

Division of Health Care Facilities

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNPL53526	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 05/28/2013
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NAME OF PROVIDER OR SUPPLIER KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916
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A 303	<p>1200-8-10-.03 (1)(c) Disciplinary Procedures</p> <p>(1) The board may suspend or revoke a license for:</p> <p>(c) Permitting, aiding or abetting the commission of any illegal act in the ASTC; This Rule is not met as evidenced by: Based on observation, review of the Code of Federal Regulations, and interview, the facility failed to follow professional and legally recognized standards of practice related to medication administration.</p> <p>The findings included:</p> <p>Observation of the locked narcotic box, on May 28, 2013, at 11:15 a.m., in the sterilization room, revealed one prescription bottle (named Pharmacy) with seventeen white pills in the bottle. Continued observation revealed the label had a (named individual) on the prescription label for "Hydrocodone 10mg (milligrams)/325 mg (Tylenol)...# (number) 20 (schedule II narcotic)..." Continued observation revealed the prescription was written by the facility's Nurse Practitioner (NP).</p> <p>Interview on May 28, 2013, at 11:15 a.m., in the sterilization room where the narcotic box was located, with the NP, revealed "...wrote the prescription to (named individual) who is an employee at the facility...rarely use Hydrocodone for our patients so the employee got the prescription filled and we give the patients the medications out of the bottle and log them...it is not economical for the facility to purchase the pills in bulk..."</p> <p>Review of the Code of Federal Regulations Title 21 Part 290- Controlled Drugs, Subpart A,</p>	A 303		

Division of Health Care Facilities LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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A 303	Continued From page 1 General Provisions, Sec. 290.5 Drugs, Statement of Required Warning, revealed "...the label of any drug listed as a 'controlled substance' in schedule 11, 111, or 1V of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: 'Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed...' "	A 303		
A 304	1200-8-10-.03 (1)(d) Disciplinary Procedures (1) The board may suspend or revoke a license for: (d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the ASTC; and This Rule is not met as evidenced by: Based on review of facility personnel files, credentialing files, interview, review of society Standards and Guidelines, review of Rules of the Tennessee Board of Medical Examiners, and review of Rules of Tennessee Department of Health Board For Licensing Health Care Facilities, the facility failed to ensure radiological/ultrasound services were performed by qualified personnel. The findings included:	A 304		

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A 304	<p>Continued From page 2</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed by the facility's Nurse Practitioner)...3/29/13..."</p> <p>Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files revealed the facility had a physician Board Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients</p>	A 304		
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A 304	<p>Continued From page 3</p> <p>by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision. Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM</p>	A 304		
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A 304	<p>Continued From page 4</p> <p>Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric, and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices, approved November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound</p>	A 304		

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A 304	<p>Continued From page 5</p> <p>Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized" certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised 2009, revealed, "...Qualifications of Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate</p>	A 304		
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A 304	<p>Continued From page 6</p> <p>training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a minimum of 1680 hours, or (2) successfully completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include</p>	A 304		

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A 304	<p>Continued From page 7</p> <p>hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the person's personnel file...authorized has the appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30</p>	A 304		

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A 304	Continued From page 8 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds.	A 304		
A 417	1200-8-10-.04 (13) Administration (13) Policies and procedures shall be consistent with professionally recognized standards of practice. This Rule is not met as evidenced by: Based on observation, review of the Code of Federal Regulations, interview, review of credentialing and personnel files, review of society Standards and Guidelines, and review of Tennessee Board of Medical Examiners and Tennessee Department of Health regulations, the facility failed to follow professional recognized standards of practice related to medication administration and failed to ensure radiological services were performed by qualified personnel. The findings included: Observation of the locked narcotic box, on May 28, 2013, at 11:15 a.m., in the sterilization room, revealed one prescription bottle (named Pharmacy) with seventeen white pills in the bottle. Continued observation revealed the label had a (named individual) on the prescription label for "Hydrocodone 10mg (milligrams)/325 mg	A 417		

