursing or the designee. The results will be compiled and forwarded to the Quality Improvement Committee for weekly review of identification of trends, development of action plans and to determine the need and /or frequency of continuing QI monitoring.<br><br>On 10/19/12 at 5:59PM, the credible allegation of compliance was validated by observations, interviews, and record review. The facility | F 329 | | |

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| F 329 | Continued From page 22<br>provided evidence of in-service training for all nursing staff and medication aides. In-services included medication administration, special precautions, dosage, packaging, MAR blocking, and side effects/toxicity of methotrexate. Audit tools and forms were reviewed. Record review ofother sampled residents receiving methotrexate revealed the medication was given according to the physician ' s orders. MARS were appropriately blocked off to ensure once weekly dosing. Observation revealed methotrexate orders were packaged in bingo cards with only a one week supply dispensed from the pharmacy. Cautionary labels and the MARS read **NOTE DOSE AND FREQUENCY!!! Other high risk medications were also labeled with cautionary labels. Interviews with all nursing staff on duty were conducted and revealed competency regarding medication administration, special precautions, dosage, packaging, MAR blocking, and side effects/toxicity of methotrexate. Interviews revealed the medication aides were no longer administering medications. Interviews revealed in-services and audits had been completed and were ongoing. Interview with the Regional Clinical Pharmacist revealed dispensing, packaging, and labeling changes for methotrexate and other high risk medications had been implemented. Medication pass observations had been completed and were ongoing. Interviews with the Administrator, DON, and administrative staff revealed monitoring tools were in place and education of the staff was ongoing. The interviews revealed active and ongoing monitoring of policy implementation. | F 329 | | |
| F 333 SS=J | 483.25(m)(2) RESIDENTS FREE OF SIGNIFICANT MED ERRORS | F 333 | Resident #170 no longer resides in the Facility. | 11-1-12 |

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| F 333 | Continued From page 23<br>The facility must ensure that residents are free of any significant medication errors.<br><br>This REQUIREMENT is not met as evidenced by:<br>Based on record review, staff interviews, and physician interview, the facility failed to prevent a significant medication error for 1 of 3 sampled residents receiving methotrexate, an anti-neoplastic agent, for the treatment of rheumatoid arthritis (resident #170). The resident was given methotrexate daily instead of weekly as ordered. The resident was sent to the emergency room for evaluation on 10/11/12. She was determined to have methotrexate toxicity and was admitted to the intensive care unit of the hospital. The resident expired on 10/12/12 at 1:00AM.<br><br>The Immediate Jeopardy began on 10/1/12 at 10AM. The facility was informed of the Immediate Jeopardy on 10/18/12 at 5:55PM. Immediate Jeopardy was removed on 10/19/12 at 5:59PM, after the facility provided a credible allegation of compliance. The facility remained out of compliance at a scope and severity level D (no actual harm with the potential for more than minimal harm that is not immediate jeopardy) for the facility to complete employee training and to monitor its corrective action.<br><br>Findings include:<br><br>The facility policy, titled Medication Administration, undated, read in part "any deviation from the following principles shall be considered a medication error: | F 333 | All orders for Residents prescribed Methotrexate were reviewed by the Director of Nursing for accuracy of transcription to the Medication Administration Record, blocking of the Medication Administration Record to reflect appropriate order schedule and to ensure the accuracy of the next scheduled dose of the medication on 10/11/12. Noted issues were corrected as identified on 10/11/12. Residents to include those receiving Methotrexate continue to receive medications as ordered and as deemed necessary by the Resident's Physician aiding in the prevention of significant medication errors.<br><br>Physical Assessments and Labs were completed for All Residents receiving Methotrexate by licensed nurses by 10-13-12. Results of the assessment and labs were reviewed with the Resident's Physician and received follow up as indicated.<br><br>All Medication Administration Records were audited by licensed Nurses to include the Supervisors with oversight by the Director of Nursing on 10/11/12 to ensure medications that were ordered less than daily were being administered and were blocked off appropriately indicating days of administration. Noted issues were corrected as identified. Verification of corrections was completed on 10-16-12. | |

