South Dakota Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	80070	A. BUILDING: _____ B. WING _____	11/04/2025

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
FLOURISH WELLNESS & BIRTH CO	2908 E 26TH ST SIOUX FALLS, SD 57103

(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
S 000	Compliance Statement A licensure survey for compliance with the Administrative Rules of South Dakota, Article 44:69, Birth Centers, requirements for birth centers, was conducted from 11/3/25 through 11/4/25. Flourish Wellness & Birth Co was found not in compliance with the following requirements: S058, S182, and S290.	S 000		
S 058	44:36:02:04 Sterilization Instruments, supplies, utensils and equipment which are not single service shall be decontaminated before sterilization in a manner that makes them safe for handling by personnel. Supplies and equipment commercially prepared and sterilized to retain sterility indefinitely are acceptable in lieu of sterilization in the birth center. Autoclaves used for steam sterilization shall be bacteriologically monitored at least weekly. Supplies and equipment sterilized and packaged in the birth center shall have the processing date on the package and shall be reprocessed in accordance with any specific manufacturer's recommendation for the packaging. This Administrative Rule of South Dakota is not met as evidenced by: Based on observation, interview, policy review, manufacturer's instruction for use (IFU) review, and administrative rules of South Dakota review, the provider failed to ensure: *Staff followed the manufacturer's mixing and temperature monitoring instructions for the Multi-Enzymatic Cleanser according to the manufacturer's IFU. *Peel-packs (disposable packages used to hold instruments during sterilization) containing surgical instruments had been placed correctly in	S 058	1. Corrective Action Taken for Each Specific Finding A. Enzymatic Cleaner Not Mixed or Monitored per Manufacturer IFU Corrective Action: Staff were re-educated on the proper mixing instructions for McKesson Multi-Enzymatic Cleanser per the manufacturer's IFU (1 Tablespoon of instrument detergent per 1/2 gallon (64 oz) of water). A calibrated thermometer has been placed in the soiled utility room, and staff were trained on correct water temperature (required 68–122°F). An update to the posted laminated "Process for Cleaning Instruments" was placed above the cleaning station. B. Peel-Packs Incorrectly Loaded/Stacked in Sterilizer Corrective Action: All staff who perform sterilization were re-trained on the McKesson pouch manufacturer's IFU, including no stacking, paper to plastic orientation, and spacing to ensure steam penetration. An "Autoclave Loading Guide" is now posted above the sterilizer showing correct pouch placement. (cont'd)	12/9/2025

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Erin Vande Lune, CNM — TITLE — (X6) DATE: 12/01/2025

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S 058	Continued From page 1 the steam sterilizer according to the manufacturer's IFU. *One autoclave steam sterilizer had been bacteriologically monitored weekly. Findings include: 1. Observation and interview on 11/3/25 at 3:00 p.m. with registered nurse (RN) A in the soiled holding room regarding the use of Multi-Enzymatic Cleanser revealed: *Contaminated instruments were transported to the soiled holding room and cleaned immediately after delivery with an enzymatic cleaner. *RN A stated staff would fill a red cleaning bin with 64 ounces (oz) of warm water and add two tablespoons (tbs) of enzymatic cleaner. *Process instructions were posted on the wall for staff to refer to, which indicated that staff were to measure 64 oz of water (one-half gallon) and two tbs of detergent. *She had not read the manufacturer's IFU of the enzymatic cleanser. *Staff did not check the temperature of the water. -She stated, "We just turn the water on hot, so it should be ok." *Instruments were soaked for at least 10 minutes, scrubbed, dried, and then placed into peel-packs for sterilization. 2. Observation and interview on 11/3/25 at 3:20 p.m. with RN A in the clean holding room revealed: *One table-top steam sterilizer was on the counter. *RN A opened a pass-through wall cupboard located between the clean and soiled holding rooms. Seven clean surgical scissors were drying on paper towels in a clear bin. *She:	S 058	C. Lack of Weekly Biological Indicator (BI) Monitoring Corrective Action: BI test kits were obtained through our supplier, and weekly BI testing is now required. The autoclave will be tested upon arrival of BI test kits on or before December 19, 2025. Documentation will be added to the Weekly Birth Center Logbook. How Other Potentially Affected Patients Were Identified •No incidents of patient infection or sterilization failure have been identified. •Staff competency validation will be expanded to all birth staff on 12/9/25 who handle sterile equipment to ensure all potentially involved individuals were retrained. 2. Systemic Changes to Achieve Sustained Compliance To ensure long-term compliance: A. Procedures Updated • Sterilization & Disinfection Procedures now includes: Updated mixing instructions. •Autoclave Biological Indicator Testing Procedures added to include: Proper pouch loading procedures and Mandatory weekly BI testing requirements. B. Standardized Logs Implemented •Autoclave Logbook •Weekly Biological Testing added to the Birth Center Logbook C. Staff Education & Competency •All birth staff to complete a mandatory training session on 12/9/25. Attendance will be documented. •Annual competency assessments will now include sterilization workflow validation and IFU comprehension. (cont'd)	12/9/2025