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A 417	<p>Continued From page 9</p> <p>(Tylenol)...# (number) 20 (schedule II narcotic)..." Continued observation revealed the prescription was written by the facility's Nurse Practitioner (NP).</p> <p>Interview on May 28, 2013, at 11:15 a.m., in the sterilization room where the narcotic box was located, with the NP, revealed "...wrote the prescription to (named individual) who is an employee at the facility...rarely use Hydrocodone for our patients so the employee got the prescription filled and we give the patients the medications out of the bottle and log them...it is not economical for the facility to purchase the pills in bulk..."</p> <p>Review of the Code of Federal Regulations Title 21 Part 290- Controlled Drugs, Subpart A, General Provisions, Sec. 290.5 Drugs, Statement of Required Warning, revealed "...the label of any drug listed as a 'controlled substance' in schedule 11, 111, or 1V of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: 'Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed...'"</p> <p>Interview on May 28, 2013, at 11:15 a.m., in the sterilization room, with the Administrator, confirmed the prescription for Hydrocodone 10mg/325mg was written by the NP (in the named employees name) and filled by the (named employee). Continued interview confirmed the medications were dispensed to patients.</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical</p>	A 417		

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A 417	<p>Continued From page 10</p> <p>licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed by the facility's Nurse Practitioner)...3/29/13..."</p> <p>Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files revealed the facility had a physician Board Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to</p>	A 417		

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A 417	<p>Continued From page 11</p> <p>perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision. Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited</p>	A 417		
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A 417	<p>Continued From page 12</p> <p>Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric, and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices, approved November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other</p>	A 417		

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NAME OF PROVIDER OR SUPPLIER KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916
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A 417	<p>Continued From page 13</p> <p>Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized' certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised 2009, revealed, "...Qualifications of Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer</p>	A 417		

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A 417	<p>Continued From page 14</p> <p>should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a minimum of 1680 hours, or (2) successfully completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education</p>	A 417		

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A 417	<p>Continued From page 15</p> <p>requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the person's personnel file...authorized has the appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but</p>	A 417		

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A 417	Continued From page 16 was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds.	A 417		
A 420	1200-8-10-.04 (16) Administration (16) The governing body shall provide for the appointment, reappointment or dismissal of members of the medical, dental, and other health professions and provide for the granting of clinical privileges. This Rule is not met as evidenced by: Based on review of credentialing files, review of facility bylaws, and interviews, the facility governing body failed to appoint a Nurse Practitioner (NP) for clinical privileges since 1988 and failed to maintain a delineated list of clinical privileges for one of one NP credentialing files reviewed. The findings included: Review of the NP's credentialing file revealed the NP has not been appointed by the Board of Directors to practice at the facility since 1988. Review of the facility bylaws of the medical staff revealed the bylaws did not address allied health professionals, such as Nurse Practitioner (NP) or define any other practitioners others than physicians.	A 420		

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A 420	<p>Continued From page 17</p> <p>Review of the credentialing file for the NP revealed no list of delineated clinical privileges approved by the Board of Directors.</p> <p>Interview with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, confirmed the NP's personnel file does not contain a list of approved delineated clinical privileges by the Board of Directors. Continued interview with the NP revealed the NP job duties include performing ultrasounds, clinic visits, and prescribing medications. Continued interview with the NP revealed "they knew me before I started working here so there was no need."</p> <p>Interview with the Administrator on May 28, 2013 at 9:30 a.m., in the staff lounge, confirmed the NP has not been credentialed by the Board of Directors since 1988.</p>	A 420		
A 437	<p>1200-8-10-.04 (20)(c)6. Administration</p> <p>(20) Infection Control.</p> <p>(c) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develops guidelines and techniques for the prevention, surveillance, control and reporting of facility infections. Duties of the committee shall include the establishment of:</p> <p>6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;</p>	A 437		

