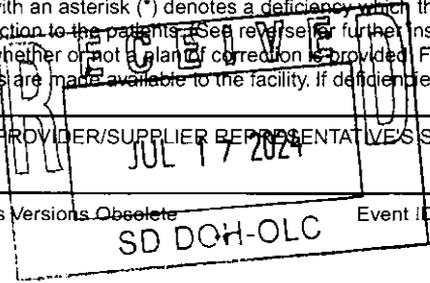


STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001025	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 06/26/2024
NAME OF PROVIDER OR SUPPLIER iSURGERY, LLC			STREET ADDRESS, CITY, STATE, ZIP CODE 905 NORTH 3RD STREET , ABERDEEN, South Dakota, 57401	
(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 6/25/24 through 6/26/24. iSurgery, LLC was found not in compliance with the following regulations: Q181 and Q241.	Q0000	Problem: The Omidria that is added to the Balance Salt Solution (BSS) irrigation for all cataract surgeries was not on any of the order sets for cataract surgery. This affects all PT's having cataract surgery. Corrective action needs to be taken because the previous intra-op orders sets cannot be corrected. Goal: The goal is to have 90% compliance in adding the Omidria/BSS order to future inta-op order sets for all patients having cataract surgery	8/5/2024
Q0181	ADMINISTRATION OF DRUGS CFR(s): 416.48(a) Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is NOT MET as evidenced by: Based on observation, and interview, the provider failed to ensure 11 of 11 sampled patients(2,3,4,5,7,9,12,14,15,18 and 21) had an order to administer balanced salt solution and Omidria (medication used to keep the pupil of the eye open) during cataract surgery. Findings include: Observation on 6/25/24 at 11:20 a.m. of patient 21's right eye intraocular lens implantation revealed: *A bottle of balance salt solution 500 milliliter (mL) with no label of added medication was used to irrigate patient 21's eye. Interview on 6/25/24 with registered nurse (RN) operating nurse (OR) infection control (IC) C regarding the irrigation solution used during above the procedure revealed: *The balance salt solution with Omidria injected into the solution was used to help keep the patient's eye dilated during the procedure. Interview on 6/26/24 3:25 p.m. with RN OR IC C regarding the order for the balance salt solution that had been injected with Omidria 4 milligrams (mg) revealed:	Q0181	Corrective Action: The need for Omidria on the Cataract order set has been acknowledged and updated. "Add Omidria 4ml to 500ml of Balance salt solution (BSS) irrigation" was added to all intra-op order sets for cataract surgery. The iSurgery staff will be verbally educated on the update to the cataract surgery intra-op order sets and made aware of the compliance goal. A sample inta-op order set will be shown to staff to make note of changes. Cataract surgery intra-op order sets will be audited until the 90% compliance rate is reached to achieve sustained compliance. Performance Monitoring: Cataract intra op order sets will be audited to verify that the Omidria/BSS order has been added upon introduction of the updated intraop order sets. The intra op order set audits will be performed by the receptionist. Audits will be performed on 100% of the patients intra op order sets weekly for 1 month, then monthly for 2 months or until the 90% compliance rate is reached. A one time audit will be performed 6 months from the updated intra op order set introduction date to verify sustained compliance is achieved. The receptionist will continue to audit intra op order sets and report audit results monthly if the compliance goal has not been met. The receptionist will report her final audit to the director of nursing following the 6 month audit. If the complianc goal is not met further education will be provided to the and the receptionist will continue to audit until the compliance goal is reached or another plan of correction is established. These reports will be included in the QAPI binder and reviewed with the Governing Board. They will be reviewed at the QAPI meeting, following audits and as needed based on compliance.	

