

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152571	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  11/15/2012
NAME OF PROVIDER OR SUPPLIER  FRESENIUS MEDICAL CARE TERRE HAUTE NORTH			STREET ADDRESS, CITY, STATE, ZIP CODE 351 MAIDEN LN TERRE HAUTE, IN 47804		
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V000000	<p>This was a follow-up visit to the ESRD expanded federal complaint investigation survey conducted at this facility on 10-09-12, 10-10-12, and 10-11-12.</p> <p>Complaint #: IN00117231 - Substantiated, deficiencies related to the allegations are cited; unrelated deficiencies are also cited.</p> <p>Facility #: 005141</p> <p>Survey Date: 11-15-12</p> <p>Surveyor: Vicki Harmon, RN, PHNS</p> <p>Four (4) conditions and sixteen (16) standard level deficiencies were found to be corrected as a result of this survey. One (1) conditions and five (5) standards remain uncorrected and were re-cited.</p> <p>FMC Terre Haute North was found to be out of compliance with Condition for Coverage 42 CFR 494.180 Governance.</p> <p>Quality Review: Joyce Elder, MSN, BSN, RN November 16, 2012</p>	V000000			

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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V000541	<p>494.90 POC-GOALS=COMMUNITY-BASED STANDARDS The interdisciplinary team as defined at §494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, and must include measurable and expected outcomes and estimated timetables to achieve these outcomes. The outcomes specified in the patient plan of care must be consistent with current evidence-based professionally-accepted clinical practice standards.</p> <p>Based on clinical record review and interview, the facility failed to ensure patients had participated in the development and implementation of the plans of care in 2 (#s 1 and 3) of 4 records reviewed creating the potential to affect all of the facility's 131 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. Clinical record number included a plan of care (PoC) developed and implemented by the interdisciplinary team (IDT) on 11-9-12. The plan evidenced the patient had signed the PoC on 11-15-12, 6 days after the plan had been developed and implemented.</li> <li>2. Clinical record number 3 included a PoC developed and implemented by the</li> </ol>	V000541	<p>On 11/2/12, the Director of Operations met with the members of the IDT, then on 11/19/12, the Regional Quality Manager met with the members of the IDT to emphasize the requirement as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan of Care that is specific to address the patient's needs and includes the opportunity for the patient to participate in the development of his/her Plan of Care. Additionally, those patients that chose not to participate must have the opportunity to review and sign their POC within 7 days of the Plan of Care meeting as defined by policy or have documentation as to why it was not signed within the appropriate time-frame.</p>	12/14/2012			

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	<p>IDT on 10-24-12. The plan evidenced the patient had signed the PoC on 11-06-12, 13 days after the plan had been developed and implemented.</p> <p>3. During the entrance conference on 11-15-12 at 10:00 AM Central Time, the Director of Operations, employee AA, stated, "All care plans and comprehensive assessments were re-done. All will be up to date."</p> <p>4. The interim clinic manager, employee CC, the Director of Operations, employee AA, and the interim assistant clinic manager, employee GG, were unable to provide any additional documentation and/or information when asked on 11-15-12 at 3:10 PM Central Time.</p>		<p>After the initial survey, 100% of all Assessments and Plans of Care were redone by 11/9/12. After the revisit, additional areas of noncompliance were identified and the Governing Body decided that to ensure compliance – the IDT would be re-educated again as noted above and 100% of all Assessments and Plans of Care will be redone a second time focusing on patient participation in the development of their Plan of Care. All Assessments including patients # 1 and 3 will be completed and presented to the IDT for completion of their Plans of Care by 12/14/12.</p> <p>The Clinical Manager or Charge Nurse will keep a checklist of each Plan of Care discussed at the POC Meeting – that requires review with the patient because the patient has chosen not to participate in the Plan of Care Meeting. The Clinical Manager or Charge Nurse will present the individual Plans of Care for review with the patients as evidenced by his/her signature at their next scheduled dialysis treatment.</p> <p>The Clinical Manager will monitor all Plans of Care monthly for patient signatures to ensure all patients whose POC has been done that month and are included on the checklist, have signatures obtained within 7 days per policy or documentation has been</p>		

