

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

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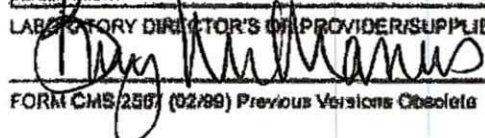
FORM APPROVED

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001006	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 08/12/2025
NAME OF PROVIDER OR SUPPLIER YANKTON MEDICAL CLINIC, PC ASC			STREET ADDRESS, CITY, STATE, ZIP CODE 1104 W 8TH ST POST OFFICE BOX 706, YANKTON, South Dakota, 57078	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Q0000	INITIAL COMMENTS A recertification health survey for compliance with 42 CFR Part 416, Subpart C, requirements for Ambulatory Surgery Centers was conducted from 8/11/25 through 8/12/25. Yankton Medical Clinic, PC ASC was found not in compliance with the following requirements: Q0100 and Q0241.	Q0000		
Q0100	ENVIRONMENT CFR(s): 416.44 The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients. This CONDITION is NOT MET as evidenced by: Based on observation, interview, policy review, Association of perioperative Registered Nurses (AORN) review, American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) review, and South Dakota Administrative Rule review, the provider failed to: *Maintain safe pressure relationships (clean and dirty air) between two of two decontamination rooms and two of three clean sterile storage rooms that were adjacent areas to prevent the spread of infections, compromise surgical equipment, and assure the health of the occupants was maintained. *Ensure one of two air pressure relationships (between rooms L42 and L44) had been maintained through a pass-through door. Findings include: 1. Observation and airflow testing on 8/11/25 at 10:30 a.m. in endoscopy decontamination room L58 revealed, with the use of a tissue at the base of the door, negative (dirty) air was blowing out into the clean corridor (hallway).	Q0100	For room L58, the supply air damper was inspected on 8/29/25 and found to be outputting 100% air volume, which caused pressure imbalance. The damper output was adjusted to 35%, restoring the decontamination room to proper negative pressure. Airflow was retested with a vanecometer and verified to be compliant. Staff were re-educated on reporting ventilation	09/17/2025

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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	CEO	9/12/25
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Q0100	<p>Continued from page 1</p> <p>-That room's airflow should have been drawn into the space, containing the contaminants within.</p> <p>Observation and interview on 8/11/25 at 11:05 a.m. in sterile supply room L42 with sterile processing tech (SPT) D and surgical tech (ST) E revealed:</p> <p>*The door to the room had been propped open.</p> <p>*A pass-through door to soiled room L44 had been left open, which allowed dirty air to flow into the clean processing room where surgical instruments were packaged and sterilized.</p> <p>-That room's airflow should have been in positive (clean air pushed out) pressure to prevent contaminants from entering.</p> <p>*SPT D had closed the pass-through door, and the airflow was tested with the use of a tissue at the base of the door, which revealed dirty air continued to blow into the clean processing room.</p> <p>*The above findings were confirmed with SPT D and ST E.</p> <p>*SPT D and ST E agreed the pass-through door should have been closed when not in use to maintain proper airflow.</p> <p>Observation and airflow testing on 8/11/25 at 11:15 a.m. outside of soiled room L44 with the use of tissue at the base of the door revealed dirty air flowing into a clean hallway.</p> <p>On 8/11/25 at 12:10 p.m. the above findings were communicated with maintenance supervisor B.</p> <p>Observation and airflow testing on 8/12/25 at 9:30 a.m. outside endoscopy decontamination room L58 where high level disinfection (HLD) was performed revealed, with the use of a vaneometer (device used to monitor the direction of airflow), dirty air was blowing into a clean corridor.</p> <p>Observation and interview on 8/12/25 at 10:09 a.m. with ambulatory surgery center (ASC) manager A and SPT C revealed:</p> <p>*With the use of a vaneometer at the base of each door:</p> <p>-Dirty air was blowing out of soiled room L44 into a clean corridor.</p> <p>-Dirty air was blowing into sterile supply room L42</p>	Q0100	<p>On 8/13/25, the exhaust unit serving the decontamination room (L42) was inspected and a failed belt was identified as the cause of improper air pressure. The belt was replaced by maintenance, restoring correct negative pressure in the decontamination room and positive pressure in the sterile supply room. Airflow was retested using a vaneometer to confirm compliance. On 8/29/25, a new rubber seal was installed on the pass-through door to further ensure proper airflow containment.</p> <p>Systemic Change: The preventive maintenance schedule has been updated to include quarterly inspection of exhaust belts, door seals, air dampers, and HVAC components affecting sterile processing areas.</p> <p>Monitoring: The ASC department will check and document airflow direction daily using a vaneometer. The Maintenance Department will check weekly at the start of each week using a vaneometer. Results will be logged and reported monthly to the ASC Quality Committee. Any deviations will result in immediate corrective action.</p>	