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 Erin Bode	TITLE Administrator	(X6) DATE 7/17/2024
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001025	(X2) MULTIPLE CONSTRUCTION A. BUILDING B. WING	(X3) DATE SURVEY COMPLETED 06/26/2024	
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Q0181	<p>Continued from page 1</p> <p>*They used that solution with every cataract procedure.</p> <p>*They would have documented the use of balance salt solution injected with Omidria on the operative record.</p> <p>*She agreed there had not been an order to use the balance salt solution that had Omidria 4 mg injected into it.</p> <p>Interview on 6/26/24 with director of nursing (DON) B and administrator A regarding the balance salt solution injected with Omidria 4mg revealed:</p> <p>*They both agreed that there was not an order for the use of the balance salt solution injected with Omidria 4 mg.</p> <p>*They both had known that solution was used in cataract procedures.</p> <p>Review of the provider's July 2024 Medication Preparation and Administration policy revealed:</p> <p>**Attach the supplementary admixture label to the intravenous (IV) bag immediately which includes:"</p> <p>- "Name of the additive."</p> <p>- "Amount of the drug additive."</p> <p>- "Identification of person mixing the IV."</p> <p>- "Flow rate."</p> <p>- "Date and time of preparation."</p> <p>Review of the provider's February 2024 Preprinted Orders policy revealed:</p> <p>**Pre-printed orders will be initiated in the surgery center. All preprinted/written orders will be dated, time, and signature of the physician."</p> <p>**If the patient medication in addition to the listed on the General, Pre-op, Intra-op, or Post-op Printed Orders a separate order will be completed."</p>	Q0181	<p>The audit reports will be reviewed with the staff and Governing Board by the director of nursing at the quarterly QAPI meetings.</p> <p>The director of nursing will audit staff to verify they were educated regarding the changes to the cataract order sets by having each staff member initial an in-service record form upon completion of the education. If they have not been educated by 8/5/2024 they will need to plan to review the education provided prior to their next shift.</p> <p>Omidria 4ML and BSS 500ML will be checked of on the operative record under the intra-op medication irrigation section as is currently being done. This section will be audited at the same time as the verification of the Omidria/BSS order.</p> <p>Correction Date: This plan of correction is anticipated to be corrected with compliance rate of 90% within 6 months from the introduction of the updated cataract order sets.</p>	
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		

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Q0241	<p>Continued from page 2 adhering to professionally acceptable standards of practice.</p> <p>This STANDARD is NOT MET as evidenced by:</p> <p>Based on observation, interview, and the manufacturer's recommended use review, the provider failed to ensure the CaviCide (surface disinfectant) had been applied as directed to surfaces in five of five pre and post operative areas. Findings include.</p> <p>Observation on 6/25/24 at 8:50 a.m. of registered nurse (RN) D cleaning the pre and post operative area two revealed she had retrieved a microfiber cloth from a container and wiped the following surfaces:</p> <ul style="list-style-type: none"> -A recliner. -A blood pressure machine. -A bedside table with four drawers. -A drop-down desk. -A clipboard. -A sharps container. -A whiteboard. -A glove holder. -A chair. -A wheeled stool. <p>Interview on 6/25/24 with RN D following the above observation revealed:</p> <ul style="list-style-type: none"> *The microfiber clothes were dampened with CaviCide solution. *They had used this method of disinfecting for all of the pre and post operative areas. <p>Interview on 6/26/24 at 9:10 a.m. with director of nursing (DON) B regarding the use of the dampened microfiber clothes for disinfection revealed:</p> <ul style="list-style-type: none"> *They had used this method for disinfecting surface since she had worked here. *She agreed after reading the manufacturer's instructions for disinfecting surfaces their method of 	Q0241	<p>Problem: The cavicide that was being used in the preoperative area as a wipe on the microfiber cloths is to be used as a spray only per the manufacturer instructions. This affects all patients that come to iSurgery. Corrective action needs to be taken because this specific Cavicide product is to be used as a spray only.</p> <p>Goal: The goal is to have 90% compliance in not using this specific Cavicide product in iSurgery in the future.</p> <p>Corrective Action: The need to change the cleaning product used in the preoperative area of iSurgery has been acknowledged and changed. The Cavicide being used on the microfiber cloths as a wipe in the preop will be replaced with a new product The product that iSurgery will be using going forward is the Caviwipe HP. The caviwipe HP has a 1 step and 1 minute universal contact time which will reduce wait time between cases and increase staff efficiency. Precleaning is required when visibly soiled and or disinfecting againsts Candida auris, HIV, HBV, and HCV. Food surfaces will need to be rinsed with potable water following disinfection. The HP formulation has been proven to have better cleaning efficacy than alcohol bases products per Metrex. The HP formulation was also chosen because disinfectants with high alcohol content are not compatible with many surfaces. The iSurgery staff will be verbally educated on the updated cleaning product to be used. Visual aids and a video in-service will also be used to show the staff what the new product looks like along with the manufacturer's instructions for use.</p> <p>Performance Monitoring: the first audit will be done upon introduction of the Caviwipes HP to verify that the Cavicide jug has been removed from the preoperative area daily making sure that the Caviwipes Hp are being used. the daily audit will be done for 1 month after the introduction to the Caviwipes HP or until 90% compliance is reached. Caviwipes will continue to be used for the glucometer only. A one time audit will be done in 6 months to verify that the caviwipes HP are continuing to be used to verify sustained compliance is achieved. The infection control nurse will report the audit findings to the director of nursing each week for 1 month then again in 6 months. If the compliance goal is not being met further education will be provided to staff and the infection control nurse will determine a new audit plan at that time until the compliance goal is met. These reports will be included in the QAPI binder and reviewed with the Governing board. They will be reviewed at the QAPI meeting following audits and as needed based on compliance.</p>	8/5/2024

