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F 000	INITIAL COMMENTS No deficiencies were cited as a result of the complaint investigation. Event ID# JM1V11.	F 000		
F 428 SS=E	483.45(c)(1)(3)-(5) DRUG REGIMEN REVIEW, REPORT IRREGULAR, ACT ON c) Drug Regimen Review (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. (3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic. (4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon. (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug. (ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.	F 428		10/18/17

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

Electronically Signed | 10/06/2017

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F 428	Continued From page 1 (iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record. (5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident. This REQUIREMENT is not met as evidenced by: Based on record reviews and pharmacy and facility staff interviews, the facility failed to maintain documentation of the pharmacist's monthly Medication Regimen Review (MRR) within the facility and readily available for 5 of 5 sampled residents (Resident #1, #18, #36, #57, and #65) reviewed for unnecessary medications. Findings included: 1. Resident #18 was admitted to the facility on 4/29/14, and her documented diagnoses included Atrial Fibrillation, Coronary Artery Disease, Diabetes Mellitus, Hallucinations and Dementia. The resident's most recent minimum data set (MDS), a quarterly assessment dated 07/21/17, documented Resident #18 required extensive assist for dressing and limited assistance for bed mobility, transfers, toileting and hygiene. Her cognition was severely impaired. She received	F 428	Consultant pharmacist has been educated on documenting progress notes in the resident□s medical records. A change in consultant pharmacist will occur for the facility, and the new consultant will be educated on the expectation of documenting progress notes for each resident on a monthly basis. For each monthly review, consultant pharmacist will document a progress note in each resident□s medical record (either in the chart or electronic system) briefly outlining key findings and any irregularities/recommendations to be made to the facility and/or prescriber. Recommendations will be generated from the consulting software and issued to the facility in a separate report for follow up by the appropriate individual(s) at the end of each monthly review.	

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F 428	Continued From page 2 antipsychotic medication and insulin for 7 out of 7 days during the assessment look-back period and antidepressant medication for 1 out of 7 days. The resident's plan of care dated 09/20/17 included interventions for cognitive fluctuations related to episodes of confusion, fluctuations in mental status and a diagnosis of Dementia with psychotic features. Behaviors included hallucinations and delusions. Review of the resident's September 2017 medication administration record (MAR) revealed she was currently receiving Risperdal twice a day to manage her psychosis and Trazodone to manage her depression. The resident was also receiving an anti-platelet medication, an anti-hypertension medication and Insulin. Review of Resident #18's Medication Regimen Review sheet revealed that starting in December 2016 through September 2017 the facility's consultant pharmacist only signed his name and documented the date of his monthly visits rather than providing a recapitulation of his monthly medication regimen reviews (MRRs). The sheet documented the consultant pharmacist reviewed Resident #18's medications on 12/08/16, 01/09/17, 02/09/17, 03/07/17, 04/07/17, 05/04/17, 06/07/17, 07/06/17, 08/7/17, and 09/11/17. At 3:30 PM on 09/19/17 the assistant director of nursing (ADON) stated that the consultant pharmacist reviewed the medication regimens of all residents monthly. However, she reported the only information he left with the facility was pharmacy recommendations made after completion of the monthly reviews. She commented the pharmacist's actual monthly	F 428	Clinical Manager will perform an audit to assure that progress notes are being documented on a monthly basis for three months, then as needed thereafter. Respectfully submitted, Brad McKee, Pharm.D., BCGP Clinical Manager Omnicare of North Carolina The clinical manager will submit the results of the audits to the facility QAPI committee for review at the next regularly scheduled meeting (last Tuesday of each month). After the first 3 audits, the DON or her designee will do a quarterly review of 5 randomly chosen charts to ensure that the consultant pharmacist is writing a monthly progress note on each resident. The results of these quarterly audits will be shared with the QAPI Committee at the next regularly scheduled meeting. The pharmacy manager will be notified in the event that the pharmacist is found to not be charting a monthly progress note.	