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			<p>provided as to why a signature is either late or still missing such as the patient has been hospitalized. Any POC's found out of compliance will be immediately presented to the Director of Operations, scheduled for completion within the next 30 days and corrective action will be taken as appropriate.</p> <p>The Clinical Manager is responsible to report a summary of findings monthly to the QAI.</p> <p>The QAI Committee provides the oversight to ensure resolution. If resolution is not occurring, the QAI Committee is responsible to analyze the results, determine a root cause analysis and resolve the issues. Ongoing non-compliance will not be tolerated and all actions will be monitored by the QAI Committee.</p> <p>The Director of Operations is responsible to ensure the results of the audits will be reviewed during the monthly QAI meeting and reported to the Governing Body.</p>		

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V000551	<p>494.90(a)(5) POC-VA MONITOR/PREVENT FAILURE/STENOSIS The patient's vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis. Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care provided for vascular access monitoring in 1 (# 3) of 4 records reviewed creating the potential to affect all of the facility's 131 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. Clinical record number 3 included a plan of care dated 10-24-12 that identified the patient's access was an arteriovenous fistula. The plan of care failed to evidence interventions to monitor and maintain the fistula.</li> <li>2. During the entrance conference on 11-15-12 at 10:00 AM Central Time, the Director of Operations, employee AA, stated, "All care plans and comprehensive assessments were re-done. All will be up to date."</li> <li>3. The interim clinic manager, employee CC, the Director of Operations, employee AA, and the interim assistant clinic manager, employee GG, were unable to</li> </ol>	V000551	<p>On 11/2/12 the Director of Operations met with members of the IDT and then on 11/19/12, the Regional Quality Manager met with the members of the IDT to emphasize the requirements as defined within the Conditions of Coverage and Fresenius policy "Comprehensive Interdisciplinary Assessment and Plan of Care" that all patients must have a Plan of Care that includes vascular access monitoring. Emphasis was placed upon including interventions to monitor and maintain the patient's access.</p> <p>After the initial survey, 100% of all Assessments and Plans of Care were redone by 11/9/12. After the revisit, additional areas of noncompliance were identified and the Governing Body decided that to ensure compliance – the IDT would be re-educated again as noted above and 100% of all Assessments and Plans of Care will be redone a second time focusing on vascular access monitoring. All Assessments</p>	12/14/2012	

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	<p>provide any additional documentation and/or information when asked on 11-15-12 at 3:10 PM Central Time.</p> <p>4. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care" policy number FMS-CS-IC-I-110-125A states, "The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Vascular Access and PD Access. Provide vascular access monitoring."</p>		<p>including patient # 3 will be completed and presented to the IDT for completion of their Plans of Care by 12/14/12.</p> <p>A tracking tool has been instituted to ensure that all new patients, patients returning from hospitalizations, and 90 day and annual Reassessments and Plans of Care will be scheduled and completed as due.</p> <p>The Clinical Manager is responsible to present a list of those patients' whose Plans of Care were due and those who's Plans of Care were completed to the QAI Committee on a monthly basis to ensure POC's are being completed when due.</p> <p>The Clinical Manager will ensure ongoing compliance by auditing all Plans of Care completed each month focusing on patient's accesses. Any Plan of Care found out of compliance will be addressed immediately, reported to the Director of Operations and corrective action will occur as appropriate. Frequency of ongoing monitoring will be determined by the QAI Committee based on monitoring results and resolution of the issues.</p>		

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			<p>The Clinical Manager is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of Correction prior to presenting the monthly data to the QAI Committee for oversight and review.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans.</p> <p>The QAI Committee provides the oversight to ensure resolution. If resolution is not occurring, the QAI Committee is responsible to analyze the results, determine a root cause analysis and resolve the issues. Ongoing non-compliance will not be tolerated and all actions will be monitored by the QAI Committee.</p>		

