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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>04D2086422     | <b>(X3) Date Survey Completed</b><br><br>04/19/2022 |
| <b>Name of Provider or Supplier</b><br><br>Interventional Pain Management  | <b>Street Address, City, State</b><br><br>525 Burnett Drive, Mountain Home, AR |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5793</b>              | <p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b><br/>CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by:<br/>Through review of CAP 2021 Urine Drug Testing Confirmatory Survey reports, January 2021 and August 2021 laboratory quality control (QC) reports for codeine urine drug Testing, corrective action documentation for codeine urine drug testing and interview with laboratory staff it was determined that corrective action to correct analysis biases for codeine confirmatory testing was unsuccessful. Findings follow:<br/>A) Review of the CAP Urine Drug Testing Confirmatory Proficiency Testing Survey 2021 event A reports revealed that the laboratory failed two of two codeine challenges ; UDC-04 reported result of 3978, with an acceptable range (1896 to 3243) + 4 standard deviation index (SDI); UDC- 06 reported result of 1880, with an acceptable range (776-1282) +7/5 SDI. B) Review of the corrective action comments for the event, identified above, revealed "Fresh internal standard - no further action needed". C) Review of the CAP Urine Drug Testing Confirmatory Proficiency Testing Survey 2021 event C reports revealed that the laboratory failed one of two codeine challenges; reported result UDC 26 of 2025 with an acceptable range (691-1365) +5.9 SDI. D) Review of the corrective action comments for the event, identified above, revealed "System Optimization". E) Review of laboratory quality control results for codeine determinations for the period of 1/1/21 to 2/1/21 revealed: * WQCS1 (Level one target) of 75 with a calculated performance mean of 81.2 and 13 of 16 determinations recorded as above target. * WQCS2 (Level two) target of 125 with a calculated performance mean of 136.6 and 14 of 16 determinations recorded as above</p> |

target. \*WQCS3 ( Level three) target of 2500 with a calculated performance mean of 2815.4 and 14 of 16 determinations recorded as above target. F) Review of laboratory quality control results for codeine determinations for the period of 8/1/21 to 9/1/21 revealed: \* WQCS1 (Level one target) of 75 with a calculated performance mean of 83.8 and 16 of 18 determinations recorded as above target. \* WQCS2 (Level two target) of 125 with a calculated performance mean of 136 and 16 of 18 determinations recorded as above target. \* WQCS (Level three target) of 2500 with a calculated performance mean of 2522.9 and 12 of 18 determinations recorded as above target. G) In an interview on 4/19/22 at 02:45 PM, the testing personnel, identified as number 7 on the CMS 209 form, stated that quality control targets are determined by specific dilutions of NIST standard stock and that corrective action taken to improve performance of codeine determinations in urine drug confirmatory testing did not appear to be successful.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Through a review of personnel records for two of two testing personnel, a lack of documentation, an interview with laboratory staff, it was determined the laboratory director failed to give written authorization for two of two testing personnel to perform testing without direct supervision. Survey findings follow: A) A review of personnel records for testing personnel revealed that two of two (#7 and #8 as listed on the CMS-209) failed to have the laboratory director's written authorization to perform testing in their records. B) Upon request, the laboratory was unable to provide written authorization to perform testing for testing personnel, identified as numbers 7 and 8 on the CMS 209 form, signed by the laboratory director. C) In an interview, at 2:12 p. m. on 4/19/2022, laboratory employee #7 (as listed on the CMS-209 form) confirmed the lack of written authorizations for employees #7 and #8.