

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  15C0001062	X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____	X3) DATE SURVEY COMPLETED  07/24/2013
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NAME OF PROVIDER OR SUPPLIER  NORTHSIDE GASTROENTEROLOGY ENDOSCOPY CENTER, L	STREET ADDRESS, CITY, STATE, ZIP CODE 8424 NAAB ROAD, SUITE 3G INDIANAPOLIS, IN 46260
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S000000	<p>This visit was for a State licensure survey.</p> <p>Facility Number: 008902</p> <p>Survey Date: 7/23/2013 through 7/24/2013</p> <p>Surveyors: Albert Daeger, CFM, SFPIO Medical Surveyor</p> <p>Saundra Nolfi, RN Public Health Nurse Surveyor</p> <p>QA: claughlin 07/31/13</p>	S000000		
S000300	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 15-2.4-2(a)</p> <p>(a) The center must develop, implement, and maintain an effective, organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the center participate. The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p>			

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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	<p>Based on document review and staff interview, the facility failed to ensure inclusion of 2 services provided by contractors as part of its comprehensive quality assessment and improvement (QAPI) program: Laboratory, Radiology.</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>Quality Management/Performance Improvement Program policy (Last approved February 21, 2013) indicates all service with direct or indirect impact on patient care quality shall be reviewed under the quality improvement program.</li> <li>The QAPI committee minutes were reviewed for the last 3 quarters of 2012 and the 1st quarter of 2013. The documentation provided by staff member #1 evidenced the Radiology and Laboratory Services were not being monitored</li> </ol>	S000300	<p>410 IAC 15-2.4-2 QUALITY ASSESSMENT AND IMPROVEMENT The Center will develop, implement, and maintain an effective organized, center-wide, comprehensive quality assessment and improvement program in which all areas of the Center participate. The Center must assure that contract services are provided in a safe and effective manner. PLAN OF CORRECTION: The Governing Body through the QAPI Committee will evaluate contract services on an annual basis to assure that they comply with State and Federal Regulations. SYSTEMIC CHANGES: A checklist for contract services of laboratory and radiology has been developed and will be used quarterly with each of these contractors providing services to the Center (Attachment A). This documentation will be maintained at the Center. RESPONSIBLE PARTY &amp; MONITORING: The Center Director will be responsible for the completion of the annual evaluation process for contracted services and will ensure that this information is completed and evaluated annually by the QAPI Committee with results and recommendations submitted to the Governing Body</p>	08/12/2013			



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	<p>and staff interview, the facility failed to ensure the composition of the Infection Control Committee complied with the Infection Control Management Plan.</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>1. The Infection Control Management Plan (Last approved February 21, 2013) states, "The QAPI Committee serves as the Infection Control Committee."</li> <li>2. The QAPI committee minutes were reviewed for the Last 3 quarters of 2012 and the 1st quarter of 2013. The QAPI committee minutes did not discuss the Infection Control items that are required to be addressed per the Infection Control Management Plan.</li> <li>3. At 2:15 PM on 7/23/2013, staff member #1 indicated he/she did not realize the Infection Control Management Plan specifies the Infection Control Committee be</li> </ol>		<p><b>CONTROL PROGRAM</b> The Center will establish a committee to monitor and guide the infection control program with will meet at least quarterly with a membership that includes the Infection Preventionist, a member of the medical staff, a member of the nursing staff, and consultants from other appropriate services as needed.</p> <p><b>PLAN OF CORRECTION:</b> The facility will ensure the composition of the Infection Control Committee complies with the Infection Control Management Plan. The QAPI Committee which serves as the Infection Control Committee will address the Infection Control items that are required to be addressed per the Infection Control Management Plan. This will be documented in the QAPI minutes. (Appendix B &amp; C)</p> <p><b>RESPONSIBLE PARTY &amp; MONITORING:</b> The Center Director is responsible to ensure adherence to the Infection Control Program. Results of Infection Control initiatives or indicators, infection control training of staff and providers, and monitoring of infection control concerns will be reported to the QAPI Committee with results</p>	

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	integrated into the QAPI Committee. The staff member indicated the staff attend an Infection Control Committee which meets at different days as the QAPI Committee. The Pharmacy Consultant attends the QAPI Committee; however, does not meet with staff discussing infection control concerns. The staff member confirmed the Infection Control team does not discuss the required infection control issues as documented in the Infection Control Management Plan in the QAPI Committee meetings.		and recommendations submitted to the Governing Body at regularly scheduled meetings.	