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Q0100	<p>Continued from page 2 despite the pass-through door being closed.</p> <p>-Outside of sterile supply room L42, dirty air was blowing into the clean room.</p> <p>-Outside of equipment supply room L41, dirty air was blowing into the clean room.</p> <p>*ASC manager A and SPT C agreed with the above findings.</p> <p>Observation and interview on 8/12/25 at 10:25 a.m. with maintenance supervisor B and ASC manager A revealed:</p> <p>*Findings of incorrect air pressures were verified in all identified rooms as listed above.</p> <p>*The pass-through door located between soiled room L44 and sterile supply room L42 revealed unsealed areas on each side of the door, which allowed dirty air to pass to the clean supply room.</p> <p>*Maintenance supervisor B attempted to adjust pressures in the ceiling during the time of the observation but had been unsuccessful. Dirty air continued to flow out of soiled room L44 into the clean corridor, and dirty air continued to flow into sterile supply room L42.</p> <p>*Maintenance supervisor B stated he would have to contact HVAC (heating, ventilation, and air-conditioning) company for further adjusting to correct air pressure relationships.</p> <p>*Maintenance supervisor B and ASC manager A had been unaware of how long the pressures had not been maintained. It was not a part of the staff's daily assigned responsibilities to verify correct airflow.</p> <p>Review of the provider's 2022 Monitoring of Temperature and Humidity policy revealed:</p> <p>"An effective ventilation system is in place to minimize airborne microbial contamination.</p> <p>"A trained HVAC service company will perform all preventive and unscheduled maintenance on the ventilation system."</p> <p>*The policy had not indicated the staff were to check the pressure relationships of those rooms within the surgical suite.</p> <p>Review of AORN's 2024 Guidelines for Perioperative Practice. Sterile Processing Area pp.322, 407-408</p>			Q0100	<p>Monitoring Section Analysis</p> <ul style="list-style-type: none"> What: "The ASC department will check and document airflow direction daily using a vaneometer. The Maintenance Department will check weekly at the start of each week using a vaneometer. Results will be logged and reported monthly to the ASC Quality Committee." → That spells out exactly what is being checked (airflow with a vaneometer). Who: → ASC staff (daily) and Maintenance Department (weekly). When: → Daily (ASC staff) and weekly at the start of each week (Maintenance). → Results are also reported monthly (to the Quality Committee). How: → Using a vaneometer to test airflow, documenting results in logs, and escalating to immediate corrective action if there are deviations. 		

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Q0100	<p>Continued from page 3 revealed:</p> <p>"Rooms where manual HLD is performed should have a negative pressure relationship with adjacent spaces.</p> <p>"Maintain the decontamination area HVAC system within the HVAC design parameters that were applicable according to regulatory and professional guidelines at the time of design or most recent renovation of the HVAC system.</p> <p>-The HVAC system controls the air quality, temperature, humidity, and pressure of the room in comparison with the surrounding areas. The HVAC system is designed in accordance with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) and local regulatory requirements to reduce the number of environmental contaminants and to provide a comfortable environment for occupants in the area.</p> <p>"Negative pressure helps prevent contaminated air from entering into positive-pressure, clean areas."</p> <p>Review of the 2020 addendum ASHRAE Standard 170-2017 Ventilation of Health Care Facilities revealed:</p> <p>"Sterile processing area. Pressure relationships to adjacent areas design parameters:</p> <p>-"Clean assembly/workroom: positive.</p> <p>-Soiled workroom/decontamination room: negative.</p> <p>-Sterile storage room (clean/sterile medical/surgical supplies: positive."</p> <p>Review of the Administrative Rules of South Dakota 44:76:11:19 ventilating systems revealed: "The mechanical ventilation systems shall be designed and balanced to provide make-up air and safe pressure relationships between adjacent areas to preclude the spread of infections and assure the health of the occupants.</p> <p>"Continuous mechanical exhaust ventilation shall be provided in all soiled areas, wet areas, and storage rooms."</p>	Q0100					
Q0241	<p>SANITARY ENVIRONMENT</p> <p>CFR(s): 416.51(a)</p> <p>The ASC must provide a functional and sanitary environment for the provision of surgical services by</p>	Q0241		09/17/2025			