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| F 333 | Continued From page 24<br>1. To the right resident<br>2. Administration of the right medication<br>3. In the right dose<br>4. By the right route<br>5. By the right method<br>6. At the right time."<br><br>Resident #170 was admitted to the facility on 12/9/10 and readmitted on 5/14/12 with multiple diagnoses including rheumatoid arthritis, stage 3 chronic kidney disease, thrombocytopenia (low platelets), chronic unspecified hepatitis, anemia, and failure to thrive.<br><br>Review of the resident's minimum data set (MDS) dated 8/8/12 revealed she was cognitively intact. The MDS revealed the resident had no signs or symptoms of a swallowing disorder.<br><br>Record review of laboratory results dated 9/18/12 revealed a complete blood count (CBC) with hemoglobin (Hg) 13 g/dl (grams/deciliter) (normal 12-15 g/dL), hematocrit 38.7% (normal 36-46%), and platelets 125 K/uL (thousand/microliter) (normal 150-400 K/uL). Results of a basic metabolic panel dated 9/18/12 revealed blood urea nitrogen (BUN) 92 mg/dL (milligram/deciliter) (normal 6-23 mg/dL), creatinine 2.43 mg/dL (normal 0.5-1.10 mg/dL), and estimated glomerular filtration rate (GFR) of 19 ml/min (milliliter/minute) (normal > 60 ml/min). BUN, creatinine, and GFR are indicators of renal function.<br><br>Record review of the rheumatologist's progress notes dated 9/18/12 revealed a diagnosis of erosive rheumatoid arthritis. Recommendations included "add methotrexate 4 tabs once a week - | F 333 | A second Medication Administration Record review was conducted on 10-12-12 by licensed nurses to include the MDS Nurses, QI Nurse, Treatment Nurses and ADON with assistance and oversight by Director of Nursing. This review included comparison of the Medication Administration Record to the current Physician Orders to ensure medications are being administered as ordered. This review also included ensuring that Medications used less than daily were blocked off indicating days for administration to aide with the prevention of medication errors. Issues were corrected as identified during the review by the licensed Nurse. Corrections for audits were completed on 10-17-12.<br><br>All staff involved in the Methotrexate Administration in question for Resident #170 were drug tested on 10/12/12 under the direction of the facility Administrator. All results were negative. The Nurse was re-educated, drug tested and suspended on 10/12/12 and remains suspended. The facility suspended use of Medication Aides indefinitely effective 10-12-12. Prior to reimplementation of Medication Aides use in the facility, the Medication Aide will receive education related to Medication Administration to include having a | |

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| F 333 | Continued From page 25<br>all tabs to be given with a meal at same time only one day a week."<br><br>Review of the resident's clinical record revealed physician orders dated 9/18/12 for Methotrexate 2.5mg (milligram) take four tablets every seven days. Methotrexate is an anti-neoplastic agent indicated for the treatment of certain neoplastic diseases, severe psoriasis, and adult rheumatoid arthritis.<br><br>The manufacturer's product information for methotrexate read in part:<br>"Warnings - Deaths have been reported with the use of methotrexate in the treatment of rheumatoid arthritis ...methotrexate elimination is reduced in patients with impaired renal function. Such patients require especially careful monitoring for toxicity. Potentially fatal opportunistic infections may occur with methotrexate therapy.<br><br>Precautions - Methotrexate has the potential for serious toxicity. Toxic effects may be related in frequency and severity to dose or frequency of administration but have been seen at all doses. The clinical pharmacology of methotrexate has not been well studied in older individuals. Due to diminished hepatic and renal function, relatively low doses should be considered, and these patients should be closely monitored for early signs of toxicity.<br><br>Geriatric use - post-marketing experience suggests that the occurrence of bone marrow suppression, thrombocytopenia, and pneumonitis may increase with age. | F 333 | Medication Pass Audit by the Pharmacy Consultant or an Administrative Nurse in order to verify competence. The retraining of certified Medication Aides will include, but will not be limited to:<br>• Six Rights of Medication Administration<br>• Importance of reading and understanding medication labels and orders<br>• Special instructions/alerts on packaging and MARs to include those for medications with unusual dosing schedules or those that could be potentially toxic, for example *****!!!!!!! or a stop sign.<br>• Infection Control measures related to the Medication Pass<br><br>Additional measure are being provided by the Dispensing Pharmacy in the dispensing and labeling process to minimize administration error potential for medications at high risk for medication error.<br><br>Examples of labeling currently in use are:<br><br>1) A "stop-sign shaped" red auxiliary label that reads "High Alert. Double-Check" affixed to the bottle dispensed to a resident or for the emergency drug kit | |

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| F 333 | Continued From page 26<br>Renal - methotrexate may cause renal damage that may lead to acute renal failure.<br><br>Overdosage - symptoms commonly reported following oral overdose include those symptoms and signs reported at pharmacologic doses, particularly hematologic and gastrointestinal reactions. For example, leucopenia (low white blood cells), thrombocytopenia, anemia, pancytopenia (low white blood cells, red blood cells, and platelets), bone marrow suppression, mucositis, stomatitis, oral ulceration, nausea, vomiting, and gastrointestinal bleeding. There have been reports of death following overdose. In these cases, events such as sepsis or septic shock, renal failure, and aplastic anemia were also reported."<br><br>Review of the resident's September medication administration record (MAR) revealed a handwritten entry dated 9/19/12 for Methotrexate 2.5mg 4 tablets by mouth every 7 days. Review of the MAR revealed 4 tablets of methotrexate were given on Wednesday 9/19/12 and Wednesday 9/26/12 at 10AM.<br><br>Review of the provider pharmacy's delivery sheet revealed 16 methotrexate 2.5mg tablets were delivered to the facility for resident #170 on 9/19/12.<br><br>The resident' October MAR read "Methotrexate tab 2.5mg 4=10 mg by mouth every 7 days ***Note Dose and Frequency!!***" There was no blocking or other marking on the MAR that noted the weekly administration times. The medication was due to be given on Wednesday 10/3/12 and Wednesday 10/10/12. Review of the MAR | F 333 | 2) A mini-monograph with conversion grid dispensed with bottle. This handout is printed on bright pink/red paper.<br>3) Statements added to prescription labels and MAR, "Double-check dose. Use calibrated syringe."<br>4) Calibrated oral dosing syringe with the dispensed bottle.<br>5) Exclamation points placed before the medication name on the MAR/product label<br>6) "Tall Man" letters will be used for sound alike and look alike drug names on the MAR/product label (per the ISMP – institute for safe medication practice – suggested list).<br><br>Beginning with the Medication delivery to the facility on 10-17-12 the following changes for dispensing Methotrexate were implemented:<br><br>-Package all Methotrexate orders in bingo packaging each time the drug is dispensed from the pharmacy<br>-Send only one week supply each time the drug is dispensed from the pharmacy.<br>-In addition to cautionary wording, **NOTE DOSE AND FREQUENCY!!!*** in sig (directions), place a *stop sign shaped caution auxiliary label* on the packaging that reads "HIGH ALERT CAUTION" | |

