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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 42D2282746 | (X3) Date Survey Completed 05/16/2025 |
| Name of Provider or Supplier Coastal Carolina Behavioral Health | Street Address, City, State 2734 Beaver Run Blvd, Myrtle Beach, SC | |
| 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 onsite initial survey was conducted at Coastal Carolina Behavioral Health on May 16, 2025 by South Carolina Department of Public Health (SC DPH). The facility was found to be out of compliance with the Medicare Condition at 42 CFR part 493 CLIA Laboratory Requirements. The following is a list of CONDITION Level deficiencies cited as a result of the CLIA INITIAL survey on May 16, 2025. |
| D2000 | <p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on records review and staff interview, the laboratory failed to enroll in a proficiency testing program approved by HHS for the specialties and subspecialties for which it seeks certification. Findings include: 1. Review of records reveals the laboratory failed to enroll in a proficiency testing program for 2 of 3 years reviewed (2023, 2024, and 2025). 2. In an interview with laboratory director (LD) on May 16, 2025, at 2:02 pm in the office the above findings were confirmed.</p> |
| D5291 | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p> |

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on records review and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. Review of policies and procedures reveals a lack of establish written policy for how the laboratory will document all quality assessment activities pre-analytical, analytical and post-analytical, when necessary what corrective actions will be taken when results fail to meet the laboratory's criteria for acceptability, how proficiency testing will be handled and evaluated, and how equipment maintenance will be performed. 2. In an interview with LD on May 16, 2025, at 2:02 pm in the office the above findings were confirmed.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on records review and staff interview, the laboratory lacks documentation of a complete verification of performance specifically as it relates to specificity, analytical sensitivity, interfering substances and any other performance characteristic required for test performance. Findings include: 1. Review of validation records reveal documentation on precision studies with no other documentation available for specificity, sensitivity or interfering substances for Bioli's 24i manufactured by Abbott on the day of survey May 16, 2025. 2. In an interview with LD on May 16, 2025, at 2:02 pm in the office the above findings were confirmed.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on records review and staff interview the laboratory lacked documentation of maintenance as defined by the manufacturer with at least the frequency specified by the manufacturer. (5 out of 24 months reviewed) Findings include: 1. Review of operator's manual for Bioli's 24i manufactured by Abbott maintenance requires monthly maintenance. 2. Review of maintenance records reveal no documentation for

5 of 24 months (March 2023, January 2025, February 2025, April 2025, May 2025) reviewed. 3. Review of operator's manual reveal 5.2 maintenance list with daily maintenance and parts exchange is different from the maintenance log that is being used and lack specific parts to be exchanged at specific intervals. 4. In an interview with LD on May 16, 2025, at 2:02 pm in the office the above findings were confirmed.