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S 058	Continued From page 2 -Placed each pair of scissors in individual peel-packs and sealed each peel-pack. -Opened the door to the sterilizer, that had three shelves to hold the peel-packs containing surgical instruments. -Stacked two peel packs on top of one another on each shelf. -Stated, "We don't stack more than two [peel packs] on each shelf." *RN A turned on the power switch for the sterilizer and poured 300 milliliters (ml) of sterile water into the chamber until the window displayed "8888" (indicating there is enough water to begin the sterilization process). *RN A shut and sealed the sterilizer to begin the sterilization process. -She stated the sterilization process took 30 minutes, but staff would wait to open the sterilizer after 90 minutes to allow for the packages to cool. *RN A confirmed that the documentation on the sterilizer log consisted of the date, number of instruments, cycle time, temperature, and initials of the staff who completed the sterilization cycle. *After instrument sterilization process was completed, the packages were inspected for the appropriate color change on the packages' indicators and were dated. *RN A confirmed that there were no other quality tests performed to ensure that sterilization parameters had been met. 3. Interview on 11/3/25 at 4:30 p.m. with clinic manager B and certified nurse midwife (CNM) C regarding the instrument disinfection and sterilization processes revealed they: *Agreed that the staff members were not mixing the enzymatic cleanser and water per the manufacturer's IFU to disinfect surgical instruments before sterilization. *Were not aware that the staff members could	S 058	3. Monitoring to Identify Future Noncompliance A. What Data Will Be Monitored 1. Sterilizer Loading Log – proper pouch placement verified, sterilization results. 2. Weekly BI Log – timely completion, pass/fail outcome. B. Who Will Perform Monitoring • The Lead RN will complete the Weekly Birth Center Logbook. • The Clinic Manager will provide oversight for birth center compliance. C. Frequency & Duration of Monitoring • Weekly audits of all logs for the first 12 weeks by the Clinic Manager. • After 12 weeks, audits will occur monthly thereafter by the Clinic Manager. • Competency Review: Annually for all staff thereafter. D. How Monitoring Will Be Integrated Into the QA System • Audit findings will be summarized on a Sterilization QA Report. • The Clinic Manager will submit reports monthly to the CNMs. • CNMs will review results and corrective actions and will include these findings in quarterly birth center meetings thereafter. • Any deviation (missed BI test, incorrect loading) will trigger: Immediate re-education, Documentation of remediation, A repeat focused audit for two consecutive weeks.	12/9/2025