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| F 333 | Continued From page 27<br>revealed methotrexate was given at 10AM `on 10/1/12, 10/2/12, 10/3/12, 10/4/12, 10/6/12, and 10/7/12, as indicated by the med aides' and nurse's initials. The entry for 10/5/12 was initialed and marked through with an "X" with no explanation on the back of the MAR. Entries for 10/8/12 and 10/9/12 were blank with no explanations on the back of the MAR. The entry for 10/10/12 was initialed and circled, indicating the medication was not given.<br><br>Review of the October MAR revealed the 8PM doses of Lotensin (antihypertensive) and Coreg (anti-arrhythmic) were held on 10/5/12, 10/8/12, and 10/9/12 due to low blood pressure.<br><br>Review of nursing notes dated 10/8/12 at 9:49AM revealed the resident refused her scheduled medications due to swallowing issues. Her Lotensin and Coreg were held due to low blood pressure. The nurse assessed the resident and called the physician. The physician ordered Diflucan and Nystatin oral suspension (antifungal agents).<br><br>Review of nursing notes dated 10/9/12 at 7:26AM revealed the resident complained of sore mouth and throat. She refused all morning meds except one-half of a Lortab 5/500 (narcotic analgesic).<br><br>Review of nursing notes dated 10/10/12 at 4:41PM revealed the resident was found with dried frank red blood to her lips with complaints of pain. The dried blood was cleansed away which revealed several open areas to the bottom lip. Pressure was applied to stop the bleeding and a lip moisturizer was applied. | F 333 | -Move Methotrexate to high risk station in pharmacy<br>-Have Registered Pharmacist double check final product in addition to initial review each time the drug is dispensed from the pharmacy.<br><br>Previous supply of Methotrexate for all Residents receiving the medication was returned to the pharmacy on 10-17-12 upon receipt of the new supply of Methotrexate in the new packaging.<br>New packaging remains in use for Resident's receiving Methotrexate.<br>In-services by the Staff Facilitator were initiated on 10/11/12 for all licensed Nurses and Medication Aides on the Six Rights of Medication Administration to include blocking the Medication Administration Record for medications given less than daily by the nurse that transcribed the medication to the Medication Administration Record or by the nurses co-signing the monthly orders to aide with ensuring that medications are administered as ordered as a deemed necessary by the Resident's Physician. In-servicing was completed on 10-31-12 Nurses hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator. | |

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| F 333 | Continued From page 28<br>Record review revealed physician orders dated 10/10/12 to hold methotrexate until the resident was seen by her rheumatologist. The physician added Duragesic (narcotic analgesic) for the resident's ulcerative stomatitis, held her prednisone (corticosteroid) and Plaquenil (arthritis medication), and started ½ normal saline solution intravenously (IV) at 70 ml/hr (milliliter/hour).<br><br>Record review revealed an Incident Report dated 10/11/12 at 9:30AM for resident #170. The report read "resident has order for methotrexate 10mg every 7 days, on MAR signed for every day for 7 days. Predisposing factors - staff related. MD notified."<br><br>Record review revealed physician orders dated 10/11/12 for a stat (immediate) methotrexate level, CBC, hepatic panel, and renal function tests. When the staff was unable to obtain an adequate blood sample for the labs, the physician sent the resident to the emergency room for evaluation.<br><br>Nursing notes dated 10/11/12 at 10:20AM revealed the resident was sent to the emergency room with hypotension and bleeding mouth sores.<br><br>Record review of the hospital Emergency Room (ER) record revealed the resident presented with hypotension and altered mental status. The physician noted some dried blood on her lips and was told she was being treated for mouth pain. The resident communicated but not clearly. The physician note read "she seems to understand my questions and will nod her head yes or no to appropriate questions. When she initially arrives, as mentioned, seems to be alert certainly to her | F 333 | Additional in-servicing was initiated on 10/12/12 by the Staff Facilitator for licensed nurses and Medication Aides on signs and symptoms of Methotrexate Toxicity. In-servicing was completed on 10-31-12. Nurses hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator.<br><br>An Interview Tool was developed and implemented on 10-18-12 to aide with validating the comprehension of the information provided. All nurses were interviewed by an Administrative Nurse prior to the beginning of their scheduled shift. Interviews were completed on 10-31-12 and will continue to be completed by the Staff Facilitator or an Administrative Nurse 1 per shift for 4 weeks, then one daily for a minimum of 4 weeks.<br><br>Medication Administration audits began on 10-12-12 for all licensed Nurses and were completed on 10/19/12 by a Supervisor or Administrative Nurse to include MDS Nurses, QI Nurse, and the ADON. The medication audits consist of the use of a Medication Pass Audit Form developed by the pharmacy which consists of observation of multiple medications and requiring a less than 5% error rate to pass. The audit includes observing to ensure the medications are given as ordered and if medications errors are occurring. Concerns were addressed at the time of the | |