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Q0241	<p>Continued from page 4 adhering to professionally acceptable standards of practice.</p> <p>This STANDARD is NOT MET as evidenced by:</p> <p>Based on observation, interview, and policy review, the provider failed to ensure ten of ten sharp and contaminated instruments (tweezers, scissors, and clamps) that could have contained blood, and bodily fluids were transported in a sealed, rigid container, and labeled as biohazardous.</p> <p>Findings include:</p> <p>1. Observation and interview on 8/12/25 at 10:39 a.m. with sterile processing technician (SPT) C in dirty room L44 revealed:</p> <ul style="list-style-type: none"> *Ten surgical instruments, including tweezers, scissors, and clamps, were wrapped in a green towel on top of a blue, sealed container labeled biohazardous on a cart with wheels. *Those contaminated instruments had been transported from the operating room (OR) into the soiled room wrapped in a green towel and had not been placed in a rigid container or labeled as biohazardous. *SPT C confirmed staff in the OR would place the instruments that had been opened out of their packaging onto the top of the blue bin to help make the cleaning process easier. -Those instruments may not have been used during a patient's procedure. *She stated: -That was the process that had been followed since she was hired. -The instruments that were wrapped in a green towel on top of the blue containers had not contained blood or bodily fluids, and could go straight to the washer instead of hand-washing each of them. -The instruments that have been used during a procedure and contained blood and bodily fluids were to be placed in the enclosed blue bin and sprayed with an enzymatic spray (cleaner). -The instruments wrapped in the green towel could have fallen off the cart when pushed from the OR into the soiled room. 	Q0241	<p>Deficiency: Transport of all instruments opened during a surgical procedure, regardless of use, must be in a container with a lid marked biohazardous when transferred from the Operating Room to Sterile Processing.</p>	

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Q0241	<p>Continued from page 5</p> <p>-Those instruments were sharp.</p> <p>-Those instruments should have been placed in the blue, sealed, and rigid container labeled biohazardous.</p> <p>Interview on 8/12/25 at 10:45 a.m. with SPT D revealed:</p> <p>*Instruments that have been opened and not used during a patient's procedure were to be wrapped in a green towel and placed on top of the blue bin.</p> <p>*The instruments that have been used and contain a gross amount of blood or bodily fluids were to be sprayed with an enzymatic spray and placed in a blue bin that was then to be sealed and labeled as biohazardous.</p> <p>*OR staff were to wrap the instruments that had been opened but not used in a green towel and then place them on top so the SPT could put those instruments directly into the washer.</p> <p>*She agreed that the instruments placed in a green towel on top of the blue bin were sharp and could fall off the cart.</p> <p>*She agreed the instruments, even if not used during a patient's procedure, were still considered contaminated and should have been transported in an enclosed, rigid container, labeled biohazardous.</p> <p>Interview on 8/12/25 at 11:40 a.m. with ASC manager A regarding transportation of contaminated instruments revealed:</p> <p>*Staff should have been placing all instruments whether they were used or not during a patient's procedure in the available blue, sealed containers labeled biohazardous.</p> <p>*She had been unaware staff had not been following this process.</p> <p>*The provider followed the Association of perioperative Registered Nurses (AORN) to guide their practice.</p> <p>Review of the provider's 5/25 Process for Cleaning Instrumentation policy revealed:</p> <p>"From the Operating Room, bring instrumentation to the Soiled Utility Room in a covered container with the proper amount of presoak enzymatic cleaner to water.</p>			Q0241	<p>What: The facility has updated the Autoclave Sterilization Policy to include the requirement that all surgical instruments opened during a procedure, whether used or unused, are to be considered clean but contaminated and will be transported from the Operating Room to Sterile Processing in a rigid container with a lid marked with a biohazard symbol. This update aligns with AORN standards and South Dakota Department of Health requirements. Policy update will be presented at the Governing Board meeting on September 16, 2025.</p> <p>Who: All surgical staff, including scrub technicians, circulating nurses, and sterile processing personnel, are responsible for ensuring compliance. Oversight will be provided by the ASC Manager.</p>		

