

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

PRINTED: 06/24/2024
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 433429	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 06/13/2024
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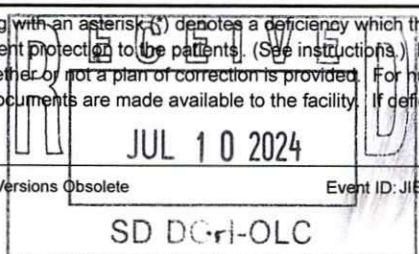
NAME OF PROVIDER OR SUPPLIER FLANDREAU MEDICAL CLINIC / AVERA HEALTH	STREET ADDRESS, CITY, STATE, ZIP CODE 212 N PRAIRIE AVENUE FLANDREAU, SD 57028
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J 000	INITIAL COMMENTS A recertification health survey for compliance with 42 CFR Part 491, Subpart A, requirements for rural health clinics, was conducted on 6/13/24. Flandreau Medical Clinic/Avera Health was found not in compliance with the following requirements: J123, J160, J161, and J162.	J 000		
J 123	STAFFING AND STAFF RESPONSIBILITIES CFR(s): 491.8(b)(2), 491.8(c)(1)(i), and 491.9(b)(1), (2), (4) 491.8(b) Physician responsibilities. The physician performs the following: (2) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's . . . written policies and the services provided to Federal program patients. 491.8(c) Physician assistant and nurse practitioner responsibilities. (1) The physician assistant and the nurse practitioner members of the clinic's . . . staff: (i) Participate in the development, execution and periodic review of the written policies governing the services the clinic . . . furnishes; § 491.9(b) Patient care policies . . . (1) The clinic's . . . health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.	J 123	A RHC Annual Program Evaluation policy was created on 6/27/24. The Annual Program Evaluation and Policy Review will be done on an annual basis by the Clinic Manager, physician and Advance Practice Providers, Hospital Administrator and a member of the Hospital Board. Both the Annual Program Evaluation and Policy Review will be completed by July 19, 2024. The review of clinic charts will be completed by a clinic nurse and signed off by the Clinic Manager. <i>KO</i> 07/09/24	07/23/2024

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Kristi Olson	TITLE Clinic Manager	(X6) DATE 6/28/24
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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 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.



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J 123	Continued From page 1 (2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic . . . staff. (4) These policies are reviewed at least biennially by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic... This STANDARD is not met as evidenced by: Based on record review, policy review, and interview, the provider failed to ensure patient care or service policies had been developed and reviewed by a group that included at least one staff physician, one staff midlevel practitioner, and one non-staff physician or midlevel practitioner at least every two years. Findings include: 1. Review on 6/13/24 of the provider's policies and procedures revealed no development or review had been performed by a group that included a staff physician, a staff midlevel practitioner, and a non-staff physician or midlevel practitioner at least every 2 years. Interview on 6/13/24 at 11:20 am with clinic manager A revealed: *Policies and procedures were documented online in the "Policy Stat" program. *As policies were reviewed, they were signed off electronically within the program. *She confirmed the policies and procedures had been reviewed by a nurse and herself on a yearly basis. *The review included the adoption of new	J 123		

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J 123	Continued From page 2 policies, the review of current policies and the retirement of outdated policies. *She confirmed the review process had not included the clinic's physician, certified nurse practioners, or a non-staff member.	J 123			
J 160	PROGRAM EVALUATION CFR(s): 491.11 §491.11 Program evaluation. This CONDITION is not met as evidenced by: Based on interview, record review, and policy review, the provider failed to ensure policies and procedures had been established and implemented to perform biennial (every two years) program evaluations. Findings include: 1. Interview on 6/13/24 at 11:20 am with clinic manager A revealed: *She was unaware that a review of clinic services was required. *She confirmed there had not been a program evaluation performed since she had started as clinic manager in 2016. There were no records or policies that indicated the provider: *Had developed and implemented a policy and procedure for the completion of biennial evaluations. Refer to J161. *Had determined if changes in patient care related policies were needed or if supervision or clinical privileges needed to be made, or if recommendations had been made and addressed by leadership. Refer to J162.	J 160	Clinic Manager developed a policy for the RHC Annual Program Evaluation. The Annual Program Evaluation will be done by July 19, 2024 by the Clinic Manager, physician, advanced practice providers, hospital administrator, and a member on the Hospital Board. <i>MD</i> 07/09/24	07/23/2024	
J 161	PROGRAM EVALUATION CFR(s): 491.11(a)-(c)	J 161			