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| F 333 | Continued From page 29<br>name and to where she is, i.e. the hospital." When the physician asked if she hurt, the resident said "my mouth hurts."<br><br>The physical examination in the ER revealed pulse of 70, respirations 16, blood pressure initially 110/41, temperature 95.4, and oxygen saturation of 90% on nasal cannula. A cardiac monitor, urinary catheter, occult blood test, and laboratory monitoring were ordered. Hematology results revealed a white blood count (WBC) of 2.1 K/mm3 (thousand/cubic millimeter) (normal 4.5 - 13.5 M/mm3), Hg 7.5 g/dL (normal 12-15 g/dL), hematocrit 22.8% (normal 36-46%), and platelet count of 11 K/uL (normal 150-400 K/uL). Chemistry results revealed a BUN of 120mg/dL (normal 6-23 mg/dL), creatinine 2.5 mg/dL (normal 0.5-1.10 mg/dL), and GFR of 20 ml/min (normal > 60 ml/min). A stool hemoccult, a test for gastro-intestinal (GI) bleeding, was positive. The resident received two units of IV fluids and her blood pressure dropped. She received two units of blood and her blood pressure stabilized. She was admitted to the Intensive Care Unit for anemia and hypotension. The ER report read "I think that she has a very poor prognosis and death would not be surprising based on the poor presentation here in the Emergency Department."<br><br>Record review revealed the resident was admitted to the Intensive Care Unit on 10/11/12 at 5PM. Orders included laboratory monitoring, oxygen, chest X-ray, blood cultures, urinalysis, IV fluids, and medications including folate, thiamine (supplements), solu-medrol (corticosteroid), Diflucan, acyclovir (anti-viral), Nexium (GI bleeding, reflux), morphine (narcotic analgesic), and Invanz (antibiotic). Blood cultures were | F 333 | observation. Nurses with a Med Pass error rate of 5% or greater received a second Med Pass Audit by an Administrative Nurse. Nurses hired after 10-19-12 will receive a Med Pass audit within 2 weeks of completion of the Orientation process. Med Pass audits will continue to be completed by an Administrative Nurse 1 per shift for 3 days a week for 4 weeks, then 1 per shift for 2 days a week for 4 weeks then 1 per shift for 1 day for a minimum of 4 weeks. Beginning 11-1-12<br><br>Beginning 10/12/12 Medication Administration Records to include for those Residents receiving Methotrexate will be reviewed by an Administrative Nurse using a current census to ensure medications given less than daily are blocked off on the MAR and are being administered as ordered and that significant medication errors are not occurring. Any concerns identified will be corrected at the time of discovery. This audit will be completed daily x 14 days then 3 x weekly for a minimum of 6 weeks.<br><br>Beginning with the November 2012, the Medication Administration Record change over will incorporate a third check by two licensed Nurses to ensure accuracy of the MAR according to current Physician Orders and to ensure all medications given less than daily have been blocked off on the MAR. A Resident Census will be used as the audit tool to show completion of the audit. | |

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| F 333 | Continued From page 30<br>positive for pseudomonas aeruginosa (bacterial infection).<br><br>The Summary of Hospital Course revealed physician notes which read in part "patient is profoundly cachectic, chronically ill appearing white female who presented from the nursing home with hypotension and decreased level of consciousness with evidence of mouth pain and dried blood on her lips. She complains of severe mouth pain. Shortly after arrival she became progressively hypotensive and unresponsive...She was noted to be markedly anemic, thrombocytopenic, and neutropenic (low white blood cells)."<br><br>An addendum dated 10/11/12 read "patient medical list was reviewed and currently is apparently taking methotrexate on a daily basis as well as Plaquenil. Not on folic acid. Indication for therapy unclear at this point. Will administer IV folate and followup level. Certainly may be contributing to the mucositis and severe pancytopenia present on admission."<br><br>The Assessment/Plan read in part "acute renal failure, hypotension/sepsis - blood pressure low. Leukopenic (low white blood cells). Etiology of sepsis unclear at present...thrombocytopenia - question if related to medication effect...oral lesions/sores, metabolic acidosis, anemia, cachexia, chronic hepatitis, deconditioning."<br><br>The hospital Death Summary read "Preliminary Cause of Death: sepsis syndrome secondary to leukopenia/pancytopenia secondary to methotrexate." The Final Diagnoses read: "sepsis syndrome secondary to | F 333 | Audit will be completed by the end of the first day of the new MAR implementation and will occur for a minimum of 3 months.<br><br>Results of the audits will be reviewed and addressed weekly as completed by the Director of Nursing, Quality Improvement Nurse or the designee. The results of the audits will be compiled and forwarded to the Quality Improvement Committee for weekly review of identification of trends, development of action plans and to determine the need and /or frequency of continuing QI monitoring. | |