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Q0241	<p>Continued from page 6</p> <p>*Solution will cover the instrumentation.</p> <p>"The instruments must remain covered in the solution for a minimum of 2 minutes and up to 15 minutes for heavily soiled."</p> <p>Review of AORN's 2024 Guidelines for Perioperative Practice: Transport to the</p> <p>Decontamination Area pg. 415 revealed:</p> <p>"7.2. Contaminated instruments must be transported to the decontamination area in a closed container or enclosed transport cart that is:</p> <ul style="list-style-type: none"> -leak proof, -puncture resistant, -large enough to contain all contents, and -labeled with a fluorescent orange or orange-red label containing a biohazard legend." 			Q0241	<p>When: This correction was effective August 12, 2025. Staff were educated on the updated policy the same day, and the policy is now active and in effect. There will be more training on Sept. 22nd at staff meeting. There is no staff on leave or on PRN status.</p> <p>How: - The Autoclave Sterilization Policy has been formally revised to include the transport procedure for clean contaminated instruments.</p> <ul style="list-style-type: none"> - All staff have been in-serviced and educated on the change verbally with the ASC Manager. - Compliance will be monitored by the ASC Manager through direct observation. Any non-compliance will be addressed with immediate re-education and corrective action. - Any observation of incorrect transportation of surgical instruments will be corrected at time of observation. All new hires will be educated upon orientation to the department. - ASC Manager will witness 10 transportation cases per month per quarter. - Audit results will be reviewed at quarterly Quality Improvement meetings to ensure sustained compliance for six months. 		

South Dakota Department of Health

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S 000	Compliance/Noncompliance A licensure survey for compliance with the Administrative Rules of South Dakota 44:76, requirements for ambulatory surgical centers, was conducted from 8/11/25 through 8/12/25. Yankton Medical Clinic, PC ASC was found not in compliance with the following requirement: S154.	S 000			
S 154	44:76:08:05 Authentication A facility shall ensure entries to the medical record timed, dated and signed or electronically authenticated. If the facility permits any portion of the medical record to be generated by electronic or optical means, policies and procedures shall exist to prohibit the use of authentication by unauthorized users. This Administrative Rule of South Dakota is not met as evidenced by: Based on record review, interview, and policy review, the provider failed to ensure all medical record entries were signed, timed, and dated for sixteen of twenty sampled medical records (2, 3, 5, 6, 7, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, and 20). Findings include: 1. Review of the above listed sampled medical records revealed: *History and physical exams had not been timed or dated in five of the reviewed medical records (2, 5, 7, 12, and 13). *Pre-anesthesia assessments performed by the certified registered nursing anesthetists (CRNA) had signatures that had not been timed and dated in eleven of the reviewed medical records (3, 6, 12, 13, 14, 15, 16, 17, 18, 19, and 20). *The CRNA had not timed and dated signatures	S 154	Deficiency: The Yankton Medical Clinic Ambulatory Surgery Center received a deficiency related to the failure of providers to consistently date and time all required signatures on clinical documentation. 44:76:08:05 Authentication. Corrective Action Taken for Affected Patients: All patient records from the survey sample were reviewed. Any missing dates and times on provider signatures have been corrected and properly documented in accordance with 44:76:08:05 Authentication. What Will Be Done to Ensure Compliance: 1. Education: Providers will be re-educated at the September 16th Board Meeting, with board approval for the updated policy. Following board approval, the ASC Manager will send out an email to all providers with the updated policy. 2. Policy Update: A written policy has been updated to emphasize that all signatures must include both date and time to comply with CMS and state requirements, including 44:76:08:05 Authentication. 3. Bylaws Update: The March 2015 Bylaws will be revised to include language requiring providers to sign, date, and time all medical record entries. What Data Will Be Monitored: - All operative reports, anesthesia records, and other provider-signed documents will be reviewed for the presence of signature, date, and time. - Any occurrence of a missing date or time will be logged as a deficiency.	09/17/25	