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V000552	<p>494.90(a)(6) POC-P/S COUNSELING/REFERRALS/HRQOL TOOL The interdisciplinary team must provide the necessary monitoring and social work interventions. These include counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.</p> <p>Based on clinical record and facility policy review and interview, the facility failed to ensure plans of care addressed identified psychosocial problems and provided for monitoring of patients' psychosocial status in 3 (#s 1, 3, and 4) of 4 records reviewed creating the potential to affect all of the facility's 131 current patients.</p> <p>The findings include:</p> <p>1. Clinical record number 1 included a plan of care (PoC) dated 11-09-2012 that evidenced issues identified in the comprehensive assessment related to "Relationship/Social network problems, pt [patient] [child] mental health issues, Advance Directives/End of life concern . . . Insurance or financial resources needs FC referral."</p> <p>A. The PoC included the expected</p>	V000552	<p>On 11/2/12, the Director of Operations reviewed the "Comprehensive Interdisciplinary Assessment and Plan of Care" policy with the Social Worker in reference to the requirement to include interventions in each patient's Plan of Care for identified psychosocial needs. Again on 11/19/12 the Regional Quality Manager met with the Social Worker to review the requirement of including interventions in each of the patient's Plan of Care for any identified psychosocial need.</p> <p>After the initial survey, 100% of all Assessments and Plans of Care were redone by 11/9/12. After the revisit, additional areas of noncompliance were identified and the Governing Body decided that to ensure compliance – the Social Worker should be</p>	12/14/2012			

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	<p>goal/outcome "Pt &amp; [spouse] continue to minimize impact of [child] on them through distance/setting boundaries [unreadable] cover."</p> <p>B. The plan failed to evidence interventions to achieve the desired goal/outcome.</p> <p>2. Clinical record number 3 included a PoC dated 10-24-12 that included the expected goal/outcome "Pt will continue status without change."</p> <p>The plan failed to evidence interventions to monitor the patient's psychosocial status to achieve the desired goal/outcome.</p> <p>3. Clinical record number 4 included a PoC dated 11-09-2012 that evidenced issues identified the comprehensive assessment related to "Coping and adjustment to dialysis . . . Insurance or financial resources."</p> <p>A. The plan included an expected goal/outcome for the "pt to verbalize improved ability to cope with chronic illness . . . MSW [medical social worker] use screening tool w/ [with] pt regarding depression. MSW address finding from screening within 6 weeks."</p>		<p>re-educated again as noted above and 100% of all Assessments and Plans of Care will be redone a second time focusing on interventions whenever psychosocial issues are identified. All Assessments including patient # 1, 3 and 4 will be completed and presented to the IDT for completion of their Plans of Care by 12/14/12.</p> <p>Monthly monitoring of all Plans of Care completed that month will be done by the Clinical Manager, to ensure the patients' psychosocial needs have been identified, are addressed and Plans of Care are being updated timely and appropriately. Any POCs found out of compliance will be addressed immediately with the Social Worker, reported to the Director of Operations, scheduled for completion within the next 30 days and corrective action will be taken as appropriate. Frequency of ongoing monitoring will be determined by the QAI Committee based on resolution of the issues.</p> <p>The Clinical Manager is responsible to analyze and trend all data and monitoring/audit results as related to this Plan of</p>				

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	<p>B. The plan failed to evidence interventions to address the identified issues to achieve the desired goal/outcome.</p> <p>4. During the entrance conference on 11-15-12 at 10:00 AM Central Time, the Director of Operations, employee AA, stated, "All care plans and comprehensive assessments were re-done. All will be up to date."</p> <p>5. The medical social worker, employee V, stated, on 11-15-12 at 1:05 PM Central Time, "Other social workers came and helped us get the care plans done. I did review all of them." Employee V indicated the plans of care did not include patient specific interventions to address identified needs and to monitor the patients' psychosocial status.</p> <p>6. The interim clinic manager, employee CC, the Director of Operations, employee AA, and the interim assistant clinic manager, employee GG, were unable to provide any additional documentation and/or information when asked on 11-15-12 at 3:10 PM Central Time.</p> <p>7. The facility's 07-04-2012 "Comprehensive Interdisciplinary Assessment and Plan of Care policy number FMS-CS-IC-I-110-125A states,</p>		<p>Correction prior to presenting the monthly data to the QAI Committee for oversight and review.</p> <p>The Director of Operations is responsible to ensure all documentation required as part of the QAI process; is presented, current, analyzed, trended and a root cause analysis completed as appropriate with the subsequent development of action plans.</p> <p>The QAI Committee provides the oversight to ensure resolution. If resolution is not occurring, the QAI Committee is responsible to analyze the results, determine a root cause analysis and resolve the issues. Ongoing non-compliance will not be tolerated and all actions will be monitored by the QAI Committee.</p>		

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	"The patient's individualized comprehensive Plan of Care must include, but is not limited to the following: . . . Psychosocial status. Provide necessary monitoring and social work interventions, including counseling services and appropriate referrals."			