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MRRs were stored in his laptop/computer, and the pharmacist could be contacted via phone to provide the information which he gathered and analyzed during those monthly reviews. The ADON clarified that the facility did not have electronic or printed copies of the MMRs on-site.

At 1:00 PM on 09/20/17 the facility's Consultant Pharmacist stated when he completed monthly MRRs he assessed the residents' psychoactive medications, gradual dose reductions, labs, weights, past pharmacy recommendations, and sometimes performed a creatinine clearance calculation. He reported he printed out reports to leave with the facility each month, and the last page of the recommendations report documented, "The following residents were reviewed and based upon the information available at the time of the review, and assuming the accuracy and completeness of such information, it is my professional judgment that at such time, the residents' medication regimens contained no new irregularities (as defined in SOM appendix PP 483.60 (c))." The pharmacist commented that following this statement there was a list of residents whose medications were reviewed, but who did not have any recommendations. According to the Consultant Pharmacist, the pharmacy for which he worked would not allow him to do double work by documenting a review in the pharmacy computer system and then having to provide the facility with a hard or electronic copy of his assessments. He stated he felt his signature and date on the Medication Regimen Review, coupled with the copies of recommendations he left with the facility each month, met the intent of the federal regulation which required MRRs be readily available to staff members and regulators who

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wished to review them.

At 11:19 AM on 09/21/17 the State Clinical Director of Pharmacy Services stated the Consultant Pharmacist could either enter his review into the computer or write it on the monthly MRR sheet in the chart. He stated there was no policy indicating how the Consultant Pharmacist should document the information and that it was an individual choice. The Clinical Director also stated the Consultant Pharmacist could choose to document in both places. He indicated that at a minimum he would expect there to be a signature and date to show the Consultant Pharmacist had completed the review. He acknowledged that one could not tell if something was missed or not reviewed by looking at a signature and a date. He stated the Consultant Pharmacists were not on call 24 hours a day, however, Pharmacy Services could be contacted, and they would attempt to call the Consultant. He indicated the only documentation Pharmacy Services was able to access were the recommendations made by the Consultant Pharmacist and not the reviews themselves. The Clinical Director stated the monthly MRRs allowed the Pharmacy Consultant to review any issues that needed follow-up. He further stated they were to be utilized by the Consultant Pharmacist to see if recommendations needed to be made. He indicated Nurses, Dieticians, and Activity Directors could access some of the same information on the MRR by looking at behavior monitoring sheets, notebooks kept in management offices, and nursing notes.

At 12:45 PM on 09/21/17 the Director of Nursing (DON) stated it was her expectation that the Consultant Pharmacist document a note

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regarding his or her monthly MRR for each resident. She also reported she expected this documentation to be readily available for staff to use in making medical and care decisions for the residents.

2. Resident #1 was readmitted to the facility on 02/17/17, and her documented diagnoses included Chronic Kidney Disease Stage 3, Hypercholesterolemia, Hypertension, Diabetes Mellitus, Hypothyroidism, Cereberal Vascular disease, and Depression.

The resident's most recent minimum data set (MDS), a quarterly assessment dated 09/11/17, documented Resident #1 required extensive assist for activities of daily living and supervison for eating. Her cognition was intact. She received Insulin and diuretics for 7 out of 7 days during the assessment look-back period and antidepressant medication for 6 out of 7 days.

Review of the resident's September 2017 medication administration record (MAR) revealed she was currently receiving Lasix and potassium to manage fluid volume and Lyrica to manage pain . The resident was also receiving an anti-platelet medication, an anti-hypertension medication and Insulin.

