

South Dakota Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 10564 AB	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/22/2017
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NAME OF PROVIDER OR SUPPLIER SANFORD USD MEDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 1305 W 18TH STREET SIOUX FALLS, SD 57117
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S 000	In compliance/Noncompliance An off-site statistical data review for compliance with SDCL 34-23A, Performance of Abortions, was conducted on 11/22/17. Sanford USD Medical Center was found not in compliance with the following requirements: S001, S002, and S003.	S 000	Correction for S000, S001, S002, and S003 The procedure completed without following SDCL 34-23A was reviewed at Sanford Medical Center by all departments involved. This was a maternal life-threatening condition that involved multiple specialties, OB/GYN, Perinatology/Maternal Fetal Medicine (MFM), and ENT. The communication of the termination of pregnancy happened between perinatology and OB/GYN physicians after consultation with Ethics Committee, but was not communicated to the Maternal Fetal Medicine nursing staff. This nursing staff supports the process to obtain the required documentation and offer Department of Health (DOH) website address for "Information on Fetal Development, Birth, Abortion and Adoption" as required by SDCL 34-23A.	
S 001	34-23A-10.1 Voluntary/informed consent required This South Dakota Codified Law is not met as evidenced by: Based on facility reports, the facility failed to obtain a voluntary and informed written consent for a procedure performed on 5/31/16 that was determined to be not a medical emergency by the physician. Findings include: 1. Review of information provided by the facility revealed: *On 5/23/16 discussion between physician and patient included a recommendation of termination of pregnancy for treatment of a medical condition. *On 5/26/16 the abortion procedure and debulking of a tumor had been scheduled for 5/31/16. *Abortion procedure only had been completed on 5/31/16. *Informed consent as required by SDCL 34-23A-10.1 had not been obtained. Review of the Report of Induced Abortion dated 11/21/17 revealed 'No' written in by the five categories addressing informed consent: SDCL 34-23A-10.1(1), 34-23A-10.1(2), 34-23A-10.3, 34-23A-52, and the offering of the DOH website address for "Information on Fetal Development, Birth, Abortion, and Adoption.	S 001	Leadership of the OB/GYN Clinic, Maternal Fetal Medicine Clinic, Labor and Delivery, Surgical Services, Risk Management and Accreditation met to discuss this omission in reporting on September 27, 2017. The process for termination of pregnancy due to fetal life threatening conditions is hardwired and no gaps have been identified. That process includes the MFM nursing staff completing the required documents and education as identified in SDCL 34-23A. The decision was made to utilize the current process for fetal abnormality related terminations for the rare maternal life threatening conditions. Education was provided on November 16, 2017 to OB/GYN providers, on December 5, 2017 to Maternal Fetal Medicine providers, and to nursing staff of both clinics on November 26, 2017 by the Director of the Clinics. Education included a review of the Medical Staff Rules and Regulation, SDCL 34-23A and the process to obtain required documentation and consent utilizing the MFM RN clinic staff.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Talle Hanson</i>	TITLE <i>Executive Vice President</i>	(X6) DATE <i>12/15/17</i>
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S 002	<p>SDCL 34-23A-35 Submission of physician's information report</p> <p>By January fifteenth of each year, each physician who performed or treated an induced abortion during the previous calendar year or the physician's agent, shall submit to the department a copy of the physicians' information report described in §34-23A-34 with the requested data entered accurately and completely.</p> <p>This South Dakota Codified Law is not met as evidenced by: Based on notification from facility and record review, the facility failed to ensure a physician's information report had been filed by 1/15/17 for a procedure performed on 5/31/16. Findings include:</p> <p>1. The department received verbal notification on 11/21/17 regarding an abortion procedure that had been performed on 5/31/16 but had not been reported by 1/15/17.</p> <p>The notification also indicated: *The procedure had been performed in a Surgery department of the facility and not in the Labor & Delivery department. *The Labor & Delivery department had not been aware of the procedure.</p> <p>The department received the Report of Induced Abortion on 11/22/17 as a self-reported incident by the facility.</p>	S 002	<p>Currently terminations are scheduled as a Dilation & Curettage or Dilation & Evacuation. Two (2) new procedure codes in the electronic medical record (EMR) will better define the surgical procedure associated with termination of pregnancy. Dilation & Curettage Termination of Pregnancy or Dilation & Evacuation Termination of Pregnancy. These two new codes will have instructions to call Maternal Fetal Medicine Clinic nurses who will validate the correct documentation has been completed per SDCL 34-23A. Physicians and clinic staff were educated to the new process the week of December 11, 2017. Education on new surgical codes will also be provided to schedulers in OB/GYN and Maternal Fetal Medicine, surgery GOUP team, Labor and Delivery and Perinatal Outpatient Services by December 15, 2017.</p> <p>To maintain awareness of SDCL 34-23A, (during the next 12 months, OB/GN and Maternal Fetal Medicine providers and designated nursing staff will receive education every 8 weeks CT12/19/17). Education will be provided during onboarding and annually for new providers and designated staff in the OB/GYN and Maternal Fetal Medicine Clinics.</p> <p>100% of (D&C Terminations and D&E Terminations CT12/19/17) that meet the requirements according to all elements for SDCL 34-23A will done with all maternal or fetal life-threatening condition related terminations by the Maternal Fetal Medicine staff. This information will be reported to SD DOH as required by SDCL 34-23A..</p>	12/15/2017
S 003	SDCL 34-23A-56 Scheduling of abortion-Prior requirements	S 003		

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S 003	<p>Continued From page 2</p> <p>This South Dakota Codified Law is not met as evidenced by: Based on facility reports, the facility failed to ensure the physician had obtained or provided the requirements found at SDCL 34-23A-56 prior to performing the abortion procedure. Findings include:</p> <p>1. Review of the information by the facility revealed the physician had not obtained or provided the information within SDCL 34-23A-56 by the required timeframes before performing the abortion procedure. In addition, on 5/26/16 the procedure had been scheduled for 5/31/16, five days later.</p> <p>Review of the Report of Induced Abortion dated 11/21/17 for that abortion procedure confirmed the procedure had been performed on 5/31/16.</p>	S 003		