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S 058	Continued From page 3 not stack instruments on top of one another in the sterilizer per the peel-packs manufacturer's IFU. *Confirmed staff were not monitoring weekly biological indicators (germ testing) to verify the steam sterilizer was functioning correctly and could effectively kill highly resistant microbes (bacteria, viruses, fungi). -Were not aware that staff should have monitored weekly biological indicators (BI) on the sterilizer. Review of the provider's undated Standard Operating Procedure for Sterilizing Medical Instruments policy revealed: *"Inspect instruments for visible contaminants and remove them using recommended cleaning agents. -2 tablespoons of instrument detergent per half gallon (64 oz) of water. *Follow manufacturer guidelines for loading instruments into the sterilization chamber." *There were no instructions for monitoring weekly BI tests. Review of the provider's undated Autoclave Compliance Check-Off competency revealed staff were to: *"Arrange instruments in the autoclave chamber to allow for proper steam circulation and penetration." *There were no instructions on how to monitor weekly BI tests. Review of the 2021 McKesson Multi-Enzymatic Cleanser IFU revealed: *"Manual Cleaning: Use ½ to 1 ounce of McKesson Multi-Enzymatic Cleanser per one gallon water for general purpose cleaning. *The enzymes selected for McKesson Multi-Enzymatic Cleanser have an optimal efficiency when used at a temperature of 95	S 058		

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S 058	Continued From page 4 degrees F [Fahrenheit]. *It is recommended that these products be used between 68-122 degrees F. *The enzymes in McKesson Multi-Enzymatic Cleanser may become ineffective in water temperatures exceeding this level." Review of the undated McKesson Sterilization Pouches manufacturer's IFU revealed: *"Before Sterilization: -Be sure to arrange pouches in such a way that there is minimal to no contact between pouches. It is recommended to place sealed pouches into autoclave vertically. -The sterilization basket should not be fully packed to leave sufficient space for pouches to expand and ventilate." Review of the undated TR250M manufacturer's IFU for the steam sterilizer did not provide instructions on BI testing. Review of the Administrative Rules of South Dakota 44:69:02:04, sterilization revealed, "Autoclaves used for steam sterilization shall be bacteriologically monitored at least weekly."	S 058		
S 182	44:69:05:03(2)(a-g) Emergency Equipment and Procedures Each birth center shall have: (2) Properly maintained equipment and supplies for routine and emergency care of women and newborn including (a) Oxygen with flow meters and masks or equivalent; (b) Mechanical suction and bulb suction; (c) Cardiopulmonary resuscitation cart, including:	S 182	1. Corrective Action for Each Identified Finding & Identification of Other Potentially Affected Patients A. Automated External Defibrillator (AED) Not Tested According to IFU • The AED located in the clean holding room was immediately inspected, tested, and confirmed functional on 11/4/25. • It was confirmed that Check AED Readiness is already included in the Weekly Birth Center Logbook. This log will be implemented immediately to be completed on a weekly basis to ensure consistent compliance. (cont'd)	12/9/2025

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S 182	Continued From page 5 (i) Resuscitation bags for mother and newborn; (ii) Endotrachael tubes for mother and newborn; (iii) Oral airways; (iv) Needles; (v) Syringes; (vi) Emergency drugs; (vii) Laryngoscope; (viii) Equipment for delivering positive pressure oxygen; and (ix) Cardiac monitor/defibrillator unit or automated external defibrillator; (d) Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn; (e) Electronic fetal monitoring equipment; (f) Infant scale; (g) Sterile suturing equipment and supplies; This Administrative Rule of South Dakota is not met as evidenced by: Based on observation, interview, and manufacturer's instructions for use (IFU) review, the provider failed to ensure: *One of one Automated External Defibrillator (AED) was tested according to the manufacturer's IFU monthly testing protocol. *Two of two oxygen (O2) cylinders were filled and and ready for patient use. *One pediatric and one adult expired carbon dioxide (CO2) detectors were not available for patient use. Findings include: 1. Observation on 11/3/25 at 2:00 p.m. in an unlocked, clean holding room revealed: *One AED on the counter with no log to indicate	S 182	• All birth center staff, including CNMs and RNs, will be re-educated on AED weekly readiness checks. B. Two Empty Oxygen (O_2) Cylinders • Both empty cylinders were removed and replaced with one full O_2 tank and one backup tank at least half full on 11/4/25. • It was confirmed that O_2 tank volume checks are already part of the Weekly Birth Center Logbook. Effective immediately, staff will complete and document these checks weekly to ensure both primary and backup tanks are full and ready for use. • Staff were instructed on proper procedures for verifying remaining O_2 volume after each use. C. Expired Pediatric and Adult CO_2 Detectors • All expired CO_2 detectors were removed and replaced with in-date devices on 12/1/25. • A full inventory sweep was completed in all birth center spaces to identify and remove any expiring or near-expiring emergency supplies (no additional were found). D. Incomplete Monthly & Weekly Emergency Equipment Checklists • The Birth Center Logbook was reviewed, and a new standardized checklist was implemented immediately. • Staff whose documentation was incomplete will be re-educated on expectations for timely and accurate completion. How Other Potentially Affected Patients Were Identified • All emergency equipment, supplies, and storage areas across the entire birth center were reviewed to ensure no additional expired items, empty tanks, or undocumented inspections. No other deficiencies were identified. (cont'd)	12/9/2025