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V000750	<p>Based on facility administrative record review and interview, it was determined the facility failed to be in compliance with this condition by failing to ensure the governing body had appointed an individual who would be responsible for the management of the facility creating the potential to affect all of the facility's 131 current patients (See V 752) and by failing to ensure a clinic manager would be present a sufficient amount of time to meet the needs of the patients creating the potential to affect all of the facility's 131 current patients (See V 757).</p> <p>The cumulative effect of these systemic problems resulted in the facility inability to be in compliance with this condition, 42 CFR 494.180 Governance.</p>	V000750	<p>The Governing Body understands and acknowledges their role and responsibilities to ensure that the facility has appointed an individual who serves as the dialysis facility administrator and is responsible for the management of the facility and the provision of all dialysis services as required by the Conditions for Coverage.</p> <p>Upon receipt of the SOD from the resurvey, the Governing Body reviewed the SOD in light of the previously submitted Plan of Correction, determined the immediate correction required and the following action steps were agreed upon and implemented:</p> <p>Effective immediately:</p> <ul style="list-style-type: none"> <li>· The Governing Body will meet weekly to review the status of the Plan of Correction specific to this Statement of Deficiencies.</li> <li>· The Clinical Manager will continue to analyze and trend all data and monitoring/audit results as related to this Plan of Correction focusing on the</li> </ul>	11/26/2012	

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			<p>specifics that were recently identified in the Statement of Deficiency prior to presenting the monthly data to the QAI Committee for oversight and review.</p> <ul style="list-style-type: none"> <li>The Director of Operations will present an update on the Plan of Correction data specific to both the original and subsequent follow up Statement of Deficiency and all other actions taken toward the resolution of the deficiencies at each Governing Body meeting through to the resolution.</li> <li>The original Plan of Correction was reviewed to determine the root cause of those Conditions/standards that were not resolved and a subsequent specific plan of action encompassing the citations as cited in the Statement of Deficiency has been added to the facility's monthly QAI (Quality Assessment and Performance Improvement) Agenda. The QAI Committee is responsible to review and evaluate the Plan of Correction to ensure it is effective and is providing resolution of both the original issues and those follow up issues not resolved.</li> </ul>		

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			<ul style="list-style-type: none"> <li>· The processes as noted in this POC will be reviewed by the Governing Body at each meeting. These meetings will ensure ongoing progress towards resolution of noted deficiencies is being provided.</li> <li>· Minutes of the Governing Body and QAI meetings, as well as monitoring forms, educational documentation will provide evidence of these actions, the Governing Body's direction and monitoring of facility activities. These will be available for review at the facility.</li> </ul> <p>The response provided for V 752 describes, in detail, the processes taken to ensure that the facility has appointed an individual who exercised responsibility for the management of the facility and the provision of all dialysis services.</p> <p>The response provided for V 757 describes, in detail, the processes and monitoring steps taken to ensure that the facility has a Clinical Manager.</p>		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  152571		X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		X3) DATE SURVEY COMPLETED  11/15/2012	
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V000752	<p>494.180(a) GOV-APPOINT CEO/ADMINISTRATOR The governing body or designated person responsible must appoint an individual who serves as the dialysis facility's chief executive officer or administrator who exercises responsibility for the management of the facility and the provision of all dialysis services, Based on facility administrative record review and interview, the governing body failed to appoint an individual who would be responsible for the management of the facility creating the potential to affect all of the facility's 131 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. The facility's governing body meeting minutes, dated 11-02-12 and 11-09-12, failed to evidence the governing body had appointed an individual to be responsible for the day to day operations of the clinic.</li> <li>2. The Director of Operations, employee AA, stated, on 11-15-12 at 12:05 PM Central Time, "[Employee CC] is ultimately responsible [for the day to day operation of the facility]. Employee CC and employee GG plan from week to week who is going to be here on what days. They talk every day. It is not reflected in the governing body meeting minutes that this is the plan until we can hire someone to fill the clinic manager position."</li> </ol>	V000752	<p>The Governing Body met on November 2, 2012 and again on November 9, 2012, to review the requirement that the facility appoints an individual that is available full time to provide oversight and management within the dialysis facility.</p> <p>Upon review of the Statement of Deficiency received post the CMS Resurvey, the Governing Body met on November 20, 2012 and reviewed the current status utilizing the Operation Manager as the Interim Manager and determined to appoint a full time qualified Clinical Manager, who although "Interim" will be available within the facility on a full time basis as the sole Interim Manager. Additionally, the Governing Body agreed that previous actions, although taken, had not been documented within the GB Minutes.</p>	11/26/2012			

