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 _____	01/11/2024

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 An initial licensure survey for compliance with the Administrative Rules of South Dakota, Article 44:69, Birth Centers, requirements for birth centers, was conducted from 1/10/24 through 1/11/24. Flourish Wellness & Birth Co was found not in compliance with the following requirements: S058 and S074.	S 000	1. Extensive research, training and education was completed by our clinic manager to fully understand and operate the autoclave. The manufacturer was contacted to receive more details regarding proper functioning and procedures for the machine. Trial runs were completed to assure that the auto-clave was functioning properly and sterilization packets were demonstrating color change. Once this process proved to be consistent and without error, a policy and procedure was developed. This procedure fully outlines the step by step process of sterilizing equipment, including the initial decontamination process with enzyme solution. A small number of staff will then be fully trained in this process and required to go through a check off procedure yearly. 2. We will be storing all sterile supplies separate from clean supplies in the clean storage room. Each instrument will be individually examines upon removal from the autoclave to ensure the color indicator has changed during the process. Furthermore, all sterilized instruments will be marked with the sterilization date once they are removed from the auto-clave. There will be a log in the clean utility room to track the start and completion of this process. 3. What: Color change, successful sterilization and staff competency will be monitored to assure this process is successful. Who: Clinical manager will oversee this process and monitor the details of training and the log book. When: The clinic manager will review the log weekly on Fridays. She will send a report to CNMs informing them of any deviations from the desired outcome. Any issues with the process will be addressed immediately. Additionally, staff will be encouraged to report any issues with	2/15/2024
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, and manufacturer's instruction for use, the provider failed to ensure: *All scissors, clamps, and forceps in peel-packs sterilized by facility staff were sterile at the time of patient use for two of two birthing rooms. -A peel-packs was a non-sterile disposable package suitable for packing instruments in to be sterilized. *Five peel-packs of clamps and three peel-packs of scissors were processed with the lock-box in	S 058		

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

Erin Vaughn

TITLE: Co-Owner, CNM

(X6) DATE: 01/31/2024

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S 058	Continued From page 1 an open position to allow sterilant to reach all areas of the instruments. *All peel-packs had been labeled with a processing date. Findings include: 1. Observation and package direction review on 1/10/24 at 12:14 p.m. in birthing room 1 revealed: *All scissors, clamps, and forceps in peel-packs were available for patient use, and the indicator on each peel-pack was blue. *The manufacturer's direction on the peel-packs stated when processed by steam sterilization the indicator color should have changed color. *There was no manufacturer's information on the peel-pack for what color the indicator change should have been when exposed to steam sterilization. 2. Observation and interview on 1/10/24 at 12:51 p.m. in the clean storage room with certified nurse midwife (CNM) B revealed: *There was one table-top steam sterilizer on the counter. *A plastic bin on the countertop with numerous instruments individually enclosed in sealed peel-packs. -Not all of the peel-packs had the processing date on the package. *Under the counter on a shelf were peel-packs that had not been used. *One end of the peel-packs was opened to allow placement of an instrument for sterilization. *Examination of those unused peel-packs revealed the indicators on those packages were also blue. -The same color blue as the peel-packs with instruments stored in birthing room 1. *The manufacturer's direction on those peel-packs stated the indicator color should have	S 058	sterilization process immediately to clinic director. All staff will be required to complete a yearly competency review toassure they are up to date and proficient in regards to the sterilization process. This process will remain in place indefinitely, or until we are no longer sterilizing our own instruments. We recently hired a Quality Measures, RN who will also be tracking this date quarterly and be directly involved with the training and competency management of the staff involved in the sterilization process. How: If the logs show that the color change is not happening 100% of the time, the process will be reviewed for errors or need for more education. The plan is to keep the # of staff utilizing the autoclave small in order to assure consistency in the sterilization process. 4. This process has already been started, a policy and procedure has been created. Training will start on 2/1/2024 and be completed for all designated staff be 2/15/2024. Data will begin being collected on 2/1/2024	

