Final Audit Report of Atlantic Diagnostic Laboratories' Medicaid Billing Practices

MEDICAID FRAUD DIVISION REPORT

Kevin D. Walsh
Acting State Comptroller

Issued October 3, 2024

NEW JERSEY
OFFICE OF THE STATE
COMPTROLLER

Table of Contents

* Exhibits C and D were omitted to maintain confidentiality.

I. Executive Summary

The Office of the State Comptroller, Medicaid Fraud Division (OSC) conducted this audit to determine whether Atlantic Diagnostic Laboratories, LLC (ADL) billed for drug tests during the audit period of January 1, 2015 through June 30, 2018, in accordance with applicable state and federal laws, regulations, and guidance. OSC selected a probability sample of ADL's claims from a population of 615,648 paid claims (304,546 episodes) totaling $31,200,172 that Medicaid paid to ADL for presumptive and/or definitive drug testing. OSC found that all of the sampled claims reviewed failed to meet one or more legal requirements. From these findings, OSC determined that ADL received overpayments and, when those amounts are combined with civil penalties, OSC seeks a total recovery of $7,352,961.

OSC's audit found that in 88 of the 261 sample episodes ADL either billed for tests that the physician or licensed practitioner had not ordered or billed for tests that lacked required documentation or signatures. For these documentation deficiencies, OSC calculated that ADL received an extrapolated overpayment of $2,943,586.[1]

OSC also found that ADL "unbundled" claims, a practice that is prohibited and typically results in a higher reimbursement rate for a provider than a bundled claim. Specifically, ADL improperly unbundled 231,091 claims for specimen validity testing separate from presumptive and definitive drug testing. For these unbundled claims, OSC determined that ADL received an overpayment totaling $1,140,043.

ADL also violated N.J.A.C. 10:61-1.7, the Basis of Reimbursement (BOR) regulation, which is intended to protect the Medicaid program from being charged rates by independent clinical laboratories that exceed the rates such laboratories charged other payers for the same services, as well as N.J.A.C. 10:61-2.4, a regulation that prohibits independent clinical laboratories from offering discounts or rebates. OSC found that ADL charged other payers as little as $2.38 per test, while it charged Medicaid between $125 and $1,035, and Medicaid paid ADL the program's fee schedule rate of between $63.40 and $180.40 for these same services. ADL continued this practice for the entirety of OSC's audit period, charging referring providers rates for thousands of drug tests that, in some cases, were so significantly discounted that they were nearly free. ADL's consistent failure to charge Medicaid its lowest rate throughout the audit period violated both the BOR regulation and the anti-rebate regulation. Despite the fact that it was violating these Medicaid regulations for the duration of OSC's review period, ADL continually submitted Medicaid claims, accepted Medicaid payments, and, in each such instance, certified pursuant to N.J.A.C. 10:49-9.8(a) that "the services billed on any claim were rendered by or under [ADL's] supervision (as defined and permitted by program regulations)" – and thus in conformity with all Medicaid laws and rules. ADL further certified under N.J.A.C. 10:49-9.8(a) that its Medicaid claims were true, accurate, and complete. For this conduct, which ADL knew violated multiple Medicaid regulations, pursuant to N.J.S.A. 30:4D-57(d)(2), N.J.S.A. 30:4D-17(e)(3), and N.J.S.A. 2A:32C-3, OSC is seeking a civil penalty of $3,269,332 from ADL for the 261 episodes in the audit sample that violated Medicaid regulations in the audit period.

[1] OSC can reasonably assert, with 90% confidence, that the total overpayment in the universe is greater than $2,943,585.67 (18.43% precision) with the error point estimate as $3,608,674.89.

OSC also found that for 75 percent of the episodes in OSC's sample, ADL did not perform at least one specific drug test that the physician or licensed practitioner ordered based on a determination of its medical necessity. In these cases, ADL improperly substituted its medical judgment for that of the ordering physician or licensed practitioner. While OSC is not seeking a monetary recovery for these deficiencies because they did not cause economic harm to the Medicaid program, OSC highlights these failings because they may have had an adverse impact on patient care.