Review of Resident #1's Medication Regimen Review sheet revealed that starting in December 2016 through September 2017 the facility's consultant pharmacist only signed his name and documented the date of his monthly visits rather than providing a recapitulation of his monthly medication regimen reviews (MRRs). The sheet documented the consultant pharmacist reviewed Resident #1's medications on 12/08/16, 01/09/17,

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F 428	Continued From page 6 02/09/17, 03/07/17, 04/07/17, 05/04/17, 06/07/17, 07/06/17, 08/7/17, and 09/11/17. At 3:30 PM on 09/19/17 the assistant director of nursing (ADON) stated that the consultant pharmacist reviewed the medication regimens of all residents monthly. However, she reported the only information he left with the facility was pharmacy recommendations made after completion of the monthly reviews. She commented the pharmacist's actual monthly MRRs were stored in his laptop/computer, and the pharmacist could be contacted via phone to provide the information which he gathered and analyzed during those monthly reviews. The ADON clarified that the facility did not have electronic or printed copies of the MMRs on-site. At 1:00 PM on 09/20/17 the facility's Consultant Pharmacist stated when he completed monthly MRRs he assessed the residents' psychoactive medications, gradual dose reductions, labs, weights, past pharmacy recommendations, and sometimes performed a creatinine clearance calculation. He reported he printed out reports to leave with the facility each month, and the last page of the recommendations report documented, "The following residents were reviewed and based upon the information available at the time of the review, and assuming the accuracy and completeness of such information, it is my professional judgment that at such time, the residents' medication regimens contained no new irregularities (as defined in SOM appendix PP 483.60 (c))." The pharmacist commented that following this statement there was a list of residents whose medications were reviewed, but who did not have any recommendations. According to the Consultant	F 428		

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Pharmacist, the pharmacy for which he worked would not allow him to do double work by documenting a review in the pharmacy computer system and then having to provide the facility with a hard or electronic copy of his assessments. He stated he felt his signature and date on the Medication Regimen Review, coupled with the copies of recommendations he left with the facility each month, met the intent of the federal regulation which required MRRs be readily available to staff members and regulators who wished to review them.

At 11:19 AM on 09/21/17 the State Clinical Director of Pharmacy Services stated the Consultant Pharmacist could either enter his review into the computer or write it on the monthly MRR sheet in the chart. He stated there was no policy indicating how the Consultant Pharmacist should document the information and that it was an individual choice. The Clinical Director also stated the Consultant Pharmacist could choose to document in both places. He indicated that at a minimum he would expect there to be a signature and date to show the Consultant Pharmacist had completed the review. He acknowledged that one could not tell if something was missed or not reviewed by looking at a signature and a date. He stated the Consultant Pharmacists were not on call 24 hours a day, however, Pharmacy Services could be contacted, and they would attempt to call the Consultant. He indicated the only documentation Pharmacy Services was able to access were the recommendations made by the Consultant Pharmacist and not the reviews themselves. The Clinical Director stated the monthly MRRs allowed the Pharmacy Consultant to review any issues that needed follow-up. He further stated they were to be utilized by the

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F 428	Continued From page 8 Consultant Pharmacist to see if recommendations needed to be made. He indicated Nurses, Dieticians, and Activity Directors could access some of the same information on the MRR by looking at behavior monitoring sheets, notebooks kept in management offices, and nursing notes. At 12:45 PM on 09/21/17 the Director of Nursing (DON) stated it was her expectation that the Consultant Pharmacist document a note regarding his or her monthly MRR for each resident. She also reported she expected this documentation to be readily available for staff to use in making medical and care decisions for the residents. 3. Resident #57 was admitted to the facility on 04/10/14, and his documented diagnoses included brain neoplasm, pseudobulbar affect (PBA--uncontrollable crying or laughter), hypertension, cerebrovascular accident, anxiety, and psychosis. The resident's most recent minimum data set (MDS), a 07/25/17 quarterly assessment, documented Resident #57 had short and long term memory impairment, was severely impaired in decision making, was completely dependent on a staff member for all his activities of daily living, received all his nutrition through tubefeeding, and received antianxiety and antidepressant medications for 6 out of 7 days during the	F 428		

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assessment look-back period.

On 07/28/17 "Psychotropic Drug Use with potential drug-related complications r/t (in regard to) antidepressant and antianxiety use. Diagnosis includes combative psychosis, anxiety, and insomnia" was identified as a problem in Resident #57's care plan. Interventions to address this problem included "Administer antianxiety and antidepressant medications as ordered. Report side effects to MD (physician). When resident has anxious complaints attempt to find cause and resolve if possible."