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S000432	<p>410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(E)(iii)</p> <p>The infection control committee responsibilities must include, but are not limited to:</p> <p>(E) Reviewing and recommending changes in procedures, policies, and programs which are pertinent to infection control. These include, but are not limited to, the following:</p> <p>(iii) Cleaning, disinfection, and sterilization.</p> <p>Based on observation, contracted cleaning service staff files, and interview, the infection control committee failed to ensure the contracted housekeeping staff used the proper cleaning products according to manufacturer instructions and adequately cleaned all patient areas.</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>1. During the tour of the pre/post area of the facility at 1:15 PM on 07/23/13, accompanied by staff member A1, the wall ledges, window sills, and wall suction canisters in the individual bays were observed to be very dusty.</li> <li>2. Review of the contracted cleaning service staff files indicated documents signed on 06/02/10 by the cleaning</li> </ol>	S000432	<p>422 410 IAC 15-2.5-1 INFECTION CONTROL PROGRAM 410 IAC 15-2.5-1(f)(2)(C)</p> <p>The infection control committee responsibilities include reviewing and recommending changes in procedures, policies and programs pertinent to infection control including cleaning, disinfection, and sterilization.</p> <p>PLAN OF CORRECTION: Ensuring environmental cleaning is performed in accordance with nationally accepted standards and manufacturer's recommendations (Attachment D, Janitorial Service Checklist).</p> <p>SYSTEMIC CHANGES: The Center Director, or her designee, provided training to the staff on the following: 1) Ensuring environmental cleaning is performed in accordance with nationally accepted standards and</p>	08/12/2013

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	<p>personnel, A8 and A10, which indicated, "I agree to use, without exception, the cleaners specified on the List of Cleaning Products while performing my housekeeping duties at [the facility]." Also in the file was the List of Cleaning Products which specified nine different products, including Neutral Cleaner and Oxivir Tb Broad Spectrum Germicidal Sanitizer.</p> <p>3. At 12:40 PM on 07/24/13, cleaning service staff member A8 was interviewed and the housekeeping storage area was toured. Staff member A8 indicated he/she used Virex 256 to mop the floors and described the process as letting it set for about a minute, then going back over it. Label directions indicated the areas were to remain wet for 10 minutes for effective disinfection. Staff member A8 also indicated he/she used TB-cide Quat on surface areas and described the process as spraying the areas, waiting 3 minutes, then wiping the surfaces. Label directions indicated surfaces were to remain wet for 5 minutes for effective disinfection. The chemicals, Virex 256 and TB-cide Quat, were observed in the housekeeping storage area, while the chemicals, Neutral Cleaner and Oxivir Tb Broad Spectrum Germicidal Sanitizer, were not.</p>		<p>manufacturer's recommendations.</p> <p>2) Ensuring that the cleaners as specified on the list of cleaning products are available in the facility for use by the contracting staff.</p> <p>RESPONSIBLE PARTY &amp; MONITORING: The Center Director is responsible for ensuring compliance with:</p> <p>1) Ensuring environmental cleaning is performed in accordance with nationally accepted standards and manufacturer's recommendations. Cleaning services will be observed weekly beginning 8/12/13 for a period of one month; if services are satisfactory they will be observed monthly for a period of three months; if services are satisfactory observations will be conducted quarterly.</p> <p>2) Ensuring that the cleaners as specified on the list of cleaning products are available in the facility for use by the contracting staff. An ongoing audit of these areas will be conducted to ensure compliance. Results of all audits will be reported to the QAPI Committee quarterly with results and any recommendations submitted to the Governing Body on a semi-annual basis.</p>		