II. Background

Atlantic Diagnostic Laboratories, LLC (ADL), located in Bensalem, Pennsylvania, has participated as an independent clinical laboratory in the New Jersey Medicaid program since March 10, 2010. N.J.A.C. 10:61-1.2 states that "'[c]linical laboratory services' means professional and technical laboratory services provided by an independent clinical laboratory when ordered by a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by the laws of the state in which he or she practices." During the audit period, ADL was one of the New Jersey Medicaid program's highest-paid providers of independent clinical laboratory services.

ADL submitted claims to the Medicaid program primarily for presumptive and definitive drug tests and, to a lesser extent, for specimen validity tests. Presumptive procedures are used to screen for the possible use or non-use of a drug or drug class. Definitive procedures are used to identify drugs or metabolites (byproducts of a drug). Specimen validity tests are conducted primarily to ensure that a specimen sample is unaltered and usable for testing.

III. Audit Objective, Scope, and Methodology

The objective of this audit was to evaluate claims for services billed by and paid to ADL by the New Jersey Medicaid program to determine whether ADL billed these claims in accordance with applicable state and federal laws, regulations, and guidance.

The scope of this audit was January 1, 2015 through June 30, 2018. This audit was conducted pursuant to the authority of the Office of the State Comptroller (OSC) as set forth in N.J.S.A. 52:15C-1 to -23, and the Medicaid Program Integrity and Protection Act, N.J.S.A. 30:4D-53 to -64.

To accomplish the audit objective, OSC reviewed a probability sample of 261 episodes with 554 unique paid claims for presumptive and/or definitive drug tests for which the Medicaid program paid ADL a total of $31,167. This sample was selected from a population of 304,546 episodes with 615,648 paid claims for presumptive and/or definitive drug tests for which the Medicaid program paid ADL a total of $31,200,172. (See Exhibit A for the procedure code descriptions.)

OSC reviewed ADL's service agreements with its referring providers, test requisitions, test results, billing claim forms, and invoices to ensure that ADL's charges to Medicaid did not exceed ADL's charges for identical services to other groups or individuals. OSC also reviewed ADL's service agreements with its referring providers, physician acknowledgment forms, test requisitions, and test results to determine whether ADL possessed documentation to substantiate the claims for these tests. Further, OSC identified and reviewed claims for specimen validity tests performed in

conjunction with a presumptive and/or definitive drug test for the same beneficiary on the same date of service that ADL billed separately and received payment under Current Procedural Terminology (CPT) codes 82570, 83986, and 84311. (See Exhibit A for these code descriptions.)

IV. Discussion of Auditee Comments

The release of this Final Audit Report concludes a process during which OSC afforded ADL multiple opportunities to provide input regarding OSC's findings. Specifically, OSC provided ADL a Summary of Findings (SOF) and offered ADL an opportunity to discuss the findings at an exit conference. OSC and ADL, represented by counsel, held an exit conference during which the parties discussed OSC's findings in the SOF. After the exit conference, ADL provided OSC with additional records. After considering ADL's submission, OSC provided ADL with a Draft Audit Report (DAR) and ADL provided a formal response to the DAR. OSC considered ADL's response and modified its overpayment amount for the Basis of Reimbursement finding, which is discussed below, from calculating an extrapolated overpayment to assessing a civil monetary penalty. Following this modification, OSC provided ADL with a Revised DAR. ADL provided a formal response to the Revised DAR, which is attached as Appendix A. After receipt of ADL's formal response to the Revised DAR, at ADL's request, OSC held another meeting with ADL's counsel to discuss the audit findings and ADL's response.