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S 058	Continued From page 2 changed when processed by steam sterilization. *There was no manufacturer's information on the peel-packs for what color the indicator change should have been when exposed to steam sterilization. *She confirmed: -The above-listed instruments and those in the plastic bin had been processed in the dental clinic's sterilizer. -The peel-pack indicator's blue color was the correct color. --They were not aware a change in the indicator color from blue to brown meant the parameters for sterilization had been met. --They were not aware instruments should have been placed in the peel-packs, sealed, and then processed in the sterilizer. -There were no manufacturer's instructions for the use of the peel-packs. -Those instruments in the bin were used to restock birthing rooms 1 and 2 and would have been used for future patients. -Instruments processed in the dental clinic's sterilizer had been used on prior patients that had delivered babies at the birthing center. *Sterilization of instruments prevented potential cross-contamination of infections to patients. *The process staff used to sterilize the above-listed instruments were the following: -The instruments were placed in the dental clinic's sterilizer and processed. -Staff donned sterile gloves, removed the instruments from the sterilizer, and put them in the sterile peel-packs. --Peel-packs do not come from the manufacturer sterile. -That was how the dental clinic staff had shown them how to sterilize instruments in their sterilizer. -That was why the peel-pack indicator had not	S 058		

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S 058	Continued From page 3 changed colors. *Only one sterilization cycle had been completed with the birthing center's new tabletop sterilizer and that same process described above had been used. 3. Observation on 1/10/24 at 1:45 p.m. in birthing room 2 revealed: *Five peel-packs of clamps and three scissors in the supply cabinet. *The peel-pack indicators were blue. -See above information regarding indicator color change. *There were no processing dates on the instrument peel-packs. 4. Review of the facility's sterilizer manufacturer's operating instructions revealed: *There was no information on packaging material usage for the sterilizer. *There was no information on how to prepare instruments for the sterilization process. *There was information on the installation requirements, sterilizer structure, operating steps, technical parameters, display window codes, and the meaning of fault diagnosis codes. Review of the Centers for Disease Control and Prevention Guideline for Disinfection and Sterilization in Healthcare Facilities (2008) webpage updated 2016, revealed disinfection and sterilization were essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients.	S 058		
S 070	44:69:02:07 Infection Control The infection control program shall utilize the concept of standard precautions as the basis for	S 070		

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S 070	Continued From page 4 infection control pursuant to chapter 44:20:04. The birth center shall have written procedures that govern the use of aseptic techniques and procedures in all areas of the birth center. Each birth center shall develop policies and procedures for the handling and storage of potentially hazardous substances (including lab specimens). This Administrative Rule of South Dakota is not met as evidenced by: Based on observation, interview, and policy review, the provider failed to ensure infection control practices were in place to decrease the risk of potential contamination in the following areas: *Furniture in two of two birthing rooms (1 and 2) had cleanable surfaces. *Medical supplies were secured from patient and visitor access in two of two birthing rooms (1 and 2). *Sterile supplies were not co-mingled (mixed together) with clean supplies in two of two birthing rooms (1 and 2). *Personal care items in two of two bathrooms (birthing rooms 1 and 2) were covered and secured from aerolization (spraying) contamination from the sink and toilet. *Paper towels used to dry hands were stored in towel dispensers that were fully enclosed and had cleanable lids in two of two patient bathrooms. *Linens used for patient care were not stored with unclean items in two of two birthing rooms (1 and 2). Findings include: 1. Observation on 1/10/24 at 12:50 p.m. in birthing room 1 with (certified nurse midwife) CNM B revealed: *The headboard attached to the bed was covered with fabric and was not cleanable.	S 070	1. All sterile instruments will be stored separately from clean supplies in clean storage room. Any sterile gloves, or other sterile medical supplies will be stored on the top shelves of medical supply room. These items have already been moved to new locations. Labels will be made for shelving to assure clean and sterile supplies do not mix. Non-sterile supplies will continue to be stored in the furniture in the birth rooms; however, a lock will be placed on each of the main doors securing these supplies from patients being able to access them. All sterile instruments and other supplies used for birth will be packaged into 'birth kits'. These will be stored in the medical supply room and clearly labeled. They will be brought individually into the birth room at time of patient admission. Along the same line, individual Peri-care packs will be made and 1 peri-pack will be placed on the open cart in the bathroom at patient admission. Products will be stored in a sealable, plastic bag. After each birth, the cart will be sanitized with purple top wipes. Any unused products will be sent home with patient for her use. Any exposed products will be discarded after patient discharge. Paper towel holders in both rooms to be replaced. Linens will be stored on separate shelves (shelves to be clearly labeled). Any other clean supplies will be stored on upper shelves separate from linens. Furniture will be replaced.	2/20/2024