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S000780	<p>4. At 1:25 PM on 07/24/13, staff member A1 confirmed the cleaning observations and also confirmed the chemicals used did not match the chemicals specified on the list. He/she indicated he/she talked with the cleaning staff to ensure the cleaning was done according to expectations, but did not actually follow the staff to observe the cleaning process.</p> <p>410 IAC 15-2.5-4 MEDICAL STAFF; ANESTHESIA AND SURGICAL 410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based on policy review, medical record review, and interview, the facility failed to ensure their policies were followed regarding standing orders in 27 of 27 patient charts reviewed (#P1 - P27).</p> <p>Findings included:</p>	S000780	410 IAC 15-2.5-4 MEDICAL STAFF, ANESTHESIA AND SURGICAL PLAN OF CORRECTION: Drugs will be prepared and administered per established policy, established standard of care, and	08/22/2013			

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	<p>1. The facility policy "Physician Orders", last approved 02/21/13, indicated, "Standing/Routine Orders-...Placed on the patient's chart and signed by the physician. A licensed nurse shall countersign and date and time all orders. A physician shall countersign the orders within 24 hours to include date and time."</p> <p>2. The facility policy "Admission Process", last approved 02/21/13, indicated, "IV [intravenous] access is established if indicated for the procedure. 9% Normal Saline or D5W will be administered per physician order."</p> <p>3. Review of the medical record for patient #P1, who had a procedure on 01/02/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 220 ml. (milliliters) of 0.9% Normal Saline solution was administered intravenously.</p> <p>4. Review of the medical record for patient #P2, who had a procedure on 01/08/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked</p>		<p>only with specific physician orders at alltimes. The Center will ensure that their policiesare followed in regard to standing orders. SYSTEMIC CHANGES: I. All medications will be ordered by aphysician or other qualified member of the medicalstaff acting within the scope of their practice,prior to the administration in the ASC. The clinical staff have been in-serviced on the ASC'spolicies on: 1) C6.3 Administration of Medication 2) C6.30 Intravenous Therapy 3) C6.24 Prescriptions (Attachment E). All medication orders will be signed prior to the administration of the medication. All staff with responsibilityfor administering medication have been provided additional education on all aspects ofmedication administration. RESPONSIBLE PARTY/MONITORING: I. The Center Director is responsible formonitoring compliance. The Center Director or her designee will audit all medical records fordocumentation of a physician's order and signature prior to administration of all medications for aperiod of 3 weeks beginning 8/26/2013. If 100% compliance is achieved, ongoing spot check monitoring shall occur on at least a monthlybasis.</p>	

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	<p>any order for any IV solution, but nursing documentation indicated 120 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>5. Review of the medical record for patient #P3, who had a procedure on 01/16/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 125 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>6. Review of the medical record for patient #P4, who had a procedure on 01/28/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 225 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>7. Review of the medical record for patient #P5, who had a procedure on 01/31/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 125 ml. of 0.9% Normal Saline solution was administered intravenously.</p>		<p>If 100% compliance is not achieved, re-education shall occur and the monitoring process will start over. Findings will be reported to the QAPI and Governing Body quarterly.</p>				

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	<p>8. Review of the medical record for patient #P6, who had a procedure on 02/06/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 100 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>9. Review of the medical record for patient #P7, who had a procedure on 02/14/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 150 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>10. Review of the medical record for patient #P8, who had a procedure on 02/20/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 100 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>11. Review of the medical record for patient #P9, who had a procedure on 02/27/13, indicated a standing order, "2.</p>			

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	<p>Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 200 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>12. Review of the medical record for patient #P10, who had a procedure on 02/28/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 200 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>13. Review of the medical record for patient #P11, who had a procedure on 03/04/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 100 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>14. Review of the medical record for patient #P12, who had a procedure on 03/12/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 225</p>						

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	<p>ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>15. Review of the medical record for patient #P13, who had a procedure on 03/14/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 175 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>16. Review of the medical record for patient #P14, who had a procedure on 03/25/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 125 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>17. Review of the medical record for patient #P15, who had a procedure on 03/29/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 125 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>18. Review of the medical record for</p>						

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	<p>patient #P16, who had a procedure on 04/01/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 200 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>19. Review of the medical record for patient #P17, who had a procedure on 04/04/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 200 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>20. Review of the medical record for patient #P18, who had a procedure on 04/15/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The record lacked any order to not place IV access; however, nursing documentation indicated, "No sedation/no oxygen/no IV." Nursing documentation also indicated 250 ml. Normal Saline was hung at 0927.</p> <p>21. Review of the medical record for patient #P19, who had a procedure on 04/19/13, indicated a standing order, "2. Place IV access unless otherwise</p>						