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S 182	Continued From page 6 when the last monthly inspection was completed. *Two empty O2 cylinders in tank holders standing on the floor. *A wheeled cart that contained emergency supplies, including one pediatric CO2 detector with an expiration date of 7/9/25, and one adult CO2 detector with an expiration date of 10/8/25. 2. Interview on 11/3/25 at 2:30 p.m. with certified nurse midwife (CNM) D regarding the clean holding room revealed: *The room was usually closed and secured, but the staff were restocking supplies. *She was unaware that staff were to perform a monthly readiness check on the AED device. *The AED located in the clean holding room was not wirelessly connected for monitoring and should have been checked for readiness monthly per the AED manufacturer's IFU. *She was unaware that the O2 cylinders were empty and would notify the clinic manager to order another cylinder. *She confirmed the two CO2 detectors had expired and were available for use. *The staff were to complete tasks on weekly and monthly checklists to ensure supplies and equipment were ready for patient use and not expired. 3. Review of the provider's Birth Center Logbook monthly checklists revealed: *No monthly checklists had been completed since 7/14/25. *Tasks to be completed weekly in the clean utility room included: -"Test AED. -Check oxygen tanks. -Monthly: check for outdates and expired items." *Completed monthly checklists were to be reviewed by the clinic manager.	S 182	2. Systemic Changes to Achieve Sustained Compliance A. Revised Emergency Equipment Checklist System • A weekly completion of the Birth Center Logbook has been initiated. • This logbook includes AED readiness testing check, O_2 tank pressure documentation, and emergency cart supply review. B. Locked Emergency Equipment Storage • The clean holding room, previously unlocked, is now restricted to authorized staff only and must remain locked at all times. C. Defined Staff Responsibilities • The Lead RN is assigned weekly to complete and signoff the Birth Center Logbook. • The Clinic Manager must review and sign off on completed logs monthly. D. Staff Re-Education • All birth center staff will be re-trained on: Emergency equipment locations, AED readiness indicators, O_2 tank replacement reporting, Expiration-date monitoring • Competency validation will be completed on 12/9/25. 3. Monitoring to Ensure Ongoing Compliance A. What Data Will Be Monitored • Weekly Emergency Equipment Checks (AED, O_2 levels, emergency cart readiness) • Monthly Expiration Audit Checks (CO_2 detectors, emergency meds, supplies) • Staff completion and documentation accuracy • Policy adherence and room security compliance B. Who Will Perform the Monitoring • The Lead RN will complete the Weekly Birth Center Logbook. • The Clinic Manager will provide oversight for birth center compliance. (cont'd)	12/9/2025