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

TITLE

(X6) DATE

STATE FORM

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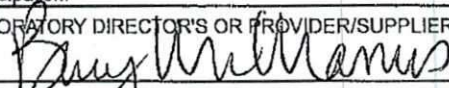
3 continuation sheet 1 of 2

South Dakota Department of Health

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S 154	<p>Continued From page 1</p> <p>for medication orders in eight of the reviewed medical records (5, 8, 12, 14, 15, 16, 17, and 18).</p> <p>*Physician orders had not been signed, timed, or dated in four of the reviewed medical records (5, 7, 11, and 12).</p> <p>*Anesthesia post-evaluation notes completed by the CRNA had not been timed or dated in three of the reviewed medical records (5, 7, and 10).</p> <p>Interview on 8/12/25 at 2:00 p.m. with ambulatory surgical center (ASC) manager A revealed:</p> <p>*There was no policy that indicated physician orders or anesthesia assessments needed to be signed, dated, and timed.</p> <p>*The medical staff bylaws had not indicated a date and time was needed with a signature.</p> <p>Review of the provider's March 2015 Bylaws and Rules policy revealed the signing, dating, and timing of medical record entries was not mentioned.</p>	S 154	<p>Who Will Be Responsible: - ASC Manager will be responsible for monitoring compliance and maintaining records of audits and any corrective actions.</p> <p>When and How Often Monitoring Will Occur: - Frequency: - Audits will be conducted daily by RNs during chart audits. Any charts missing required date and time will be sent back to the provider for correction. - Audit results will be compiled and reported at Quarterly ASC Committee meetings. - Duration: - The process will be maintained for 12 months and then reviewed for continuation or adjustment based on compliance rates.</p> <p>How It Will Be Monitored and Documented: - The ASC Manager will maintain an audit log documenting: - Date of audit - Number of charts reviewed - Number of charts compliant - Number of charts with missing date/time - Results will be reported at Quarterly Quality Improvement Committee meetings and included in the Quality Assurance and Performance Improvement (QAPI) program. - Any non-compliance identified will result in immediate notification to the responsible provider for correction and re-education as necessary.</p> <p>Systemic Changes and Long-Term Compliance: - Audit results will be used to determine if additional interventions are required (e.g., one-on-one training, policy updates). - Sustained compliance at 100% for two consecutive quarters will allow the ASC to move audits to a random sampling process.</p>		

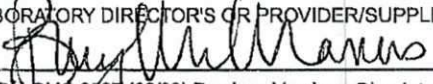
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K0000 Bldg. 01	<p>INITIAL COMMENTS</p> <p>A recertification survey for compliance with 42CFR 416.44(b)(1), requirements for ambulatory surgery centers, was completed on 8/11/25. Yankton Medical Clinic, PC ASC was found in compliance.</p>			K0000			

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the Institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE CEO	(X6) DATE 9/4/2025
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001006		(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 08/11/2025	
NAME OF PROVIDER OR SUPPLIER YANKTON MEDICAL CLINIC, PC ASC				STREET ADDRESS, CITY, STATE, ZIP CODE 1104 W 8TH ST POST OFFICE BOX 706 , YANKTON, South Dakota, 57078			
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE
E0000	<p>Initial Comments</p> <p>A recertification survey for compliance with 42 CFR Part 416, Subpart C, Subsection 416.54, Emergency Preparedness, requirements for ambulatory surgery centers (ASC), was conducted on 8/11/25. Yankton Medical Clinic, PC ASC was found in compliance.</p>			E0000			

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See reverse for further instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE CEO	(X6) DATE 9/4/2025
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