Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2244794	03/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medway Air Ambulance	570 Briscoe Boulevard, Lawrenceville, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on March 15, 2024. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on SOP, documents review and staff interviews, the laboratory director failed to enroll in a CMS approved Proficiency Testing (PT) program from August 2022 to March 2024 in the specialty of Clinical Chemistry. Findings: 1. Review of laboratory SOP revealed the laboratory failed to follow its own procedure by NOT enrolling in a CMS accredited PT testing program from August 2022 to March 2024. 2. Interviews with the Technical Supervisor(TS) (TP #5 CMS 209), lab director and office manager in the review room at approximately 1:00 PM on 03/15/2024 confirmed NO PT records and enrollment in a CMS approved PT program from 2022 to 2024.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document ALL quality assessment activities on a monthly basis as stated in their QA policy manual from 2022 to 2024. Findings: 1. A review of the laboratory QA documents revealed the technical Consultant (TC) who is also the Technical Consultant did not review and sign ALL monthly quality activities(QA) checklists, neglecting Proficiency Testing (PT) 2022 thru the date of survey March 2024 in the Specialty of Clinical Chemistry. 2. Interviews with the second TC (TP#5 CMS 209) and office manager on 03/15/2024, at approximately 1:00 pm in the review room confirmed NOT ALL (QA) checklist activities were monitored and signed off by the second (TC) or Lab director from 2022 thru day of survey, March 15, 2024.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on documents review and interview with the Technical Supervisor (TS), the Lab Director(LD) failed to ensure that ALL Quality Assurance (QA) guidelines were followed to identify and fix problems in the laboratory from 2022 to 2024 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Monthly QA document review revealed the Lab director and the Technical Consultant (TC), did NOT realize that the laboratory was NOT enrolled in a CMS accredited Proficiency Testing program from 2022 to 2024.. 2. An interview with the laboratory's (TC) (TP# 5 CMS 209 and office manager in the review room on 03/15/2024 at approximately 1: 35 PM, confirmed the Lab Director failed to ensure proper oversight of the laboratory testing from 2022 to 2024.