ADL, in its response to the Revised DAR, generally did not agree with OSC's findings. ADL also provided OSC with a corrective action plan to address OSC's recommendations, which referenced corrections that ADL claimed it made after OSC's audit review period. Furthermore, despite providing its corrective action plan, ADL generally disagreed with OSC's recommendations. In its corrective action plan, ADL referenced the New Jersey Department of Medical Assistance and Health Services Newsletter Vol. 31, No. 11, which instituted changes in Medicaid reimbursement for drug testing by limiting the frequency of presumptive and definitive testing as well as limiting the number of definitive drug classes that may be billed. ADL stated that following this change, it no longer matters how many drug classes it lists on its drug test orders since there would only be one reimbursement rate. OSC notes that ADL's position does not alter OSC's findings because drug testing is requested by the ordering physician, not the testing laboratory, and tests are requested based on the patient's medical needs. Accordingly, regardless of the reimbursement rate for its services, as a Medicaid provider, ADL's documentation must clearly and accurately reflect the drug testing ordered and performed. OSC addresses each argument raised by ADL in more detail in Appendix B.

V. Audit Findings

A. Deficient Documentation and Billing Irregularities for Presumptive and Definitive Drug Testing

OSC reviewed ADL's documentation to determine whether ADL properly documented the services it billed to the Medicaid program. OSC found that 88 of the 261 sample episodes (33.7 percent) resulted in 88 exceptions. (See Exhibit B.) OSC extrapolated the error dollars, $3,997 of $31,167 for the sample episodes, to the sample universe of 304,546 episodes (615,648 claims), totaling

$31,200,172. Applying this process, OSC calculated that ADL received an overpayment of at least $2,943,586,[2] for which OSC is seeking recovery. Set forth below is a discussion of each type of deficiency that OSC found.

Missing Documentation

ADL could not provide OSC with a test requisition for 1 of the 261 sample episodes.

N.J.A.C. 10:49-9.8(b) requires providers to keep such records as are necessary to disclose fully the extent of services provided for a minimum of five years from the date the service was rendered. Further, in accordance with N.J.A.C. 10:61-1.6(a), orders shall be on file with the billing laboratory and shall be available for review by Medicaid/NJ FamilyCare representatives upon request.

Invalid Standing Orders

OSC found that in 7 of the 261 sample episodes, ADL processed standing orders that failed to comply with N.J.A.C. 10:61-1.6 and N.J.A.C. 10:49-9.8(a) and (b). Standing orders are patient-specific drug test orders that are effective for up to 12 months for patients who need regular and recurring drug tests as part of their treatment plan. The standing orders at issue were invalid because the dates of service for the drug tests were outside the effective date range of each of the standing orders.

N.J.A.C. 10:61-1.6(c) states that standing orders shall be:

1. Patient-specific and not blanket requests from the physician or licensed practitioner;
2. Medically necessary and related to the diagnosis of the recipient; and
3. Effective for no longer than a 12-month period from the date of the physician's/practitioner's order.

N.J.A.C. 10:49-9.8(a) states that "all providers shall certify that the information furnished on the claim is true, accurate, and complete." Pursuant to N.J.A.C. 10:49-9.8(b), providers shall "keep such records as are necessary to disclose fully the extent of services provided . . . for a minimum period of five years from the date the service was rendered."

Missing Signatures

OSC found that test requisitions for 1 of the 261 sample episodes failed to include the signature of the physician or other licensed practitioner who ordered the services in a written requisition.

Pursuant to N.J.A.C. 10:61-1.6(a), "orders for clinical laboratory services shall be in the form of an explicit order personally signed by the physician or other licensed practitioner requesting the services." Pursuant to N.J.A.C. 10:61-1.2, "'[c]linical laboratory services' means professional and technical laboratory services provided by an independent clinical laboratory when ordered by a

[2] See Footnote 1.

physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by the laws of the state in which he or she practices." Moreover, under N.J.A.C. 10:49-9.8(b), providers shall "keep such records as are necessary to disclose fully the extent of services provided . . . for a minimum period of five years from the date the service was rendered."

Definitive Testing Billed but Not Performed

In 4 of the 261 sample episodes, ADL billed and was reimbursed for a definitive test even though the physician or licensed practitioner had not ordered a definitive test and ADL had not performed one.

N.J.A.C. 10:49-9.8(b) requires providers to keep such records as are necessary to disclose fully the extent of services provided for a minimum of five years from the date the service was rendered. Additionally, N.J.A.C. 10:49-5.5(a)13 states that Medicaid will not cover services billed for which the corresponding records do not adequately and legibly reflect the requirements of the procedure code utilized by the billing provider.

Definitive Testing Billed but Not Ordered

OSC found that for 1 of the 261 sample episodes, ADL failed to provide documentation to support that the referring physician or licensed practitioner had ordered the definitive drug testing that was performed by ADL. For this sample episode, the referring provider's requisition to ADL did not include any definitive tests, but ADL submitted a claim and was paid for definitive testing.

Pursuant to N.J.A.C. 10:49-5.5(a)13, Medicaid will not cover services billed for which the corresponding records do not adequately and legibly reflect the requirements of the procedure code utilized by the billing provider. In accordance with N.J.A.C. 10:49-5.5(a)13(i), "[f]inal payment shall be made in accordance with a review of those services actually documented in the provider's health care record." Further, N.J.A.C. 10:61-1.6(d)4 states that laboratories must ensure that all orders contain the tests to be performed. N.J.A.C. 10:49-9.8(b) requires providers to "keep such records as are necessary to disclose fully the extent of services provided . . . for a minimum period of five years from the date the service was rendered."

Improper Billing of Presumptive and Definitive Testing

OSC found that in 71 of the 261 sample episodes, ADL billed and was paid for a greater level of definitive drug testing than ordered by the referring physician or licensed practitioner or billed for an incorrect procedure code.

Referring providers submitted test requisitions to ADL either electronically or manually. When a referring provider submitted a manual test requisition, the test requisition listed the drug tests ordered, including the type of testing (i.e., presumptive/definitive) and the specific drugs to be tested. Because these manual requisitions provided a clear description of what the referring provider ordered, OSC did not have to perform any additional steps to validate the testing ordered. When a referring provider submitted a test requisition electronically, however, the test requisition did not specify the type of testing (i.e., presumptive/definitive) or the specific drugs to be tested, but instead listed a test code that corresponded to a pre-determined list of drugs to be tested. After finding that the electronic test requisitions did not contain enough information to validate

these claims, OSC reviewed additional documentation to ascertain whether ADL properly submitted each claim. ADL advised that its referring providers completed a service agreement that listed the type of drug test ordered (i.e., presumptive/definitive) for specified drugs or drug classes. Additionally, ADL explained that as part of its service agreement process with referring providers, ADL required referring providers to complete a physician acknowledgment form through which the physician or licensed practitioner created the drug test panel(s) that would be used for testing. ADL assigned these panels a unique test code that the physician or licensed practitioner would select when ordering a drug test. OSC found that despite this process, the testing ADL performed and the claims ADL billed in these 71 sample episode claims were inconsistent with the respective service agreements or physician's acknowledgment forms.

The American Medical Association's (AMA) Healthcare Common Procedure Coding System (HCPCS) codes recognize multiple levels of definitive drug testing. The definitive codes identify drugs or metabolites (byproducts of a drug) that will be tested, with billing categories that increase in cost based on the number of drug classes that will be tested. The lowest level of definitive testing, which has the lowest Medicaid reimbursement rate, covers 1 to 7 drug classes, with progressively higher reimbursement levels for 8 to 14 drug classes, 15 to 21 drug classes, and, finally, 22 or more drug classes, which has the highest Medicaid reimbursement rate. Additionally, each drug or drug class is separately identified by a distinct AMA CPT code that is used to bill a specific definitive drug test. OSC found that ADL billed and was reimbursed for higher-level definitive drug tests than were ordered by the referring physician or licensed practitioner. OSC adjusted or downcoded these claims to conform to the level of definitive drug testing that the referring physician or licensed practitioner ordered, as supported by the documentation reviewed. OSC then used the corresponding Medicaid reimbursement rate for the downcoded level of testing to determine the amount that ADL should have been paid by Medicaid.

Pursuant to N.J.A.C. 10:49-5.5(a)13, Medicaid will not cover services billed for which the corresponding records do not adequately and legibly reflect the requirements of the procedure code utilized by the billing provider. In accordance with N.J.A.C. 10:49-5.5(a)13(i), "[f]inal payment shall be made in accordance with a review of those services actually documented in the provider's health care record."

In addition to downcoding claims where ADL billed for more tests than its documentation supported, OSC's review of the sample episodes also revealed that ADL did not always perform drug tests that referring providers ordered. OSC found that in 195 of 261 sample episodes (74.7 percent), ADL did not perform at least one specific drug test included on the drug test order. (See Exhibit C.) For example, ADL often failed to perform definitive tests ordered following positive and/or negative methadone presumptive test results. OSC notes this because it highlights the inconsistencies among the test services ordered, the tests that ADL performed, and the tests for which ADL billed the Medicaid program. OSC is not seeking a monetary recovery for these omissions because they did not lead to any economic harm to the Medicaid program but highlights this finding because ADL's lack of oversight of its testing procedures was improper and may have had an adverse effect on patient care.

Underbilled Presumptive and Definitive Testing

OSC found that in 3 of 261 sample episodes, ADL underbilled, which means that it billed a lower amount than it should have for the test ordered and performed. OSC accounted for these

underbilled claims in its extrapolation calculation by giving credit for the correct amount that ADL should have billed.

B. Improper Billing of Specimen Validity Testing

OSC found that ADL improperly submitted claims for specimen validity testing separately from claims submitted for presumptive and definitive drug tests for the same beneficiary on the same date of service. A laboratory is not permitted to seek payment for specimen validity tests and presumptive and/or definitive tests performed on the same day for the same beneficiary when specimen validity tests are performed to confirm that the specimen is unadulterated. Instead, in such cases, the laboratory shall seek payment only for the presumptive and/or definitive tests. Submitting claims and receiving payment for specimen validity tests and presumptive and/or definitive tests performed on the same day constitutes improper unbundling. During the audit period, ADL unbundled 231,091 specimen validity claims for which it received an overpayment of $1,140,043. (See Summary Table I below and Exhibit D.) OSC is seeking a direct recovery of this amount.

Table I: Paid Specimen Validity Claims by Year

Year	Number of Paid Claims	Total Dollars Paid
2015	159,427	$ 786,501
2016	71,664	$ 353,542
	231,091	$ 1,140,043

In accordance with N.J.A.C. 10:49-9.8(a), "all providers shall certify that the information furnished on the claim is true, accurate, and complete." In addition, pursuant to the 2016 HCPCS and CPT guidelines, presumptive and definitive drug tests include sample validation or specimen validity testing. Additionally, the Medicaid National Correct Coding Initiative (NCCI), which requires correct coding methodologies and thereby seeks to reduce inappropriate Medicaid payments, states that specimen validity testing is not separately billable from drug tests. The 2015 and 2016 Medicaid NCCI Chapter X(E) states:

> Providers performing validity testing on urine specimens utilized for drug testing should not separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed.

C. Charge to Medicaid Exceeded Charge to Other Groups or Individuals for Identical Services

OSC reviewed ADL's service agreements with its referring providers, monthly billing invoices, test requisitions (a referring provider's order for testing), and test results. From this review, OSC found that ADL charged Medicaid an amount significantly greater than the amount it charged other groups for presumptive and definitive drug tests. An independent clinical laboratory is prohibited

from charging the Medicaid program more for a test or service than the laboratory charges another group or individual for an identical test or service. N.J.A.C. 10:61-1.7 provides that "[i]n no event shall the charge to the Medicaid/NJ FamilyCare program exceed the provider's charge for identical services to other groups or individuals."

During OSC's audit period, ADL charged groups other than the Medicaid program a flat fee for presumptive and definitive drug tests that was significantly lower than the fee ADL charged Medicaid for these same tests. OSC reached this determination after reviewing ADL's charges to multiple referring providers for thousands of drug tests during the audit period, which ensured that these were not isolated incidents but rather demonstrated a pattern of conduct. For example, as shown in Table II below, ADL charged one referring provider, labeled Provider D, a rate as low as $2.38 for presumptive and definitive drug tests, while it charged Medicaid between $125 and $1,035 for identical services. Medicaid, pursuant to its fee schedule, paid ADL between $63.40 and $180.40 for these services.

Table II: Comparison of ADL's Charges for Presumptive and/or Definitive Tests

	Charge to Medicaid	Amount Paid by Medicaid	Lowest Charge to Other Group or Individual*	Earliest Drug Test Billed to Provider During Audit Period*
Provider A	$ 70.25 - 527.00	$ 20.37 - 215.07	$ 5.00	1/2/2015
Provider B	$ 125.00 - 590.00	$ 16.80 - 153.67	$ 5.00	1/2/2015
Provider C	$ 125.00 - 160.00	$ 20.33 - 86.28	$ 5.00	3/27/2015
Provider D	$ 125.00 - 1,035.00	$ 63.40 - 180.40	$ 2.38	4/30/2015
*Based on information received from ADL and its referring providers				

For all 261 sample episodes reviewed, ADL improperly charged Medicaid an amount that exceeded ADL's charge to other non-Medicaid payers for identical services during the same periods.

The extrapolated overpayment amount that ADL would owe, if OSC held ADL to the lowest charges and sought a recovery, is roughly $29.7 million, almost the entire Medicaid payment to ADL for the audit period. Given that the extrapolated overpayment, due to ADL's consistent violations of the BOR regulation, would result in ADL being required to return almost all the funds it received from the Medicaid program during the audit period, and since OSC does not allege that ADL failed to provide all of the billed services, OSC did not to seek the extrapolated overpayment. Instead, in accordance with its authority under N.J.S.A. 30:4D-57(d)(2), N.J.S.A. 30:4D-17(e)(3), and N.J.S.A. 2A:32C-3, OSC is assessing a civil penalty based on ADL's pervasive pattern of misconduct throughout the audit period. Specifically, for the entire audit period, ADL submitted hundreds of thousands of claims to the Medicaid program and received payment for these claims despite knowingly charging the Medicaid program far more for services than it charged other non-Medicaid payers for identical services. Despite the fact that it knew that each time it charged this marked difference for identical services, it violated the BOR regulation, as part of each Medicaid claim, ADL represented that its claims were in conformity with all laws and regulations and were true, accurate, and complete, which was not the case. For these reasons, OSC is assessing ADL

a civil penalty of $3,269,332 for the 261 episodes in the audit sample that violated Medicaid regulations in the audit period.[3]

D. ADL Provided Improper Rebates

OSC found that ADL violated N.J.A.C. 10:61-2.4, a regulation that prohibits rebates, including money discounts and other considerations, whether or not a rebate is involved. As discussed above, ADL charged referring providers an amount much lower than it charged Medicaid for identical services. Compared to the rate charged to Medicaid, the lower rates that ADL charged referring providers constituted a "discount" in violation of N.J.A.C. 10:61-2.4. In short, the same overall course of conduct that violated N.J.A.C. 10:61-1.7, which is discussed above, also violated N.J.A.C. 10:61-2.4.

In addition, although OSC did not request nor did it otherwise perform an in-depth review of ADL's documentation for the purpose of identifying rebate related practices, OSC found that ADL advertised on its social media that it would be a returning sponsor of the third annual golf outing for one of its referring providers on September 16, 2019, which was organized to raise funds for this provider to construct a new facility. OSC contacted this referring provider and confirmed that ADL made contributions of $10,000 dollars each year in May 2017, May 2018, and August 2019 for sponsorship of this referring provider's annual golf outings. OSC notes that the August 2019 contribution fell outside of the audit review period but nonetheless considers the contributions violations of N.J.A.C. 10:61-2.4 because these actions constitute forms of "other considerations" that are prohibited by N.J.A.C. 10:61-2.4.

Pursuant to N.J.A.C. 10:61-2.4, "[r]ebates by reference laboratories, service laboratories, physicians or other utilizers or providers of laboratory service are prohibited under the Medicaid/NJ FamilyCare program. Rebates shall include refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value. Laboratories shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved."

As outlined in Section C above, OSC is assessing a civil penalty of $3,269,332 for the 261 episodes in the sample that violated both N.J.A.C. 10:61-1.7 and N.J.A.C. 10:61-2.4.

VI. Recovery and Penalties

As explained above, OSC found that based on ADL's deficient documentation, improper unbundling of claims, and knowingly applying improper billing practices, ADL received

[3] N.J.S.A. 30:4D-17(e)(3) provides OSC authority to penalize conduct in accordance with the civil penalty range allowed under the federal False Claims Act (FCA), 31 U.S.C. 3729 et seq., as adjusted for inflation. Pursuant to 28 C.F.R. 85.3(a)(9), the minimum penalty for FCA violations occurring on or before November 2, 2015, is $5,500 per violation. The minimum applicable penalty for a FCA violation after November 2, 2015, is $13,508 per violation. 28 C.F.R. 85.5. Thirty-two episodes in the sample occurred before November 2, 2015, with the remaining 229 occurring after that date. By applying the applicable penalty rate to the sample episodes, the minimum penalty for ADL's conduct is $3,269,332.

overpayments from the Medicaid program. OSC seeks to recover from ADL a total of $7,352,961, which is comprised of a $2,943,586[4] extrapolated recovery for documentation deficiencies, a $1,140,043 direct recovery for unbundling specimen validity claims, and a $3,269,332 civil penalty for knowingly submitting claims that violated the BOR and anti-rebate regulations.

VII. Recommendations

ADL shall:

1. Reimburse the Medicaid program $7,352,961.

2. Ensure that the charge to the Medicaid program does not exceed ADL's charge for identical services to other groups or individuals.

3. Ensure that all orders for clinical laboratory services and all records and documentation are maintained by ADL and comply with applicable state and federal laws, regulations, and guidance, including the regulations cited above.

4. Maintain the necessary documentation and ensure that only those drug tests ordered by the physician or other licensed practitioner requesting services are tested and billed. ADL must contemporaneously document all changes to the tests ordered.

5. Ensure all test orders indicate the test(s) to be performed, including the specific drugs or class of drugs as defined by AMA.

6. Ensure that all drug testing ordered by a physician or licensed practitioner is performed and reported on the drug test results.

7. Ensure that all claims for drug tests comply with all applicable state and federal laws, regulations, and guidance.

8. Ensure that it refrains from separately submitting claims for specimen validity testing from claims submitted for presumptive and definitive drug tests.

9. Refrain from offering rebates, including refunds, discounts, or kickbacks, whether in the form of money, supplies, equipment, or other things of value to its referring providers or any other entities. ADL shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved.

10. Provide training to staff to foster compliance with Medicaid requirements under applicable state and federal laws and regulations.

11. Provide OSC with a Corrective Action Plan indicating the steps it will take to implement procedures to correct the deficiencies identified in this report.

[4] See Footnote 1.

AMA CPT Code Descriptions - Presumptive

Code	Code Descriptor
80301	Drug screen, any number of drug classes from Drug Class List A; single drug class method, by instrumented test systems (e.g., discrete multichannel chemistry analyzers utilizing immunoassay or enzyme assay), per date of service
80302	Drug screen, presumptive, single drug class from Drug Class List B, by immunoassay (e.g., ELISA) or non-TLC chromatography without mass spectrometry (e.g., GC, HPLC), each procedure
80307	Drug test(s), presumptive, any number of drug classes, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.

AMA HCPCS Code Descriptions - Presumptive

Code	Code Descriptor
G0431	Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter.
G0434	Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter.
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analysers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service

AMA CPT Code Descriptions - Definitive

Code	Code Descriptor
80102	Drug confirmation, each procedure
80152	Amitriptyline
80154	Benzodiazepines
80156	Carbamazepine; total
80160	Desipramine
80166	Doxepin
80174	Imipramine
80175	Lamotrigine
80177	Levetiracetam
80178	Lithium
80182	Nortriptyline
80183	Oxcarbazepine
80184	Phenobarbital

AMA CPT Code Descriptions - Definitive (continued)