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leukopenia/immunosuppression contributed to by methotrexate, acute renal failure secondary to acute tubular necrosis, thrombocytopenia, anemia, and metabolic acidosis secondary to acute renal failure." The resident expired on 10/12/12 at 1:00AM.

In an interview on 10/18/12 at 3:16PM, medication aide #1 stated the procedure for giving oral medications was to first check the MAR, check the medication in the cart, remove the medication from the cart, then double check the medication against the MAR to be sure the right medication and dose were given. After the medication was given, she initialed the entry on the MAR. If a medication was not given for any reason, she initialed the MAR, and circled her initials. For medications ordered weekly, a square box was made around the day on the MAR that the medication was due or the days it was not given were "X'd" out. The med aide reviewed the methotrexate order on resident 170's MAR. She acknowledged she had initialed it as given on 10/3/12 but stated "I don't remember if I gave it or not." Her initials were circled on 10/10/12 indicating the medication was not given. She had noticed the methotrexate was not supposed to be given but every seven days and reported it to the nurse. She also reported the resident's complaint of mouth pain at that time.

In an interview on 10/18/12 at 3:43PM, nurse #1 stated the procedure for giving medication was to check the order on the MAR, check the medication label versus the MAR, pour and give the medication, and then sign the MAR. For medication ordered weekly, the MAR was marked

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| F 333 | Continued From page 32<br>with a square box on the day it was due and X'd out the other days. The nurse that took the original order was responsible for marking the current MAR. Two nurses checked the new MARS for accuracy before the first of the month and were responsible for marking the boxes and X's for medications not given daily. Nurse #1 reviewed the methotrexate order on resident 170's MAR. The nurse acknowledged she had initialed it on 10/5/12 but then crossed it out. She had also worked on 10/8/12 and left the entry for methotrexate blank. The nurse stated there was no methotrexate in the cart and she did not give it. The nurse stated she should have circled her initials and indicated a reason on the back of the MAR. She did not realize the methotrexate was ordered only every seven days. She did not report the resident was out of medication or call the pharmacy. The nurse stated she knew methotrexate was given for arthritis but was not aware that it was usually given only once weekly.<br><br>In an interview on 10/18/12 at 4:07PM, medication aide #2 stated when she gave medications, she checked the MAR for accuracy, then checked the drug label, and then checked the drug label against the MAR again. For medications not ordered daily, the MAR was marked with an X on the days it was not given and marked with a box on the day it was given. The nurse was responsible for marking the appropriate days on the MAR. The nurses also checked the new MARS twice against the old MARS and new orders. The med aide reviewed the methotrexate order on resident 170's MAR and acknowledged she had given it on 10/1/12, 10/2/12, and 10/4/12. She stated "it was an oversight." | F 333 | | |

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| F 333 | Continued From page 33<br><br>In an interview on 10/18/12 at 4:29PM, medication aide #3 stated she was trained to read the MAR, check the dose, route, and patient name versus the medication label. She removed the medication from the cart and checked it again versus the MAR before administering the medication. For medication not ordered daily, the MARS were usually X'd out on the days it was not given. The nurses marked the X's on the MARS and also checked them monthly for accuracy. The med aide reviewed the methotrexate order on resident 170's MAR and acknowledged she had given it on 10/6/12 and 10/7/12. The med aide offered no explanation why she gave it daily.<br><br>In a telephone interview on 10/18/12 at 5:15PM, the attending physician stated the resident was referred to a rheumatologist due to her severe rheumatoid arthritis. The rheumatologist ordered methotrexate once weekly. The physician stated he observed one sore on the resident's lateral tongue on 10/9/12. When he assessed her two days later, her whole mouth was affected and he sent her to the emergency room for evaluation. The physician stated the facility had notified him of the medication error. The resident was supposed to get methotrexate once weekly but he was unsure how much she had actually received.<br><br>An interview was conducted on 10/19/12 at 10:11AM with one of the nurses (nurse #2) responsible for checking resident 170's October MAR. Nurse #2 stated the new MARS came to the facility on the 21st of each month. Two nurses checked for new orders daily and added them to the new MARS. The MARS were checked again on the last day of the month to | F 333 | | |

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ensure all new orders had been added and the MARS were correct. For unusual dosages such as weekly administration, the MARS were X' out on the days the medication was not to be given. The nurse stated she checked the resident's October MAR to be sure it was correct but did not mark or X out the days methotrexate was not to be given. She stated the nurse giving the medication was responsible for marking the MAR.