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S 182	Continued From page 7 4. Interview on 11/4/25 at 10:15 a.m. with clinic manager B revealed: *Staff were to check oxygen tanks for volume, test the AED weekly for proper functioning, and perform monthly checks for expired supplies and replace if needed. *Staff were to document completion of tasks on the checklist. *Those tasks were last documented as completed on 7/14/25. *She was unaware that those tasks were not completed. *She expected the staff to complete tasks that were on a checklist and document completion of those tasks weekly. *A policy on operating and maintaining the AED was requested, but she stated the provider did not have one. 5. Interview on 11/4/25 at 11:50 a.m. with registered nurse (RN) A revealed: *Staff were to keep a full O2 tank and another O2 tank at least half full available for patient use. *She agreed that both tanks in the clean holding room were empty and should have been replaced. *She confirmed staff had not kept track of how much oxygen was left in the tanks, but after each birth, staff on duty were to verify how much oxygen was left in each tank and would change out tanks if needed. Review of the 2021 AED manufacturer's Maintaining a State of Readiness instruction for use revealed: *"Device readiness should be verified at least each month. If your device has wireless access to LIFELINKcentral AED Program Manager or LIFENET System, you can verify the device	S 182	C. Frequency & Duration of Monitoring • Weekly audits of all logs for the first 12 weeks by the Clinic Manager. • After 12 weeks, audits will occur monthly thereafter by the Clinic Manager. • Competency Review: Annually for all staff thereafter. D. Reporting into the QA System • Audit findings will be summarized on an Emergency Equipment QA Report. • The Clinic Manager will submit reports monthly to the CNMs. • CNMs will review results and corrective actions and will include these findings in quarterly birth center meetings thereafter. • Any deviation (missed AED test, expired supplies) will trigger: Immediate re-education, Documentation of remediation, A repeat focused audit for two consecutive weeks	12/9/2025

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S 182	Continued From page 8 status remotely. If your device does not have wireless access, you must check the Readiness indicator on the devices. *If the device does not have wireless capability or is unable to automatically connect to LIFELINKcentral AED Program Manager or LIFENET System (for example, if no Internet connection is available where the device is located), you should check the Readiness indicator on the device at least once each month. If the device is not ready, the Readiness indicator does not flash, and an alert tone sounds every 15 minutes." 44:69:07:03 Storage and Labeling of Medications and Drugs All drugs or medications shall be stored in a well illuminated, locked storage area that is well ventilated, maintained at a temperature appropriate for drug storage, and inaccessible to individuals, clients, or visitors at all times. This Administrative Rule of South Dakota is not met as evidenced by: Based on observation, interview, refrigerator temperature documentation review, and policy review, the provider failed to ensure: *Medications stored in one of one unlocked medication refrigerators were secured. *The temperature of one of one medication refrigerator was monitored and documented to maintain the safe temperature range between 35.6 degrees Fahrenheit (F) and 46.4 degrees F to store medications according to the provider's policy. Findings include:	S 182 S 290	1. Corrective Actions for Each Finding & Identification of Other Potentially Affected Patients A. Medications stored in an unlocked medication refrigerator Corrective Action: • Effective immediately, the clean holding room door was secured, and staff were re-educated on ensuring the room remains closed and locked at all times unless actively in use. • Because the current refrigerator is not capable of being locked, a new keypad lock has been installed on the clean holding room door to ensure the room remains a fully secured, restricted-access medication storage area. • The Medication Storage Policy has been updated to clarify that the refrigerator itself does not need to lock if it is housed within a locked, access-controlled room. B. Medication refrigerator temperatures were not monitored and documented weekly Corrective Action: • Refrigerator temperatures were checked immediately on 11/4/25 and confirmed within the acceptable range. (cont'd)	12/9/2025