Review of the resident's September 2017 medication administration record (MAR) revealed he was currently receiving ativan to manage his anxiety and trazadone to manage his depression. The resident was also receiving an anti-platelet medication, medication for PBA control, a narcotic pain medication, an anti-hypertension medication.

Review of the resident's September 2017 physician order recap sheet revealed he had orders to draw labs which included complete blood counts, comprehensive metabolic panels, and lipid/liver panels.

Review of Resident #57's Medication Regimen Review sheet revealed that starting in December 2016 through September 2017 the facility's consultant pharmacist only signed his name and documented the date of his monthly visits rather than providing a recapitulation of his monthly medication regimen reviews (MRRs). The sheet documented the consultant pharmacist reviewed Resident #57's medications on 12/08/16, 01/09/17, 02/09/17, 03/07/17, 04/07/17, 05/04/17,

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06/07/17, 07/06/17, 08/7/17, and 09/11/17.

Review of the facility's pharmacy recommendation revealed that the consultant pharmacist provided the facility with recommendations regarding Resident #57's medications on 01/09/17, 02/09/17, 06/07/17, and 08/07/17.

At 3:30 PM on 09/19/17 the assistant director of nursing (ADON) stated that the consultant pharmacist reviewed the medication regimens of all residents monthly. However, she reported the only information he left with the facility was pharmacy recommendations made after completion of the monthly reviews. She commented the pharmacist's actual monthly MRRs were stored in his laptop/computer, and the pharmacist could be contacted via phone to provide the information which he gathered and analyzed during those monthly reviews. The ADON clarified that the facility did not have electronic or printed copies of the MMRs on-site.

At 1:00 PM on 09/20/17 the facility's Consultant Pharmacist stated when he completed monthly MRRs he assessed the residents' psychoactive medications, gradual dose reductions, labs, weights, past pharmacy recommendations, and sometimes performed a creatinine clearance calculation. He reported he printed out reports to leave with the facility each month, and the last page of the recommendations report documented, "The following residents were reviewed and based upon the information available at the time of the review, and assuming the accuracy and completeness of such information, it is my professional judgment that at such time, the residents' medication regimens

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contained no new irregularities (as defined in SOM appendix PP 483.60 (c))." The pharmacist commented that following this statement there was a list of residents whose medications were reviewed, but who did not have any recommendations. According to the Consultant Pharmacist, the pharmacy for which he worked would not allow him to do double work by documenting a review in the pharmacy computer system and then having to provide the facility with a hard or electronic copy of his assessments. He stated he felt his signature and date on the Medication Regimen Review, coupled with the copies of recommendations he left with the facility each month, met the intent of the federal regulation which required MRRs be readily available to staff members and regulators who wished to review them.

At 11:19 AM on 09/21/17 the State Clinical Director of Pharmacy Services stated the Consultant Pharmacist could either enter his review into the computer or write it on the monthly MRR sheet in the chart. He stated there was no policy indicating how the Consultant Pharmacist should document the information and that it was an individual choice. The Clinical Director also stated the Consultant Pharmacist could choose to document in both places. He indicated that at a minimum he would expect there to be a signature and date to show the Consultant Pharmacist had completed the review. He acknowledged that one could not tell if something was missed or not reviewed by looking at a signature and a date. He stated the Consultant Pharmacists were not on call 24 hours a day, however, Pharmacy Services could be contacted, and they would attempt to call the Consultant. He indicated the only documentation Pharmacy Services was able

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to access were the recommendations made by the Consultant Pharmacist and not the reviews themselves. The Clinical Director stated the monthly MRRs allowed the Pharmacy Consultant to review any issues that needed follow-up. He further stated they were to be utilized by the Consultant Pharmacist to see if recommendations needed to be made. He indicated Nurses, Dieticians, and Activity Directors could access some of the same information on the MRR by looking at behavior monitoring sheets, notebooks kept in management offices, and nursing notes.