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Q0241	Continued from page 3 cleaning would not ensure enough of the disinfectant would have properly cleaned the area. Review of the manufacturer's instructions for use of disinfecting surfaces revealed "Spray directly on the surface and let stay on the surface for 3 minutes, then wipe with surface and let dry."	Q0241	Staff education will be monitored for completion by having each staff member initial an in-service record form upon completion of the education. They will be reviewed with the staff and governing board by the director of nursing at the quarterly QAPI meeting. Correction date: The plan of correction is anticipated to be corrected with a compliance rate of 90% within 6 months form the introduction of the Caviwipes HP.	

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E0000	Initial Comments A recertification survey for compliance with the Life Safety Code (LSC) (2012 existing ambulatory surgical center) was conducted on 6/25/24. iSurgery, LLC was found in compliance with 42 CFR 416.44 (b)(1) requirements for Ambulatory Surgical Centers.	E0000		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Erin Bode	TITLE Administrator	(X6) DATE 7/17/2024
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTIONS		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 43C0001025	(X2) MULTIPLE CONSTRUCTION A. BUILDING 01 - BUILDING 01 B. WING	(X3) DATE SURVEY COMPLETED 06/27/2024
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K0000	INITIAL COMMENTS A recertification survey for compliance with the Life Safety Code (LSC) (2012 existing ambulatory surgical center) was conducted on 6/25/24. iSurgery, LLC was found not in compliance with 42 CFR 416.44 (b)(1) requirements for Ambulatory Surgical Centers. iSurgery was found not in compliance with the following requirement(s): K353 and K355.	K0000	Problem: The automatic sprinklers were not continuously maintained due to the quarterly flow test not being done and the gauges nto being dated. This has a potential to affect all patients by increasing their risk of death or injury due to a fire therefore corrective action needs to be taken Goal: The goal is to have 100% compliance in doing the quarterly flow test and dating the gauges Will audit until sustained compliance is achieved.	8/5/2024
K0353	Sprinkler System - Maintenance and Testing CFR(s): NFPA 101 Sprinkler System - Maintenance and Testing Automatic sprinkler and standpipe systems are inspected, tested, and maintained in accordance with NFPA 25, Standard for the Inspection, Testing, and Maintaining of Water-based Fire Protection Systems. Records of system design, maintenance, inspection and testing are maintained in a secure location and readily available. a) Date sprinkler system last checked _____ b) Who provided system test _____ c) Water system supply source _____ Provide in REMARKS information on coverage for any non-required or partial automatic sprinkler system. 9.7.5, 9.7.7, 9.7.8, and NFPA 25 This STANDARD is NOT MET as evidenced by: Based on observation, record review and interview, the provider failed to continuously maintain automatic sprinklers in reliable operating condition (quarterly flow tests were not done and the gauges were not dated).	K0353	Corrective Action: The need for quarterly flow tests and dating the gauges has been acknowledged and updated. Maintenance will have Building sprinkler systems train him on doing the quarterly flow tests. He will also ask Building sprinkler systems to date the gauges going forward Performance Monitoring: Maintenance will be required to provide quarterly flow test dates to the iSurgery Administrator following each test to achieve sustained compliance each quarter throughout the year. The maintenance report is added to the QAPI binder monthly. Correction Date: The plan of correction is anticipated to be corrected with a compliance rate of 90% within 6 months from the introduction of this new policy.	