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S 290	Continued From page 9 1. Observation and interview on 11/3/25 at 1:45 p.m. with certified nurse midwife (CNM) D in the clean holding room revealed: *The door to the room, which contained medications, sterile and clean supplies, needles, a defibrillator, a sterilizer, and a medication refrigerator, was propped open and unlocked. *CNM D stated the door was usually closed and secured, but the staff were restocking supplies. *The medication refrigerator could not be locked because of its design. *That refrigerator had two boxes of methergine (medication to treat excessive bleeding after childbirth) and a thermometer to measure the temperature in degrees F. -The provider's thermometer reading was 42 degrees F at the time of the observation. *CNM D stated that staff were to check the medication refrigerator's temperatures and document the temperatures on a checklist weekly. *If temperatures were out of range, staff were to notify the person in charge per provider's policy. 2. Review of the provider's Birth Center Logbook monthly checklists regarding refrigerator temperatures revealed: *The medication refrigerator temperatures were not documented as completed on the checklist since 7/14/25. *Temperatures were to be documented weekly. *Completed monthly checklists were to be reviewed by the clinic manager. 3. Review of the provider's 1/2023 Medicine Fridge policy revealed: *Medicines must be maintained between 35.6 degrees F and 46.4 degrees F. *"Refrigerator maximum/minimum temperatures must be monitored and recorded regularly.	S 290	• A Daily Medication Refrigerator Temperature Log has been created, implemented, and posted directly next to the medication refrigerator. • Check Medication Refrigerator Temperature Log has been added to the Weekly Birth Center Logbook to ensure consistent compliance. • Staff were re-educated on documenting temperatures and immediately reporting deviations. Identification of Others Potentially Affected: • A full review of the medications stored in the refrigerator was completed and no concerns were identified regarding product integrity. • No additional issues or patterns of failure were identified. 2. Systemic Changes to Achieve Sustained Compliance A. Updated Medication Storage Policy • The policy has been revised to clarify that: A pharmaceutical-grade refrigerator is not required. A refrigerator that does not lock is acceptable as long as it is stored in a locked, restricted-access medication room. No annual external refrigerator inspection is required. • Clear instructions have been added requiring staff to: Check and document refrigerator temperatures daily. Notify the Clinic Manager immediately if temperatures fall outside the safe range (35.6–46.4°F). B. Environmental Control Improvement • The clean holding room will remain locked at all times unless staff are actively restocking or retrieving supplies. • A new "This Door to Remain Locked" sign has been posted on the clean holding room door. (cont'd)	12/9/2025

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FLOURISH WELLNESS & BIRTH CO	2908 E 26TH ST SIOUX FALLS, SD 57103

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S 290	Continued From page 10 *Temperature records should identify any temperature deviations and give details of corrective actions taken as a result. *All staff should be aware that they must inform the person in charge immediately if the refrigerator fails *Medicine refrigerators must be kept locked at all times." 4. Interview on 11/4/25 at 10:15 a.m. with clinic manager B revealed: *She agreed that the clean holding room where medications were stored should have been locked due to the medication fridge not having the ability to lock. *The medication refrigerator temperature was last documented on the checklist on 7/14/25. *She expected the staff to check and document the medication refrigerator temperatures weekly and notify the person in charge with any deviations. *She was unaware that the temperature of the medication refrigerator had not been checked and that she was supposed to review these monthly checklists for completion.	S 290	C. Staff Education • All birth center staff will be re-educated on: Medication storage expectations. Temperature documentation requirements. Secure access to supply and medication areas. D. Enhanced Administrative Oversight and Logbook Verification • Monthly logbook review has been incorporated into the Clinic Manager's administrative checklist. E. Revised Birth Center Logbook • A dedicated Medication Refrigerator Temperature line item was added to eliminate confusion and allow easy verification of daily documentation. 3. Monitoring to Ensure Ongoing Compliance A. What Data Will Be Monitored • Daily Medication Refrigerator Temperature Logs. • Monthly Logbook Completion Check. • Compliance with keeping the clean holding room locked. B. Who Will Perform the Monitoring • The Lead RN will complete the Weekly Birth Center Logbook. • The Clinic Manager will provide oversight for birth center compliance. C. Frequency & Duration • Weekly audits of all logs for the first 12 weeks by the Clinic Manager. • After 12 weeks, audits will occur monthly thereafter by the Clinic Manager. • Competency Review: Annually for all staff thereafter. D. How Monitoring Will Be Integrated Into Quality Assessment • Audit findings will be summarized on a Med Storage QA Report. • The Clinic Manager will submit reports monthly to the CNMs. • CNMs will review results and corrective actions and will include these findings in quarterly birth center meetings thereafter. • Any deviation (unlogged temps, unlocked room door) will trigger: Immediate re-education, Documentation of remediation, A repeat focused audit for two consecutive weeks.	12/9/2025