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A 437	<p>Continued From page 18</p> <p>This Rule is not met as evidenced by: Based on observation and interview, the facility failed to maintain a safe and clean environment in the sterilization room.</p> <p>The findings included:</p> <p>Observation on May 28, 2013, at 12:15 p.m., in the clean sterilization room where sterile instruments and equipment are packaged and sterilized, revealed individual ceramic dolls, a personal fan, and individual (employee) pictures on the counters.</p> <p>Observation on May 28, 2013, at 12:30 p.m., in the clean sterilization room, revealed numerous unwrapped clean vaginal speculums in a plastic bin, stored on the counter.</p> <p>Interview with the Administrator and the facility Nurse Practitioner (NP), on May 28, 2013, at 12:30 p.m., in the clean sterilization room, confirmed the personal employee items were stored with clean sterile supplies. Continued interview revealed the clean vaginal speculums were unwrapped and stored next to personal items. The Administrator and NP confirmed clean items were stored with dirty items.</p>	A 437		
A 602	<p>1200-8-10-.06 (1)(b) Basic Services</p> <p>(1) Surgical Services.</p> <p>(b) If the facility provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality</p>	A 602		

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A 602	<p>Continued From page 19</p> <p>with inpatient care in accordance with the complexity of services offered.</p> <p>This Rule is not met as evidenced by: Based on review of facility personnel files, credentialing files, interview, review of society Standards and Guidelines, review of Rules of the Tennessee Board of Medical Examiners, and review of Rules of Tennessee Department of Health Board For Licensing Health Care Facilities, the facility failed to ensure radiological/ultrasound services were consistent in quality with inpatient care and performed by qualified personnel.</p> <p>The findings included:</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed</p>	A 602		

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A 602	<p>Continued From page 20</p> <p>by the facility's Nurse Practitioner)...3/29/13..." Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files revealed the facility had a physician Board Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who</p>	A 602		

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A 602	<p>Continued From page 21</p> <p>interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision. Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric,</p>	A 602		

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A 602	<p>Continued From page 22</p> <p>and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices, approved November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized' certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and</p>	A 602		

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A 602	<p>Continued From page 23</p> <p>Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised 2009, revealed, "...Qualifications of Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal</p>	A 602		
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A 602	<p>Continued From page 24</p> <p>ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a minimum of 1680 hours, or (2) successfully completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical</p>	A 602		

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NAME OF PROVIDER OR SUPPLIER KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916
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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) COMPLETE DATE
A 602	<p>Continued From page 25</p> <p>Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the person's personnel file...authorized has the appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds.</p>	A 602		
A 604	<p>1200-8-10-.06 (1)(d) Basic Services</p> <p>(1) Surgical Services.</p> <p>(d) The organization of the surgical services must be appropriate to the scope of the services offered.</p>	A 604		

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A 604	<p>Continued From page 26</p> <p>This Rule is not met as evidenced by: Based on review of facility personnel files, credentialing files, interview, review of society Standards and Guidelines, review of Rules of the Tennessee Board of Medical Examiners, and review of Rules of Tennessee Department of Health Board For Licensing Health Care Facilities, the facility failed to ensure radiological/ultrasound services were performed by qualified personnel.</p> <p>The findings included:</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed by the facility's Nurse Practitioner)...3/29/13..."</p> <p>Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files</p>	A 604		

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NAME OF PROVIDER OR SUPPLIER KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916
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A 604	<p>Continued From page 27</p> <p>revealed the facility had a physician Board Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision.</p>	A 604		

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A 604	<p>Continued From page 28</p> <p>Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric, and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the</p>	A 604		
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A 604	<p>Continued From page 29</p> <p>Accreditation of Ultrasound Practices, approved November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized" certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised</p>	A 604		

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A 604	<p>Continued From page 30</p> <p>2009, revealed, "...Qualifications of Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a</p>	A 604		

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A 604	<p>Continued From page 31</p> <p>minimum of 1680 hours, or (2) successfully completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the</p>	A 604		

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A 604	<p>Continued From page 32</p> <p>person's personnel file...authorized has the appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds.</p>	A 604		
A 609	<p>1200-8-10-.06 (1)(i) Basic Services</p> <p>(1) Surgical Services.</p> <p>(i) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.</p> <p>This Rule is not met as evidenced by: Based on review of facility personnel files, credentialing files, interview, review of society</p>	A 609		