In an interview on 10/19/12 at 11:44AM, nurse #3 stated a nursing assistant had asked her to look at resident #170 on 10/10/12. The resident complained of mouth pain and had blood on her lower lip. The nurse applied a cool washcloth to the resident's lip. The physician was notified, the methotrexate was held, and an IV fluid was started. On 10/11/12, nurse #3 noted documentation that the resident hadn't been eating or drinking well. She thought it could be due to the medication. She checked the resident's MAR and discovered that the methotrexate was signed as given daily instead of weekly. The nurse checked the resident ' s vital signs and called the physician. The physician ordered stat labs and then sent the resident to the hospital. Nurse #3 stated the MARS and physicians' orders were checked at the end of the month to be sure they matched. For medication ordered weekly, the nurse doing the first MAR check was supposed to mark the next month's MAR with a box on the days the medication was to be given. The nurse was supposed to X out or draw a line through the other days on the MAR.

In an interview on 10/19/12 at 4:33PM, the Director of Nursing (DON) stated the staff was trained to thoroughly read the MARS and confirm

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| F 333 | Continued From page 35<br>the accurate medication, dose, time, and route. The DON stated two nurses checked the MAR for accuracy at the end of the month. For weekly medications, the nurses marked the MARS with an X or drew a line through the days it was not to be given. The nurses that checked the new MARS at the end of the month were responsible for marking them. If a new order was started after the first of the month, the nurse taking the order was responsible for marking the MAR. The DON stated she expected the staff to observe the five rights of medication administration. She expected them to check the MAR versus the label and the medication. If staff was unfamiliar with the indication, dosage, or side effects of a medication, she expected them to research the information from one of the available references, or ask other nursing staff and/or the pharmacy. Her expectation was for the nurses that checked the monthly MARS to mark them to ensure that medications ordered less than daily were given correctly. The DON stated she considered the daily administration of methotrexate for resident #170 to be a significant medication error.<br><br>In a telephone interview on 10/25/12 at 4:05PM, the physician that treated resident 170 in the ICU stated she had multiple contributing factors, including her age, chronic diseases, and debility. The physician stated the methotrexate may have contributed to the resident's pancytopenia. He stated adverse reactions to methotrexate were possible at usual doses and it would take days for the medication to clear after it was stopped. The physician stated he wasn't sure the amount of methotrexate the resident received would be considered an overdose but that it certainly contributed to her condition and death. | F 333 | | |

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| F 333 | Continued From page 36<br><br>The Administrator was notified of the Immediate Jeopardy on 10/18/12 at 5:55PM. The facility provided a credible allegation of compliance on 10/19/12 at 4:30PM. The allegation of compliance indicated:<br><br>On 9/18/12 Resident # 6758 received an order for Methotrexate 2.5mg 4=10mg po Q 7 days by the Physician. Resident #6758 was administered Methotrexate per Physician ' s order on 9/19/12 and 9/26/12 by the Medication Aide. Resident #6758 was assessed by the licensed Nurse on 10/8/12 and was noted to have a blood pressure of 90/50 and difficulty swallowing in which all 8pm blood pressure medications were held and the MD was notified in person of Resident's change in condition by the licensed Nurse. On 10/8/12 the MD assessed the Resident and wrote an order for Nystatin suspension 5ml swish and spit TID and Diflucan 100mg daily x 10days. Resident #6758 was reassessed on 10/9/12 by the licensed Nurse and complained of sore mouth and sore throat, ½ Lortab 5/500 was administered by the license Nurse. On 10/10/12 Resident # 6758 lips were assessed by the licensed Nurse and the MD, new orders were received to hold Prednisone and Plaquenil, hold/stop Methotrexate, Duragesic 25mcg patch change Q 72 hours, and IV ½ normal saline @ 70 cc per hour. On 10/11/12 resident #6758 blood pressure, mouth, and mental status was assessed by the licensed Nurse and the MD and the RP was notified of Resident ' s change in condition, new order was received to send to ER for evaluation. On 10/11/12 at 1023 am Resident was sent to the ER for evaluation. The Director of Nursing was informed the morning of 10/12/12 the resident | F 333 | | |

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| F 333 | Continued From page 37<br>was deceased.<br><br>All staff involved were drug tested 10/12/12. All results came back negative. The nurse was re-educated, drug tested and suspended on 10/12/12 and remains suspended at this time. The medication aides were re-educated. The facility has suspended use of medication aides. All medication aides are working as certified nursing assistants giving direct patient care.<br><br>All other Residents prescribed Methotrexate initial orders were reviewed by the Director of Nursing for accuracy of transcription on to the MAR, blocking of the MAR for every seven day administration and to ensure the accuracy of the next scheduled dose of the medication on 10/11/12. There were no doses scheduled to be given at the time of the audit. Noted issues were corrected as identified on 10/11/12. Physical Assessments were completed on Residents on Methotrexate by licensed nurses and labs obtained by 10/12/12.<br><br>The determination was made by the Director of Nursing after review of the medication administration record (MAR) that the orders were transcribed correctly to the MAR. The medication error was the direct result of the licensed/certified staff not following the six rights of medication administration (right resident, right medication, right dose, right route, right method, right time) resulting in the medication being administered incorrectly. The medication administration record not being blocked off for medication to be given every seven days was a contributing factor to the medication error. | F 333 | | |