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Erin Bode	TITLE iSurgery Administrator	(X6) DATE 7/17/2024
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K0353	Continued from page 1 Findings include: 1. Observation on 6/25/24 at 10:30 a.m. revealed the fire sprinkler gauges had not been dated. Record review on 6/25/24 at 2:00 p.m. revealed no record of a gauge change. Interview with the administrator at the time of the record review confirmed that condition. 2. Record review on 6/25/24 at 2:00 p.m. revealed the required quarterly flow tests had not been performed in the past year. A flow test had been performed in March 2024 during the annual testing, but no quarterly testing had been performed during the past year. Interview with the administrator at the time of the record review confirmed that condition. Failure to continuously maintain the automatic sprinkler system as required increases the risk of death or injury due to fire. The deficiency affected two of numerous items for the automatic sprinkler system.	K0353	Problem: The problem stated was that the monthly fire extinguisher checks were not being done. The monthly checks were being done, however the fire safety officer took the tags when she replaced the fire extinguishers in May 2024. Goal: The goal is to have the fire extinguisher tags copied and kept at iSurgery. Corrective Action: The need to keep the fire extinguisher tags in the iSurgery facility for proof of monthly fire extinguisher checks has been acknowledged and updated. The fire safety officer was notified and informed that we will need her to make copies of the tags as needed and/or leave the tags in the facility. Performance Monitoring: The iSurgery Safety Office will continue to do monthly fire extinguisher checks and will continue to date and initial the tags on the fire extinguishers as was previously done. She will also continue to document this on the clean and safe environment audit monthly. The director of nursing will continue to note this in the monthly QAPI minutes. Correction Date: This plan of correction has already been done as the safety office was notified of the need to keep the tags or copies of them in the iSurgery facility for proof of monthly fire extinguisher checks.	7/11/2024
K0355 Bldg. 01	Portable Fire Extinguishers CFR(s): NFPA 101 Portable Fire Extinguishers Portable fire extinguishers are selected, installed, inspected, and maintained in accordance with NFPA 10, Standard for Portable Fire Extinguishers. 20.3.5.3, 21.3.5.3, 9.7.4.1, NFPA 10 This STANDARD is NOT MET as evidenced by: Based on observation and interview, the provider failed to perform monthly fire extinguisher checks as required by NFPA 101 Life Safety Code, and further explained under NFPA 10, 7.2.1. Findings include:	K0355	Annual service was done for the Fire Extinguishers was done on May 2024. The dated and signed tages were taken at that time. Our tags that were signed and dated were done by our safety officer, Char Doerr from Fire and Safety first (605-380-3433) came for her yearly inspection 5/10/2024. She is completing a letter stating these fire extinguisher checks are and have been done. This is also noted in the monthly minutes and the clean and safe environment audit. See Attached document	

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K0355 Bldg. 01	Continued from page 2 1. Observation and interview on 7/25/24 at 9:45 a.m. revealed the extinguisher in the ground floor mechanical room wall had received annual service in March, 2024. However, no monthly inspections were performed since that time. Interview with the administrator revealed she was not aware monthly inspections were necessary. Further inspection of the remainder of the facility revealed none of the fire extinguishers had received monthly inspections. The deficiency had the potential to affect the entire facility.	K0355	The tag on the extinguisher in the mechanical room states annual service in May 2024. Again tags were taken at that time. Survey in June 2024.	

South Dakota Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 60223 S	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/26/2024
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NAME OF PROVIDER OR SUPPLIER ISURGERY, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 905 N 3RD STREET ABERDEEN, SD 57401
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S 000	<p>Compliance/Noncompliance</p> <p>A licensure survey for compliance with Administrative Rules of South Dakota 44:76, requirements for ambulatory surgical centers, was conducted from 6/25/24 through 6/26/24. iSurgery, LLC was found in compliance.</p>	S 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE **7/10/24**

STATE FORM **WJML11** If continuation sheet 1 of 1

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