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A 609	<p>Continued From page 33</p> <p>Standards and Guidelines, review of Rules of the Tennessee Board of Medical Examiners, and review of Rules of Tennessee Department of Health Board For Licensing Health Care Facilities, the facility failed to provide radiological/ultrasound services to achieve and maintain high standards of medical practice and patient care by ensuring ultrasounds were performed by qualified personnel.</p> <p>The findings included:</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed by the facility's Nurse Practitioner)...3/29/13..."</p> <p>Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files revealed the facility had a physician Board</p>	A 609		

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A 609	<p>Continued From page 34</p> <p>Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision. Documentation of this training must be</p>	A 609		
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A 609	<p>Continued From page 35</p> <p>maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric, and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices, approved</p>	A 609		
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A 609	<p>Continued From page 36</p> <p>November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized" certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised 2009, revealed, "...Qualifications of</p>	A 609		

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NAME OF PROVIDER OR SUPPLIER KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916
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A 609	<p>Continued From page 37</p> <p>Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a minimum of 1680 hours, or (2) successfully</p>	A 609		
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A 609	<p>Continued From page 38</p> <p>completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the person's personnel file...authorized has the</p>	A 609		
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A 609	<p>Continued From page 39</p> <p>appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds.</p>	A 609		
A 635	<p>1200-8-10-.06 (1)(p)14. Basic Services</p> <p>1. Surgical Services.</p> <p>(p) A crash cart must be available and include at a minimum the following medication and supplies:</p> <p>14. xylocaine (lidocaine)</p> <p>This Rule is not met as evidenced by: Based on observation and interview, the facility failed to ensure the required medications were available on the emergency crash cart.</p>	A 635		

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A 635	Continued From page 40 The findings included: Observation of the crash cart, on May 28, 2013, at 10:50 a.m., in the postoperative care area, revealed the emergency crash cart did not contain the required medications Lidocaine (medication given for cardiac dysrhythmia's). Interview with the facility Nurse Practitioner (NP), on May 28, 2013, at 10:50 a.m., confirmed the crash cart did not have the Lidocaine (a required medication) on the crash cart.	A 635		
A 680	1200-8-10-.06 (5) Basic Services (5) Pharmaceutical Services. The ASTC must provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times. This Rule is not met as evidenced by: Based on observation, review of the Code of Federal Regulations and interview, the facility failed to follow professional recognized standards of practice related to medication administration and failed to safely store medications. The findings included: Observation of the locked narcotic box, on May 28, 2013, at 10:35 a.m., in the sterilization room, revealed eleven individual small pill cups with two unidentified white pills in each cup.	A 680		

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A 680	<p>Continued From page 41</p> <p>Interview on May 28, 2013, at 10:35 a.m., in the sterilization room, with the NP, revealed the medications were "Vistaril (medication used for anxiety) 25mg and Phenergan (medication used for nausea) 25mg. Continued interview revealed the medications were taken from the pre-packaged containers and placed in the cup the last surgery day (Saturday May 25, 2013). Continued interview confirmed the medications were not labeled and the medications should have been discarded.</p> <p>Observation of the locked narcotic box, on May 28, 2013, at 11:15 a.m., in the sterilization room, revealed one prescription bottle (named Pharmacy) with seventeen white pills in the bottle. Continued observation revealed the label had a (named individual) on the prescription label for "Hydrocodone 10mg (milligrams)/325 mg (Tylenol)...# (number) 20 (schedule II narcotic)..." Continued observation revealed the prescription was written by the facility's Nurse Practitioner (NP).</p> <p>Interview on May 28, 2013, at 11:15 a.m., in the sterilization room where the narcotic box was located, with the NP, revealed "...wrote the prescription to (named individual) who is an employee at the facility...rarely use Hydrocodone for our patients so the employee got the prescription filled and we give the patients the medications out of the bottle and log them...it is not economical for the facility to purchase the pills in bulk..."</p> <p>Review of the Code of Federal Regulations Title 21 Part 290- Controlled Drugs, Subpart A, General Provisions, Sec. 290.5 Drugs, Statement of required warning, revealed "...the label of any drug listed as a 'controlled substance' in schedule</p>	A 680		