At 12:45 PM on 09/21/17 the Director of Nursing (DON) stated it was her expectation that the Consultant Pharmacist document a note regarding his or her monthly MRR for each resident. She also reported she expected this documentation to be readily available for staff to use in making medical and care decisions for the residents.

4. Resident #65 was readmitted to the facility on 02/07/17 with diagnoses of non-Alzheimer's dementia, anxiety disorder, and depression.

A review of Resident #65's most recent quarterly Minimum Data Set (MDS) dated 08/03/17 revealed the resident received an antianxiety, antidepressant, and diuretic on each of the 7 days during the look back period.

A review of Resident #65's paper and electronic medical records revealed the consultant

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pharmacist conducted a Medication Regimen Review (MRR) on 11/15/16. However, MRR's were not available for the months of December 2016, January 2017, February 2017, March 2017, April 2017, May 2017, June 2017, July 2017, August 2017, or September 2017. Instead of a review, the MRR contained a date and the signature of the consultant pharmacist.

At 3:30 PM on 09/19/17 the ADON stated that the consultant pharmacist reviewed the medication regimens of all residents monthly. However, she reported the only information he left with the facility was any pharmacy recommendations made after completion of the monthly reviews. She commented the pharmacist's actual monthly medication regimen reviews were stored in his laptop/computer, and the pharmacist could be contacted via phone to provide the information which he reviewed during those monthly reviews. The ADON clarified that the facility did not have electronic or printed copies of the monthly medication regimen reviews on-site.

At 1:00 PM on 09/20/17 the facility's consultant pharmacist stated when he completed monthly medication regimen reviews (MRRs) he assessed the residents' psychoactive medications, gradual dose reductions, labs, weights, past pharmacy recommendations, and sometimes performed a creatinine clearance calculation. He reported he printed out reports to leave with the facility each month, and the last page of the recommendations report documented, "The following residents were reviewed and based upon the information available at the time of the review, and assuming the accuracy and completeness of such information, it is my professional judgment that at such time, the residents' medication regimens

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contained no new irregularities (as defined in SOM appendix PP 483.60 (c))." The pharmacist commented that following this statement there was a list of residents whose medications were reviewed, but who did not have any recommendations. According to the consultant pharmacist, the pharmacy for which he worked would not allow him to do double work by documenting a review in the pharmacy computer system and then having to provide the facility with a hard or electronic copy of his assessments. He stated he felt his signature and date on the Medication Regimen Review, coupled with the copies of recommendations he left with the facility each month, met the intent of the federal regulation which required MRRs be readily available to staff members and regulators who wished to review them.

In a telephone interview on 09/21/17 at 11:19 AM the State Clinical Director of Pharmacy Services stated the consultant pharmacist could either enter his review into the computer or write it on the monthly Medication Regimen Review (MRR) sheet in the chart. He stated there was no policy indicating how the consultant pharmacist should document the information and that it was an individual choice. The Clinical Director also stated the consultant pharmacist could choose to document in both places. He indicated that at a minimum he would expect there to be a signature and date to show the consultant pharmacist had completed the review. He acknowledged that one could not tell if something was missed or not reviewed by looking at a signature and a date. He stated the consultant pharmacists were not on call 24 hours a day. However, pharmacy services could be contacted and they would attempt to call the consultant. He indicated the only

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documentation pharmacy services would be able to access were the recommendations made by the consultant pharmacist and not the review itself. The Clinical Director stated the purpose of the monthly MRR was so that the consultant pharmacist was able to review any issues that needed follow-up. He further stated they were to be utilized by the consultant pharmacist to see if recommendations needed to be made. He indicated nurses, dieticians, and activity directors could access some of the same information on the MRR by looking at behavior monitoring sheets, notebooks kept in management offices, and nursing notes.

In an interview on 9/21/17 at 12:45 PM the Director of Nursing (DON) stated that it was her expectation that the consultant pharmacist document a note regarding his or her monthly medication review for each resident. She also expected the documentation to be readily available to staff.