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
	<p>indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 100 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>22. Review of the medical record for patient #P20, who had a procedure on 04/30/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 450 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>23. Review of the medical record for patient #P21, who had a procedure on 05/02/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 225 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>24. Review of the medical record for patient #P22, who had a procedure on 05/09/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 150 ml. of 0.9% Normal Saline solution was</p>			

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NAME OF PROVIDER OR SUPPLIER  NORTHSIDE GASTROENTEROLOGY ENDOSCOPY CENTER, L				STREET ADDRESS, CITY, STATE, ZIP CODE 8424 NAAB ROAD, SUITE 3G INDIANAPOLIS, IN 46260			
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	<p>administered intravenously.</p> <p>25. Review of the medical record for patient #P23, who had a procedure on 05/17/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 125 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>26. Review of the medical record for patient #P24, who had a procedure on 05/20/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 100 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>27. Review of the medical record for patient #P25, who had a procedure on 05/31/13, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 250 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>28. Review of the medical record for patient #P26, who had a procedure on</p>						

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	<p>08/01/12 and was transferred, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 370 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>29. Review of the medical record for patient #P27, who had a procedure on 05/14/13 and was transferred, indicated a standing order, "2. Place IV access unless otherwise indicated." The standing orders lacked any order for any IV solution, but nursing documentation indicated 350 ml. of 0.9% Normal Saline solution was administered intravenously.</p> <p>30. At 1:50 PM on 07/24/13, staff member A1 confirmed the medical record findings and confirmed the lack of any physician orders for the IV fluids. He/she indicated the policies needed to be changed to reflect the practice of standing orders on the electronic medical records.</p>			

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S001024	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES 410 IAC 15-2.5-6(3)(E)</p> <p>Pharmaceutical service must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(E) Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms and the following: Based on observation, policy review, and interview, the facility failed to ensure syringes of medication were labeled according to policy and standard of practice.</p> <p>Findings included:</p> <ol style="list-style-type: none"> <li>During the tour of the procedure areas at 2:00 PM on 07/23/13, accompanied by staff member A1, two syringes of predrawn medication were observed in a locked drawer in procedure room #2. One syringe had a label wrapped around it that indicated "Versed 5 7/23" and the label on the other syringe only indicated "Fentanyl".</li> <li>The facility policy "Administration of</li> </ol>	S001024	<p>410 IAC 15-2.5-6 PHARMACEUTICAL SERVICES PLAN OF CORRECTION: The Center will ensure that drugs are prepared and administered according to established policies and acceptable standards of practice. The Center will ensure that all medications drawn up are clearly labeled with the drug name, dosage, date and initials of the person who prepared the medication. SYSTEMIC CHANGES: 1) The article "Syringe Labeling Made Simple," has been reviewed with all clinical Center staff 2) The article "Syringe Swaps in the OR Still Harming Patients" has been reviewed with all clinical Center staff.</p>	08/12/2013

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	<p>Medication", last approved 02/21/13, indicated, "All medications are prepared using clean or sterile techniques, and all 'drawn up' medications will be labeled with the name of drug, strength, amount, date prepared and initials of preparer."</p> <p>3. At 2:30 PM on 07/23/13, staff member A1 indicated staff were aware of the proper way to label the predrawn syringes and confirmed the syringes were not labeled according to policy.</p>		<p>3) The Article from APIC "Safe injection, infusion, and medication vial practices in healthcare." (Attachment F) RESPONSIBLE PARTY AND MONITORING: The Center Director is responsible for monitoring compliance. The Center Director or her designee will monitor the Center's syringe labeling for unlabeled and improperly labeled medications each month for 3 months beginning 8/12/2013. The Center Director or her designee will spot check each area for a period of one month. If 100% compliance is achieved, ongoing spot check monitoring shall occur on at least a monthly basis and will be documented on the Medication Label Audit Form (Attachment G). If 100% compliance is not achieved, re-education shall occur and the monitoring process will start over. The results of all audits will be tabulated and presented to the QAPI Committee on a quarterly basis or review and recommendations. Recommendations will be presented to the Governing Body quarterly for review and approval.</p>		