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A 680	<p>Continued From page 42</p> <p>11, 111, or 1V of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: 'Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed...' "</p> <p>Interview on May 28, 2013, at 11:15 a.m., in the sterilization room, with the Administrator, confirmed the prescription for Hydrocodone 10mg/325mg was written by the NP (for named employee) and filled by the (named employee). Continued interview confirmed the medications were dispensed to patients.</p> <p>Observation on May 28, 2013, at 10:48 a.m., in the recovery room crash cart revealed:</p> <ol style="list-style-type: none"> 1. One vial of Valium 5 milligram (mg) to 1 milliliter (ml) opened and not dated 2. One 10 ml bottle of Hydroxyzine (medication for anxiety and allergic reaction) opened and not dated 3. One 10 ml syringe of Normal Saline opened and not dated <p>Interview with the Nurse Practitioner, at that time, confirmed the medications were opened, available for use, and not dated.</p>	A 680		
A 682	<p>1200-8-10-.06 (7) Basic Services</p> <p>(7) Radiological Services. The ASTC shall provide within the facility, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical treatment center.</p>	A 682		

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A 682	<p>Continued From page 43</p> <p>This Rule is not met as evidenced by: Based on review of facility personnel files, credentialing files, interview, review of society Standards and Guidelines, review of Rules of the Tennessee Board of Medical Examiners, and review of Rules of Tennessee Department of Health Board For Licensing Health Care Facilities, the facility failed to ensure radiological/ultrasound services were performed by qualified personnel.</p> <p>The findings included:</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed by the facility's Nurse Practitioner)...3/29/13..."</p> <p>Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files</p>	A 682		

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A 682	<p>Continued From page 44</p> <p>revealed the facility had a physician Board Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision.</p>	A 682		

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A 682	<p>Continued From page 45</p> <p>Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric, and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the</p>	A 682		

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A 682	<p>Continued From page 46</p> <p>Accreditation of Ultrasound Practices, approved November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized" certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised</p>	A 682		

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A 682	<p>Continued From page 47</p> <p>2009, revealed, "...Qualifications of Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a</p>	A 682		

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A 682	<p>Continued From page 48</p> <p>minimum of 1680 hours, or (2) successfully completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the</p>	A 682		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: TNPL53526	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 05/28/2013
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NAME OF PROVIDER OR SUPPLIER KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 1547 WEST CLINCH AVENUE KNOXVILLE, TN 37916
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A 682	<p>Continued From page 49</p> <p>person's personnel file...authorized has the appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds.</p>	A 682		
A 686	<p>1200-8-10-.06 (7)(c)1. Basic Services</p> <p>(7) Radiological Services.</p> <p>1. Personnel - The ASTC shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.</p> <p>This Rule is not met as evidenced by:</p>	A 686		

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A 686	<p>Continued From page 50</p> <p>Based on review of facility personnel files, credentialing files, interview, review of society Standards and Guidelines, review of Rules of the Tennessee Board of Medical Examiners, and review of Rules of Tennessee Department of Health Board For Licensing Health Care Facilities, the facility failed to ensure radiological/ultrasound services were performed by qualified personnel and supervised by a full-time or part-time radiologist.</p> <p>The findings included:</p> <p>Review of facility personnel files revealed the facility had one Director of Counseling who held a Masters in Divinity and no health/medical licenses, training, or certifications. Further review of facility personnel files revealed the facility had an employee in the position of Counselor with no health/medical licenses, training, or certifications. Further review of the personnel files for both counselors revealed documentation of Basic Ultrasound Skills Evaluation. Review of the Basic Ultrasound Skills Evaluation for the Counselor revealed, "...Date 3-28-13...Number of Sonograms Performed: approximately 150...Evaluation of Trainer...Approved...Approved by Trainer (signed by the Director of Counseling/Masters of Divinity)...3-28-13..."</p> <p>Review of the Basic Ultrasound Skills Evaluation for the Director of Counseling revealed, "...Date 3-29-13 Number of Sonograms Performed: 2780 estimate for 5 ½ yrs (years) employment...Evaluation of Trainer...Approved...Approved by Trainer (signed by the facility's Nurse Practitioner)...3/29/13..."</p> <p>Review of the files revealed no other continuing education or ongoing training in ultrasounds.</p> <p>Review of facility credentialing and personnel files</p>	A 686		
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A 686	<p>Continued From page 51</p> <p>revealed the facility had a physician Board Certified in Obstetrics and Gynecology with privileges delineated. Further review revealed the facility had, on staff, a Nurse Practitioner (NP) who was an employee of the facility and no credentialing or privileging had been completed.</p> <p>Interview with the NP on May 28, 2013, at 10:25 a.m., in the Ultrasound room, revealed Abdominal and Transvaginal (a probe inserted into the vaginal vault to look at a woman's reproductive organs) Ultrasounds were performed on patients by the "counselors" to determine the gestational age of the fetus. Further interview revealed counselors are non-licensed/non-certified staff members who had been trained by the NP to perform the ultrasounds. Further interview revealed the facility followed National Abortion Federation (NAF) Clinical Policy Guidelines.</p> <p>Review of the NAF Clinical Policy Guidelines 2013 Compliance Agreement signed by the physician March 16, 2013, provided by the facility revealed, "...Please ask your Medical Director to read NAF's 2013 Clinical Policy Guidelines and to initial each section and sign at the bottom to confirm that your facility complies with the practices set forth by NAF...Limited Sonography in Abortion Care (initialed by the physician)...I certify that my facility complies with NAF's 2013 Clinical Policy Guidelines (initialed by the physician)...I agree to comply with NAF's Medical Personnel Credentialing Policies (initialed by the physician)...Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision.</p>	A 686		