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	3. The facility's undated "Governing Body General Rules" document states, "The Chairperson is responsible for the agenda of the meeting. Agenda items include but are not limited to the following: . . . Resignation of a Key Member of the facility staff and the appointment of a replacement or interim replacement (Interim coverage meaning responsible for all aspects of the position until permanent replacement is found.)"		By November 19, 2012, the Director of Operations will update- through late entry – the most recent Governing Body Minutes to reflect all personnel changes taken to ensure the facility has a FT qualified Clinical Manager in place who is responsible for the management of the facility.  On 11/26/12, the Operations Manager was replaced with a new interim manager who was appointed upon review of the Statement of Deficiency received post the CMS Resurvey, the Governing Body met on November 19, 2012 and reviewed the current status utilizing the Operation Manager as the Interim Manager and determined to appoint a full time qualified Clinical Manager, who although "Interim" will be available within the facility on a full time basis as the sole Interim Manager. Additionally, the Governing Body agreed that previous actions, although taken, had not been documented within the GB Minutes.  By November 26, 2012, the		

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			<p>Director of Operations will update- through late entry – the most recent Governing Body Minutes to reflect all personnel changes taken to ensure the facility has a FT qualified Clinical Manager in place who is responsible for the management of the facility.</p> <p>On 11/26/12, the Operations Manager was replaced with a new interim manager who was adopted by the GB during their weekly GB call. Documentation is available within the Governing Body Minutes.</p> <p>The Interim Clinical Manager will report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body. by the GB during their weekly GB call. Documentation is available within the Governing Body Minutes.</p> <p>The Interim Clinical Manager will report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.</p>		

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V000757	<p>494.180(b)(1) GOV-STAFF # &amp; RATIO MEET PT NEEDS The governing body or designated person responsible must ensure that-</p> <p>(1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of patients; Based on facility administrative record review and interview, the governing body failed to ensure a clinic manager would be present a sufficient amount of time to meet the needs of the patients creating the potential to affect all of the facility's 131 current patients.</p> <p>The findings include:</p> <ol style="list-style-type: none"> <li>1. The facility's governing body meeting minutes, dated 11-02-12 and 11-09-12, failed to evidence the governing body had appointed an individual to be responsible for the day to day operations of the clinic.</li> <li>2. The Director of Operations, employee AA, stated, on 11-15-12 at 12:05 PM Central Time, "[Employee CC] is ultimately responsible [for the day to day operation of the facility]. Employee CC and employee GG plan from week to week who is going to be here on what days. They talk every day. It is not reflected in the governing body meeting minutes that this is the plan until we can hire someone to fill the clinic manager</li> </ol>	V000757	<p>The Governing Body met on November 2, 2012 and again on November 9, 2012, to review the requirement that the Clinical Manager is present a sufficient amount of time to meet the needs of the patients and fulfill the management needs of the dialysis facility.</p> <p>Upon review of the Statement of Deficiency received post the CMS Resurvey, the Governing Body met on November 20, 2012 and reviewed the current status utilizing the Operation Manager as the Interim Manager. The GB determined that in order to ensure the Interim Clinical Manager is present within the facility a sufficient amount of time to meet the needs of the patients that a different full time qualified Clinical Manager will be appointed and be available full time as the sole Interim Clinical Manager.</p>	11/26/2012			

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	position."  3. The facility's undated "Governing Body General Rules" document states, "The Chairperson is responsible for the agenda of the meeting. Agenda items include but are not limited to the following: . . . Resignation of a Key Member of the facility staff and the appointment of a replacement or interim replacement (Interim coverage meaning responsible for all aspects of the position until permanent replacement is found.)"		On 11/26/12, the Operations Manager was replaced with a new interim manager who was appointed by the GB during their weekly GB call. Documentation is available within the Governing Body Minutes.  The Interim Clinical Manager will report a summary of findings monthly in QAI and compliance will be monitored by the Governing Body.		