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The dispensing pharmacy has identified the following medications as being at high risk for medication errors and has taken steps in the dispensing and labeling process to minimize administration error potential:

1. Methotrexate- Effective 10-17-12 the following changes for dispensing Methotrexate will be implemented. Beginning with the medication delivery on 10-17-12:

-Package all Methotrexate orders in bingo packaging each time the drug is dispensed from the pharmacy
-Send only one week supply each time the drug is dispensed from the pharmacy.
-In addition to cautionary wording, **NOTE DOSE AND FREQUENCY!!!*** in sig (directions), place a
stop sign shaped caution auxiliary label on the packaging that reads "HIGH ALERT CAUTION"
-Move Methotrexate to high risk station in pharmacy
-Have Registered Pharmacist double check final product in addition to initial review each time the drug is dispensed from the pharmacy.

2. Concentrated liquid morphine and oxycodone:
1) A "stop-sign shaped" red auxiliary label that reads "High Alert. Double-Check" affixed to each bottle dispensed to a resident or for the emergency drug kit
2) A mini-monograph with conversion grid dispensed with each bottle. This handout is printed on bright pink/red paper.
3) The following statement is added to each concentrated morphine and oxycodone prescription label and MAR, "Double-check dose.

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| F 333 | Continued From page 39<br>Use calibrated syringe."<br>4) Calibrated oral dosing syringe is dispensed bottle.<br><br>3. For Warfarin products exclamation points are placed before the medication name on the MAR/product label<br><br>4. "Tall Man" letters are used for sound alike and look alike drug names on the MAR/product label (per the ISMP - institute for safe medication practice - suggested list).<br><br>Methotrexate, for the Residents continuing to receive the medication have been returned to the pharmacy upon receipt of the 10-17-12 delivery. Validating of Methotrexate doses occurred by 2 licensed Nurses prior to Administration until new packaging was available. Signage to alert staff of Residents receiving Methotrexate and the need to verify dose with a second Nurse was inserted in the Resident's Medication Record. The new packaging arrived in the facility on 10/17/12. Medications in the old packaging have been returned to the pharmacy.<br><br>As a precautionary measure on 10/12/12 the facility temporarily suspended the use of Medication Aides pending medication administration retraining and a medication pass audit by the Pharmacy Consultant or an Administrative Nurse. The retraining of certified medication aides will include, but will not be limited to:<br>· the six rights of medication administration<br>· the importance of reading and understanding medication labels and orders<br>· being aware of special instructions/alerts on | F 333 | | |

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| F 333 | Continued From page 40<br>packaging and MARs to include those for medications with unusual dosing schedules or those that could be potentially toxic, for example *****!!!!!!! or a stop sign.<br>· infection control<br><br>All Medication Administration Records were audited by licensed Nurses to include the Supervisors with oversight by the Director of Nursing on 10/11/12 to ensure medications that were ordered less than daily were blocked off on the MAR and are being administered as ordered. Noted issues were corrected as identified. Verification of corrections was completed on 10-16-12.<br><br>In-services were started by the Staff Facilitator, RN on 10/11/12 for all licensed Nurses and Medication Aides on the six rights of medication administration, blocking the MAR for medications given less than daily by the nurse that takes off the telephone order to the MAR or by the nurses co-signing the monthly orders, notification of MD and RP of significant change in condition. Staff will be in-serviced prior to beginning their shift, to include staff on vacation and those that only work weekends by an Administrative Nurse.<br><br>In-service was started on 10/12/12 by Staff Facilitator for licensed nurses and Medication Aides on signs and symptoms of Methotrexate Toxicity. Staff will be in-serviced prior to beginning their shift, to include staff on vacation and those that only work weekends.<br><br>Nurses hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator related to the Six Rights of Medication | F 333 | | |

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| F 333 | Continued From page 41<br>Administration, Blocking the MAR for Medications given less than daily, Notification of MD and RP of significant change in condition and the Signs and Symptoms of Methotrexate toxicity.<br><br>In-service was started on 10/12/12 by the Staff Facilitator for the certified Nursing Assistants on change in Resident conditions that need to be reported to the Nurse. Staff will be in-serviced prior to beginning their shift, to include staff on vacation and those that only work weekends.<br><br>Nursing Assistants hired after 10-12-12 will be in-serviced during their orientation process by the Staff Facilitator related to the Changes in Resident conditions that need to be reported to the Nurse.<br><br>An Interview Tool has been developed related to in-servicing material covered with Nurses and Medication Aides related to the Six Rights of Medication Administration, Blocking the MAR for Medications given less than daily, Notification of MD and RP of significant change in condition and the Signs and Symptoms of Methotrexate toxicity. Implementation of the interview tool will occur on 10-18-12. All nurses will be interviewed by an Administrative Nurse prior to the beginning of their scheduled shift. The Staff Facilitator or Administrative nurse will use the interview tool on one nurse per shift for 4 weeks, then one nurse daily for 4 weeks. Results of interviews will be reviewed weekly by the Quality Improvement Committee.<br><br>On 10/12/12 a review of all current MARs was initiated by licensed nurses to include MDS Nurses, QI Nurse, Treatment Nurses and ADON | F 333 | | |