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A 686	<p>Continued From page 52</p> <p>Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented...Standard 2: a system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges...References: 2. AIUM (American Institute of Ultrasound in Medicine) Official Statement: Limited Obstetrical Ultrasound. Approved November 2009...3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007..."</p> <p>Review of AIUM Official Statement: Limited Obstetrical Ultrasound, approved November 2009, revealed, "...Lack of qualification or inexperience of the sonographer/sonologist does not justify performance of a limited ultrasound examination when a standard examination is indicated. Sonographer/sonologist qualifications are described in the Training Guidelines for Physicians Who Evaluate and Interpret Diagnostic Ultrasound Examinations and the Standards and Guidelines for the Accreditation of Ultrasound Practice..."</p> <p>Review of the AIUM Practice Guidelines for the Performance of Obstetric Ultrasound Examinations, 2007, and revised 2013, revealed, "...Qualifications and Responsibilities of Personnel. See the AIUM Official Statement Training Guidelines for Physicians Who evaluate and Interpret Diagnostic Abdominal, Obstetric, and/or Gynecologic Ultrasound Examinations and the AIUM Standards and Guidelines for the Accreditation of Ultrasound Practices..."</p> <p>Review of AIUM Standards and Guidelines for the</p>	A 686		

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A 686	<p>Continued From page 53</p> <p>Accreditation of Ultrasound Practices, approved November 5, 2011, revealed, "...Ultrasound Practice Personnel...Physician Director of Ultrasound. The practice must designate a physician director of ultrasound who is responsible for overseeing the quality and appropriateness of ultrasound operations of the practice, including ensuring that appropriate clinical services are provided, that support services are sufficient, and for certifying that the practice continues to meet the Standards and Guidelines for the Accreditation of Ultrasound Practices. The physician director of ultrasound may supervise the entire operation of the facility or may delegate specific operations to associates and sonographers...Sonographers and Other Nonphysicians Who Perform Ultrasound Examinations...Chief Sonographer...The chief sonographer must meet all additional requirements for sonographers and other nonphysicians who perform ultrasound examinations...All sonographers must be certified in the specialty or specialties for which the practice seeks accreditation or must become certified before reaccreditation...The following certifications are acceptable: American Registry for Diagnostic Medical Sonography (ARDMS)...American Registry of Radiologic Technologists (ARRT) 'AIUM-recognized" certification in general sonography for abdomen, obstetrics and gynecology. American Registry of Radiologic Technologists (ARRT)..."</p> <p>Review of ACR (American College of Radiology) -ACOG (American College of Obstetricians and Gynecologists)-AIUM Practice Guideline For the Performance of Obstetrical Ultrasound, Revised 2007, and ACR-ACOG-AIUM-SRU (Society of Radiologists in Ultrasound) Practice Guideline for the Performance of Pelvic Ultrasound, Revised</p>	A 686		