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J 161	Continued From page 3 § 491.11 Program evaluation. (a) The clinic or center carries out, or arranges for, a biennial evaluation of its total program. (b) The evaluation includes review of: (1) The utilization of clinic or center services, including at least the number of patients served and the volume of services; (2) A representative sample of both active and closed clinical records; and (3) The clinic's or center's health care policies. (c) The purpose of the evaluation is to determine whether: (1) The utilization of services was appropriate; (2) The established policies were followed; and (3) Any changes are needed. This STANDARD is not met as evidenced by: Based on interview, record review, and procedure review, the provider failed to: *Assess the overall program. *Identify needs or areas to improve. *Take any needed corrective actions, or to make any changes to policies and procedures or patient care services offered biennially (every two years). Findings include: 1. Interview on 6/13/24 at 11:20 with clinic manager A revealed: *She was unaware that a review of clinic services was required.	J 161	Clinic Manager has a policy in place that an evaluation will be done annually to review state of scope of practice, CPT code analysis, review of encounters by type, volume of offered services, utilization of offered services, review of clinic medical records (both open and closed) of 5% or 50 records, review of current outreach programs provided, and improvements to the current programs. This will be done by July 19, 2024 by the Clinic Manager, physician, advanced practice providers, hospital administrator, and a member on the Hospital Board. <i>MD</i> 07/09/24	07/23/2024	

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J 161	Continued From page 4 *She confirmed there had not been a program evaluation performed since she had started as clinic manager in 2016. There were no records or policies that indicated the provider had: *Performed biennial program evaluations since 2016. *Identified who was to perform the program evaluations or what their qualifications were to do so. *Developed a policy that specified when and how the program evaluation was to be done and what would be covered. *Determined whether appropriate types and volumes of services were provided based on the needs of its patient population. *Evaluated if patient policies and procedures were followed and if changes were required. Specific additional training for staff could not be identified. *Conducted a review of active and closed patients' medical records by qualified individuals to determine if services were appropriate. *Created a summary report with recommendations if needed to address problems identified in the evaluation and submitted that report to the provider's leadership. *Recommendations from the provider's leadership related to a summary report.	J 161			
J 162	PROGRAM EVALUATION CFR(s): 491.11(d) 491.11(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary. This STANDARD is not met as evidenced by: Based on interview, record review, procedure	J 162	There is a RHC Annual Program Policy created and will be completed by July 19, 2024. <i>ND</i> 07/09/24 The Clinic Manager is in the process of creating an Annual Summary for the clinic that will assess the overall RHC program, services offered, identify needs or areas to improve and if action is necessary.	07/23/2024	

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J 162	<p>Continued From page 5</p> <p>review, the provider failed to:</p> <ul style="list-style-type: none"> *Assess the overall rural health clinic program. *Identify needs or areas to improve. *Take any needed corrective actions, or make any needed changes to the patient care services offered biennially (every two years). Findings include: <p>1. Interview on 6/13/24 at 11:20 am with clinic manager A revealed:</p> <ul style="list-style-type: none"> *She was unaware that a review of clinic services was required. *She confirmed there had not been a program evaluation performed since she had started as clinic manager in 2016. <p>There were no records or policies that indicated the provider had performed biennial program evaluations or</p> <ul style="list-style-type: none"> *If changes in policies were necessary. *If training of staff was necessary. *If changes were necessary in the areas of supervision or clinical privileges. *Where and when the evaluation findings and recommendations were considered and by whom. *Rationale for decisions when leadership did not take the corrective actions recommended as a result of the evaluation or if different actions were taken than those recommended. 	J 162		
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E 000	<p>Initial Comments</p> <p>A recertification survey for compliance with 42 CFR Part 491.12, Subpart A, Emergency Preparedness requirements for rural health clinics, was conducted on 6/13/24. Flandreau Medical Clinic/Avera Health was found in compliance.</p>	E 000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE Kristi Olson	TITLE Clinic Manager	(X6) DATE 6/28/24
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