5. Resident #36 was admitted to the facility on 09/7/11. Her cumulative diagnoses included congestive heart failure (CHF), diabetes (DM), hypertension (HTN), dementia, and acute respiratory failure.

A review of Resident #36 ' s most recent quarterly Minimum Data Set (MDS) assessment dated 09/6/17 revealed the resident had severe cognitive impairments, and received an antipsychotic, mood stabilizer, seizure

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medication, diuretic, and insulin.

Review of Resident #36's Medication Regimen Review sheet revealed that starting in January 2017 through September 2017 the facility's consultant pharmacist only signed his name and documented the date of his monthly visits rather than providing a recapitulation of his monthly medication regimen reviews (MRRs). The sheet documented the consultant pharmacist reviewed Resident #36's medications on 01/9/17, 02/9/17, 03/6/17, 04/7/17, 05/4/17, 06/6/17, 07/6/17, 08/7/17, and 09/11/17.

At 3:30 PM on 09/19/17 the assistant director of nursing (ADON) stated that the consultant pharmacist reviewed the medication regimens of all residents monthly. However, she reported the only information he left with the facility was any pharmacy recommendations made after completion of the monthly reviews. She commented the pharmacist ' s actual monthly medication regimen reviews were stored in his laptop/computer, and the pharmacist could be contacted via phone to provide the information which he reviewed during those monthly reviews. The ADON clarified that the facility did not have electronic or printed copies of the monthly medication regimen reviews on-site.

At 1:00 PM on 09/20/17 the facility's consultant pharmacist stated when he completed monthly medication regimen reviews (MRRs) he assessed the residents ' psychoactive medications, gradual dose reductions, labs, weights, past pharmacy recommendations, and sometimes performed a creatinine clearance calculation. He reported he printed out reports to leave with the facility each month, and the last page of the recommendations

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report documented, "The following residents were reviewed and based upon the information available at the time of the review, and assuming the accuracy and completeness of such information, it is my professional judgment that at such time, the residents' medication regimens contained no new irregularities (as defined in SOM appendix PP 483.60 (c))." The pharmacist commented that following this statement there was a list of residents whose medications were reviewed, but who did not have any recommendations. According to the consultant pharmacist, the pharmacy for which he worked would not allow him to do double work by documenting a review in the pharmacy computer system and then having to provide the facility with a hard or electronic copy of his assessments. He stated he felt his signature and date on the Medication Regimen Review, coupled with the copies of recommendations he left with the facility each month, met the intent of the federal regulation which required MRRs be readily available to staff members and regulators who wished to review them.

In a telephone interview on 09/21/17 at 11:19 AM the State Clinical Director of Pharmacy Services stated the Consultant Pharmacist could either enter his review into the computer or write it on the monthly Medication Regimen Review (MRR) sheet in the chart. He stated there was no policy indicating how the Consultant Pharmacist should document the information and that it was an individual choice. The Clinical Director also stated the Consultant Pharmacist could choose to document in both places. He indicated that at a minimum he would expect there to be a signature and date to show the Consultant Pharmacist had completed the review. He acknowledged that

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one could not tell if something was missed or not reviewed by looking at a signature and a date. He stated the Consultant Pharmacists were not on call 24 hours a day, however, Pharmacy Services could be contacted and they would attempt to call the Consultant. He indicated the only documentation Pharmacy Services was able to access were the recommendations made by the Consultant Pharmacist and not the review itself. The Clinical Director stated the purpose of the monthly MRR was so that the Pharmacy Consultant was able to review any issues that needed follow-up. He further stated they were to be utilized by the Consultant Pharmacist to see if recommendations needed to be made. He indicated Nurses, Dieticians, and Activity Directors could access some of the same information on the MRR by looking at behavior monitoring sheets, notebooks kept in management offices, and nursing notes.

An interview with the DON, on 9/21/17 at 12:45 PM, she stated that it was her expectation that the consultant pharmacist document a note regarding his or her monthly medication review for each resident. She also reported that she expected this documentation to be readily available to staff.