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S 070	Continued From page 5 *There was a couch for the patient and visitor(s) to use that had been covered with fabric that was not cleanable. *There was a buffet-style cabinet inside of the room that was filled with various medical supplies. -The medical supplies were stored in the cabinet so the staff could have quick access to them during an infant delivery. -The doors had no security mechanism in place to ensure the patients and visitors had no access to them which created a risk for potential contamination. -The sterile supplies were co-mingled with clean supplies. *There were two hand towel dispensers by both of the sinks. -The front of the towel dispensers were open down the middle and exposed the clean paper towels for potential contamination. -The lids on the towel dispensers were wooden. The surface of the wood was porous and created an uncleanable surface. *A three-tiered rolling cart was in the bathroom located between the toilet and the sink. -The shelves were open and contained personal care items for the patient's to use. -There was the potential for contamination through aerolization of those items when the toilet and sink were used. *There was a cupboard above the sink in the birthing room. -Inside of the cupboard were clean towels that were used during a delivery. -There were unclean items stored next to the towels. Those items included enema bags, a tub of disinfecting wipes, a breast pump, and soap dispenser refills. Observation on 1/10/24 at 1:45 p.m. in birthing	S 070	2. All of the above changes will be implemented. Monthly checks of storage and inventory will be done to assure compliance with preventing contamination of supplies or the spread of infection. These checks will be documented in a logbook kept in the clean utility room. 3. What—Monthly checks of proper inventory and storage will be documented in log book. Who—Staff will be assigned this monthly duty and document completion in log book When—Monitored monthly by staff How—Each area will be assessed and then documented complete in log book. Clinic manager will also then double check and review logbook monthly. 4. These processes will be complete by 2/15/2024. Headboard and couches will either be cleanable or removed from rooms by 2/25/2024	

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S 070	Continued From page 6 room 2 with CNM B revealed the same observations as above in birthing room 1 except the headboard attached to the bed was cleanable. Interview on 1/10/24 at the time of the observations with CNM B confirmed the above findings. That was their usual process for storing various medical supplies and linens. She was not aware the headboard, couches, and wooden surfaces were not cleanable. The staff was not aware that those processes could have created a potential for cross-contamination of bacteria from one patient to another and were infection control concerns. Review of the provider's 1/1/23 Storage and Cleaning policy revealed: *General practices: -"Store clean and sterile supplies in a designated area that is separate from other areas and is clean and dry. -Handle, transport, and store clean and sterile supplies separate from dirty supplies. -Minimize supplies in patient rooms/care areas and establish quotas and maximums for each care area. -Surfaces in storage areas, including floors, walls, ceilings, shelving and fixtures are made of materials that are smooth, non-porous, non-shedding and easily cleanable." *Handling and distribution of clean and sterile supplies: -"Ideally, sterile supplies are stored separately from clean supplies. -If clean and sterile supplies are stored within the same enclosed area, separate one from the other by storing the sterile items on the upper shelves and the clean items on the lower shelves to prevent lint dust, and other debris from falling on	S 070		

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S 070	Continued From page 7 the sterile items."	S 070		

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S 000	Compliance Statement An onsite revisit for compliance with the Administrative Rules of South Dakota, Article 44:69, Birth Centers, requirements for birth centers, was conducted on 2/22/24. Flourish Wellness & Birth Co was found in compliance.	S 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE