Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2106915	04/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Center For Wellness And Pain Care Of Las Vegas	6930 S Cimarron Rd Ste 260, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on April 12, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing (PT) results for the 2022 Drug Monitoring for Pain Management (DMPM) events A and B, the laboratory's test menu, review of the analytes covered by the DMPM program, and an interview with the laboratory general supervisor, the laboratory failed to ensure that the accuracy of the analytes tested by LC-MS/MS was verified at least twice annually. Findings include: 1. Review of the CAP PT results for the 2022 DMPM event A revealed that specimen DMPM-01 had unacceptable results for four of four analytes for confirmatory testing, DMPM-02 had unacceptable results for four of four analytes for confirmatory testing, and specimen DMPM-03 had unacceptable results for one of two analytes for confirmatory testing. 2. Review of the CAP PT results for the 2022 DMPM event B revealed that the laboratory had not submitted PT results for this event due to instrument problems. 3. There was no documentation of an alternative proficiency test or twice per year verification for confirmatory testing analytes in 2022. 4. Review of the laboratory test menu and the analytes covered by the CAP DMPM proficiency testing revealed that zolpidem and phentermine are not covered by this program. There was no documentation of alternative proficiency

	testing or twice per year verification for these analytes. 5. The general supervisor confirmed these findings in an interview on April 12, 2023, at approximately 2:00 PM. The laboratory performs approximately 91,800 chemistry tests per year.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition of Analytic Systems was not met. Findings include: 1. The laboratory failed to follow their director approved policy for establishing acceptable ranges for Quality Controls. Refer to D5401. 2. The laboratory failed to ensure that all procedures and changes in procedures were approved by the laboratory director prior to use. Refer to D5407. 3. The laboratory failed to provide the the manufacturer's established limits for and complete all items on the daily function check logs. Refer to D5431. 4. The laboratory failed to establish a procedure for overlaps in the acceptable Quality Control ranges for positive and negative controls for toxicology screening tests. Refer to D5469. The laboratory performs approximately 91,800 chemistry tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) policy for screening, the QC lot Number Verification from December 2022, a QC result report from May 31, 2022, and an interview with the technical consultant, the laboratory failed to follow their director approved procedure for determining the acceptable ranges for the screening controls. Findings include: 1. Section 5 of the Quality Control policy for screening, states that "The QC will be [run], preferably over 5 days and the means taken for each [QC level], each positive and negative control will have new ranges established [plus or minus] 20% from the new mean using new lot assay worksheet. The General supervisor will update the LIS QC file for the new ranges if needed." 2. Review of the "New QC Lot Number Verification" worksheet from December 31, 2022, revealed that the plus or minus 20% of the means from the new lot had not been calculated. The ranges marked as acceptable for the QCs were carried over from a previous lot and were not the calculated ranges for the nine analytes at positive and negative levels that were included in the new control materials. 3. Review of the Quality Control Result Report from May 31, 2022, revealed that the acceptable ranges for QC being utilized in patient testing were consistent with the carried over ranges from the

	December 31, 2022 QC verification worksheet. 4. An interview with the technical consultant at approximately 11:00 AM on April 12, 2023, confirmed these findings. The laboratory performs approximately 91,800 chemistry tests per year.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the bench policy being utilized by the laboratory, a patient report, and an interview with the general supervisor, laboratory failed to ensure that all procedures and changes in procedures were approved by the laboratory director prior to use. Findings include: 1. The LC-MS /MS policy being utilized at the bench by the laboratory was not director approved. 2. Review of results from the confirmatory testing for patient initials GR reported by the laboratory on January 17, 2023, the director approved Laboratory Test Menu and Specimen Cut-off policies, and the bench policy revealed that: a. The Laboratory test menu policy included 17 analytes that were not being reported by the laboratory including: amobarbital, amphetamine, clonazepam, flunitrazepam, flurazepam, JWH018 (a synthetic cannabinoid), MDA, MDEA, MDPV (bath salts), meperidine, methadone, methylone, normeperidine, oxycodone, phencyclidine (PCP), phenobarbital, and carboxy-THC (THCA). b. There were 13 analytes that were included in the Test Menu policy but not in the Specimen Cut-off policy (which determines the concentration at which an analyte is reported positive) including: amobarbital, flurazepam, JWH018, MDA, MDEA, MDPV, meperidine, methylone, normeperidine, oxycodone, PCP, phenobarbital, and THCA. c. There were 15 analytes that were included in the Specimen Cut-off policy but not in the patient report including: amphetamine, clonazepam, flunitrazepam, flurazepam, JWH018, MDA, MDEA, MDPV, meperidine, methylone, normeperidine, oxycodone, PCP, and THCA. d. There were nine analytes that were included in the Test Menu policy but not in the bench policy including: amobarbital, flunitrazepam, flurazepam, JWH018, MDA, MDPV, meperidine, methylone, and oxycodone. e. There were 12 analytes that were included in the bench policy but not in the Test Menu policy including: butalbital, cyclobenzaprine, desipramine, doxepin, imipramine, midazolam, naloxone, naltrexone, nordiazepam, normeperidine, nortriptyline, and sufentanil. f. There were 19 analytes that were included in the bench policy that were not included in the patient report including: amphetamine, butalbital, clonazepam, cyclobenzaprine, desipramine, doxepin, imipramine, MDA, MDEA, methadone, midazolam, naloxone, naltrexone, normeperidine, nortriptyline, PCP, phenobarbital, sufentanil, and THC. 3. Review of the currently reported results by the laboratory and the Specimen Cut-off Values policy revealed that the policy indicated that the cut-offs to determine positive reporting for benzoylecgonine and methylphenidate were each 50 ng/mL, however the patient report indicates that the cut-offs are 10 ng/mL and 100 ng/mL, respectively. 4. The number and levels of calibrators do not agree between the General Operating Procedure and the bench procedure. The General Operating Procedure indicates six levels of calibrators will be used in each batch. The bench procedure indicates that seven levels of calibrators are used. The general supervisor indicated that the laboratory uses seven levels described in the bench policy. 5. The General Operating Procedure section 7.3.1.1 regarding the acceptance criteria for standards (calibrators) indicates that standards should be within plus or minus 20% of their target

	concentration, except for the lower limit of quantitation (LLOQ) which should be plus or minus 25% of its target. It also indicates that sample outside of these criteria should be excluded from the regression calculation and that at least 75% of all the remaining standards need to be within plus or minus 20% of their target concentrations for the batch to be acceptable." 6. The acceptance criteria for the remaining calibration points after exclusion does not match between the bench procedure and the General Operating Procedure. The bench procedure indicates two of the seven calibrators may be up to 30% off of target, without being excluded when they are on opposite sides of the mean where the General Operating Procedure indicates that 75% of all remaining standards must be within 20% of their target value. The general supervisor indicated that this is the procedure that was used. 7. The batch acceptance worksheet included with the General Operating Procedure does not match the General Operating Procedure. The General Operating Procedure section 7.3.1.5 indicates that the R^2 value, which is used to determine the accuracy of the calibrators and the calibration curve should be greater than 0.95. The worksheet indicates that the calibration curve R^2 value should be greater than or equal to 0.99. The general supervisor indicated that the laboratory uses 0.95 for the R^2 value's acceptability criteria. 8. The bench procedure does not match the General Operating Procedure regarding acceptability criteria for QC samples. The General Operating Procedure, section 7.3.2.1 states that, "Quality control samples (internally prepared or external QC) should be within [plus or minus] 30% of their target concentrations for a batch to be acceptable. The procedure being utilized on the bench states in section 9.3 that, "QC concentrations at each level must fall within [plus or minus] 25 or 30% of target (depending on Compound)." The general supervisor indicated that this is the procedure that was used. 9. The number and levels of QC do not agree between the General Operating Procedure and the bench procedure. The General Operating Procedure section 5.4 indicates a low and high QC will be used in each batch. The bench procedure indicates that three levels of QC should be used including a low, mid, and high QC. The general supervisor indicated that the laboratory used the three levels of QC described in the bench policy. 9. An interview with the general supervisor on April 12, 2023, at approximately 2:30 PM confirmed these findings. The laboratory performs approximately 91,800 chemistry tests per year.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the 2022 and 2023 AB Sciex LCMS Daily Maintenance Logs and an interview with the general supervisor, the laboratory failed to provide the manufacturer's established limits for all criteria on the logs and failed to fully complete all logs. Findings include: 1. Review of the 2022 and 2023 AB Sciex LCMS Daily Maintenance Logs revealed that Pump A post Equilibration and Pump B post Equilibration were to be checked daily. The general supervisor indicated that this was the pressure at each pump. 2. The laboratory failed to include the manufacturer's established pressure limits for Pump A post Equilibration and Pump B post Equilibration on the logs. 3. The laboratory failed to document Pump A post Equilibration and Pump B post Equilibration for 21 of 21 days in December 2022 and

	for seven of seven days in April 2023 prior to patient testing. 4. The general supervisor confirmed these findings in an interview on April 12, 2023 at approximately 2:00 PM The laboratory performs approximately 91,800 chemistry tests per year.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) policy for screening, the QC lot Number Verification from December 2022, a QC result report from May 31, 2022, and an interview with the technical consultant, the laboratory failed to establish a policy for determining the acceptable ranges of QC reagents when the acceptable positive and negative ranges overlapped. Findings include: 1. Review of the Quality Control policy for screening found that there were no provisions to prevent positive and negative QC ranges from overlapping around the cut-off. 2. Review of the "New QC Lot Number Verification" worksheet from December 31, 2022, revealed that the ranges marked as acceptable for the QCs for Oxycodone were carried over from a previous lot and were 5-110 ng/mL for the DOAT-2 control and 105-350 ng/mL for the DOAT-3 control. 3. Review of the results for patients RL from March 10, 2022 and ZC from August 31, 2022 indicated that the laboratory is using 100 ng/mL as the cut-off to determine presumptive positive patient results for oxycodone. The acceptable QC ranges documented on the new lot verification worksheet of 5-110 ng/mL for the DOAT-2 control and 105-350 ng/mL for the DOAT-3 control, overlap at this cut-off level. 4. An interview with the technical consultant at approximately 11:00 AM on April 12, 2023, confirmed these findings. The laboratory performs approximately 91,800 chemistry tests per year.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition of the Laboratory Director fulfilling their responsibilities was not met. Findings include: 1.

	The laboratory director failed to ensure that an approved corrective action plan was followed for unacceptable proficiency testing results. Refer to D6092. 2. The laboratory director failed to ensure that the monthly Quality Assurance program was sufficient to detect failures in quality as they occurred. Refer to D6094. 3. The laboratory director failed to ensure that a current and approved manual was available for testing procedures done by LC-MS/MS. Refer to D6106. 4. These findings were confirmed in interviews with the technical consultant and the general supervisor on April 12, 2023, at approximately 10:30 AM and 2:30 PM, respectively. The laboratory performs approximately 91,800 chemistry tests annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory documentation for the College of American Pathologists (CAP) proficiency testing (PT) for the 2022 Drug Monitoring for Pain Management (DMPM) event A and B, and an interview with the general supervisor, the laboratory director failed to document the corrective action for unacceptable and unsubmitted PT results. Findings include: 1. Review of the CAP PT results for the 2022 Drug Monitoring for Pain Management (DMPM) event A revealed that specimen DMPM-01 had unacceptable results for four of four analytes for confirmatory testing, DMPM-02 had unacceptable results for four of four analytes for confirmatory testing, and specimen DMPM-03 had unacceptable results for one of two analytes for confirmatory testing. 2. The laboratory was unable to provide documentation of the investigation and corrective action plan for these unsuccessful analytes. 3. The general supervisor confirmed these findings in an interview on April 12, 2023 at approximately 2:00 PM. The laboratory performs approximately 91,800 chemistry tests per year.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's monthly Quality Assessment (QA) checklist, policies and procedures, proficiency testing documentation and interviews with the technical consultant and general supervisor, the laboratory director failed to ensure that the QA program identified failures in quality. Findings include: 1. The QA program failed to ensure that all analytes tested by the laboratory were assessed twice per year for accuracy. Refer to D5217. 2. The QA programed failed to identify that the procedure being used at the bench for LC-MS/MS testing was not director approved, and that there were discrepancies between the bench policy and the director approved policies utilized for LC-MS/MS testing, including the test menu and cut-off levels. Refer to D5407 3. The QA program failed to identify discrepancies between the policy and laboratory practice for setting quality control ranges for the screening

	instrument. Refer to D5401. 4. The QA program failed to identify overlap in the screening QC ranges for oxycodone. Refer to D5469. 5. The QA program failed to identify that there was no corrective action plan for unsuccessful or proficiency tests. Refer to D6092. 6. Interviews with the technical consultant and general supervisor on April 12, 2022, at approximately 10:30 AM and 2:30 PM, respectively confirmed these findings. The laboratory performs approximately 91,800 chemistry tests per year.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the LC-MS/MS Specific Laboratory Policies and an interview with the general supervisor, the laboratory director failed to ensure that director approved policies and procedures were revised and director approved prior to changing laboratory practices for confirmation testing. Findings include: 1. The following procedures were signed by the director on June 20, 2018. General Standard Operating Procedure, Laboratory Test Menu, Specimen Cut-off Values, Reportable Ranges. 2. Clonazepam and Flunitrazepam had been manually crossed out on the Specimen Cut-off Values procedure. There was no indication that the director had approved the revised procedure. 3. Review of patient reports indicated that the laboratory was currently reporting results for 34 confirmatory analytes. There were no policies or procedures that included only the 34 confirmatory analytes. 4. The general supervisor confirmed these findings in an interview at approximately 2:30 PM on April 12, 2023. The laboratory performs approximately 91,800 chemistry test annually.