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A 686	<p>Continued From page 54</p> <p>2009, revealed, "...Qualifications of Personnel...See the ACR-SPR (Society for Pediatric Radiology)-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations..."</p> <p>Review of the ACR-SPR-SRU Practice Guideline for Performing and Interpreting Diagnostic Ultrasound Examinations Revised 2011, revealed, "...Diagnostic Medical Sonographer. When a sonographer performs the examination, that person should be qualified by appropriate training to do so. This qualification can be demonstrated by certification or eligibility for certification by a nationally recognized certifying body (e.g., ARDMS or ARRT). The sonographer should have ongoing continuing education in ultrasound..."</p> <p>Review of the qualifications for certification through ARRT revealed candidates must complete an accredited educational program.</p> <p>Review of ARDMS requirements revealed, "...Prerequisite 7...High school graduate...Minimum 48 months full-time clinical ultrasound/vascular experience and a minimum of 3,200 cases in each applied specialty area...Full-time is defined as 35 hours per week, at least 48 weeks per year. If working part time, the requirements are prorated. Twenty hours per week would take approximately two years. The full-time definition applies to both paid clinical ultrasound/vascular experience and experience earned through completion of a formal ultrasound/vascular program... Clinical ultrasound/vascular experience may be obtained one of two ways: (1) being employed as an ultrasound/vascular sonographer in a clinical setting for a minimum of 12 months and a</p>	A 686		

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A 686	<p>Continued From page 55</p> <p>minimum of 1680 hours, or (2) successfully completing a formal, full-time ultrasound/vascular program that is a minimum of 12 months in length, a minimum of 1680 total program hours, including appropriate clinical and didactic hours, and requires a clinical internship/externship to complete the program...It is recommended that an applicant be directly involved in a minimum of 800 diagnostic cases during his/her clinical experience in each specialty area for which he/she is applying. Clinical diagnostic settings include hospitals, clinics and private practices. ARDMS does not accept volunteer, instructorship, unpaid, barter or veterinarian experience...Clinical experience earned to document the education requirement cannot also be used to support the clinical requirement..."</p> <p>Review of the of Tennessee Board of Medical Examiners Chapter 0880-5, General Rules and Regulations Governing the Utilization of X-Ray Operators in Physician's Offices revealed rule 0880-5-.10(4), "...all radiographic procedures or functions...are within the American Society of Radiological Technologists' (A.S.R.T.) scope of practice for radiographers..." Continued review revealed rule 0880-5-.10(7), "...certification pursuant to these rules does not authorize the certificate holder to perform MRI (Magnetic Resonance Imaging) or Ultrasound procedures, both of which are beyond the scope and capabilities of limited licensed operators..."</p> <p>Review of Tennessee Board of Medical Examiners Chapter 0880-9, General Rules and Regulations Governing Radiologist Assistants revealed rule 0880-9-.08(1), "...before being authorized to perform any x-ray procedure or operate any x-ray equipment...certificate in the</p>	A 686		

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A 686	<p>Continued From page 56</p> <p>person's personnel file...authorized has the appropriate certification required...procedure being performed..."</p> <p>Review of the Rules of Tennessee Department of Health Board For Licensing Health Care Facilities Chapter 1200-08-01-.06, Standards for Hospitals revealed rule 1200-08-01-.06, "...x-ray personnel shall be qualified by education, training and experience for the type of service performed..."</p> <p>Interviews with the NP on May 28, 2013, at 9:30 a.m., in the staff lounge, and at 10:25 a.m., in the Ultrasound room, confirmed the NP had not been credentialed and did not have delineated privileges to include performing ultrasounds, but was responsible for the training of "counselors" or non-licensed/non-certified staff members to perform the abdominal and transvaginal ultrasounds on patients. Interviews confirmed the physician was responsible for the final interpretation of the ultrasounds, but had not been involved in training or direct supervision of non-licensed staff performing the ultrasounds, and there was no radiologist on staff full-time or part-time.</p>	A 686		