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| F 333 | Continued From page 42<br>with assistance and oversight by Director of Nursing to include comparison of October MAR to the September MAR and telephone orders to ensure medications are being administered as ordered. Medication used less than daily were reviewed to ensure the MAR was blocked off. Issues were corrected as identified during the review by the licensed Nurse. Corrections were completed on 10-17-12.<br><br>Beginning 10/12/12 the licensed Nurses reviewed nurse notes on all Residents from 9/11/12 to 10/12/12 ensure there are no acute issues that have not been addressed. A general assessment was completed on each Resident by a licensed Nurse to ensure Residents did not have a change in condition that warranted the notification of the MD and/or RP. Identified issues were addressed as indicated by the licensed Nurse.<br><br>On 10/12/12 Medication Administration audits were started for all licensed Nurses and were completed by 10/19/12. The medication audits consist of the use of a Medication Pass Audit Form developed by the pharmacy which consists of observation of multiple medications and requiring a less than 5% error rate to pass. Concerns were addressed by the auditing Nurse at the time of the observation. Nurses with a Med Pass error rate of 5% or greater received a second Med Pass Audit by an Administrative Nurse. Nurses hired after 10-19-12 will receive a Med Pass audit within 2 weeks of completion of the Orientation process. The Med Pass audit will be completed by an Administrative Nurse.<br><br>Beginning 10/12/12, all telephone orders will be reviewed by the Administrative Nurse to ensure | F 333 | | |

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| F 333 | Continued From page 43<br>accurate transcription and blocking of the MARS for medications given less than daily on the medication administration record using copies of the telephone orders daily x 14 days, 3 x weekly x 6 weeks and then as determined necessary by the QI team.<br><br>Beginning 10/12/12 MARs will be reviewed by the Administrative Nurse using a current census to ensure medications that ware given less than daily are blocked off on the MAR and are being administered as ordered daily x 14 days, 3 x weekly 6 weeks and then as determined necessary by the QI team<br><br>Beginning 10/12/12 the MARs of residents taking Methotrexate will be reviewed by the Administrative Nurses using a current census to ensure accurate administration of the medication daily x 14 days, 3 x weekly x 6 weeks and then as determined necessary by the QI team.<br><br>Beginning with the November MAR, the MAR change over will incorporate a third check by two licensed Nurses on the first day of the month to ensure accuracy of the November MAR and to ensure all medications given less than daily have been blocked off on the MAR. MARs will continue to be signed off by two Nurses, the first Nurse will do the initial check when MARs arrive and the second check will be on the last day of the month prior to change over. Two licensed Nurses will audit 100% of MARs monthly x 3 months by performing a check of the hard copy MAR from the previous month and comparing it to the hard copy MAR for the current month and also incorporating the telephone orders in the third check. The two Nurses completing the third | F 333 | | |

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| F 333 | Continued From page 44<br>check will sign off on each hard copy and use a current census as the audit tool to show completion of the audit. Audit will be completed by the end of the first day of the new month.<br><br>Results of the audit will be reviewed and addressed weekly by the Director of Nursing or the designee. The results will be compiled and forwarded to the Quality Improvement Committee for weekly review of identificationof trends, development of action plans and to determine the need and /or frequency of continuing QI monitoring.<br><br>On 10/19/12 at 5:59PM, the credible allegation of compliance was validated by observations, interviews, and record review. The facility provided evidence of in-service training for all nursing staff and medication aides. In-services included medication administration, special precautions, dosage, packaging, MAR blocking, and side effects/toxicity of methotrexate. Audit tools and forms were reviewed. Record review of other sampled residents receiving methotrexate revealed the medication was given according to the physician ' s orders. MARS were appropriately blocked off to ensure once weekly dosing. Observation revealed methotrexate orders were packaged in bingo cards with only a one week supply dispensed from the pharmacy. Cautionary labels and the MARS read **NOTE DOSE AND FREQUENCY!!! Other high risk medications were also labeled with cautionary labels. Interviews with all nursing staff on duty were conducted and revealed competency regarding medication administration, special precautions, dosage, packaging, MAR blocking, and side effects/toxicity of methotrexate. | F 333 | | |

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| F 333 | Continued From page 45<br>Interviews revealed the medication aides were no longer administering medications. Interviews revealed in-services and audits had been completed and were ongoing. Interview with the Regional Clinical Pharmacist revealed dispensing, packaging, and labeling changes for methotrexate and other high risk medications had been implemented. Medication pass observations had been completed and were ongoing. Interviews with the Administrator, DON, and administrative staff revealed monitoring tools were in place and education of the staff was ongoing. The interviews revealed active and ongoing monitoring of policy implementation. | F 333 | | |