Code	Code Descriptor
80185	Phenytoin; total
80299	Quantitation of drug, not elsewhere specified
80321	Alcohol biomarkers; 1 or 2
80324	Amphetamines; 1 or 2
80332	Antidepressants, serotonergic class; 1 or 2
80336	Antidepressants, tricyclic and other cyclicals; 3-5
80337	Antidepressants, tricyclic and other cyclicals; 6 or more
80339	Antiepileptics, not otherwise specified; 1-3
80342	Antipsychotics, not otherwise specified; 1-3
80345	Barbiturates
80346	Benzodiazepines; 1-12
80347	Benzodiazepines; 13 or more
80348	Buprenorphine
80349	Cannabinoids, natural
80353	Cocaine
80354	Fentanyl
80356	Heroin metabolite
80358	Methadone
80359	Methylenedioxyamphetamines (MDA, MDEA, MDMA)
80361	Opiates, 1 or more
80362	Opioids and opiate analogs; 1 or 2
80363	Opioids and opiate analogs; 3 or 4
80365	Oxycodone
80367	Propoxyphene
80368	Sedative hypnotics (non-benzodiazepines)
80369	Skeletal muscle relaxants; 1 or 2
80370	Skeletal muscle relaxants; 3 or more
80373	Tramadol
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3
82055	Alcohol (ethanol); any specimen except breath
82101	Alkaloids, urine, quantitative
82145	Amphetamine or methamphetamine
82205	Barbiturates, not elsewhere specified
82520	Cocaine or metabolite
82646	Dihydrocodeinone
82649	Dihydromorphinone
82742	Flurazepam
83805	Meprobamate
83840	Methadone
83925	Opiate(s), drug and metabolites, each procedure
83992	Phencyclidine (PCP)

AMA HCPCS Code Descriptions - Definitive

Code	Code Descriptor
G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.
G0481	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.
G0482	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.
G6031	Assay of benzodiazepines
G6040	Assay of alcohol (ethanol); any specimen except breath
G6044	Assay of cocaine or metabolite
G6045	Assay of of dihydrocodeinone
G6046	Assay of dihydromorphinone
G6051	Assay of flurazepam
G6052	Assay of meprobamate
G6053	Assay of methadone
G6056	Opiate(s), drug and metabolites, each procedure
G6058	Drug confirmation, each procedure

AMA CPT Code Descriptions - Validity

Code	Code Descriptor
82570	Creatinine; other source
83986	pH; body fluid, not otherwise specified
84311	Spectrophotometry, analyte not elsewhere specified

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
1	80301	$ 16.80	-	-	$ 16.80	X											$ -
2	G0434	$ 15.87	-	-	$ 15.87	X											$ -
3	G0434	$ 15.87	-	-	$ 15.87	X											$ -
4	G0434	$ 15.83	82055	$ 4.50	$ 20.33	X	X			X							$ 20.33
5	G0434	$ 15.87	-	-	$ 15.87	X	X						X		G0434, 80349	$ 37.92	$ (22.05)
6	G0434	$ 15.87	82055	$ 4.50	$ 20.37	X	X				X				G0434	$ 15.87	$ 4.50
7	G0434	$ 15.87	82055	$ 4.50	$ 20.37	X	X				X				G0434	$ 15.87	$ 4.50
8	-	-	82055	$ 4.50	$ 4.50	X	X						X		G0434, 80349	$ 37.88	$ (33.38)
9	G0434	$ 15.87	82520	$ 17.00	$ 32.87	X											$ -
10	80301	$ 16.80	-	-	$ 16.80	X											$ -
11	G0434	$ 15.87	-	-	$ 15.87	X											$ -
12	G0434	$ 15.83	-	-	$ 15.83	X											$ -
13	G0434	$ 15.87	82055	$ 9.00	$ 24.87	X	X				X				G0434	$ 15.87	$ 9.00
14	G0434	$ 15.87	-	-	$ 15.87	X											$ -
15	G0434	$ 15.87	82055	$ 4.50	$ 20.37	X	X				X				G0434	$ 15.87	$ 4.50
16	80301 G0434	$ 16.80 $ 15.83	-	-	$ 32.63	X	X						X		80301	$ 16.80	$ 15.83
17	G0434	$ 15.83	-	-	$ 15.83	X											$ -
18	80301	$ 16.80	-	-	$ 16.80	X											$ -
19	80301	$ 16.80	-	-	$ 16.80	X											$ -
20	G0434	$ 15.87	-	-	$ 15.87	X											$ -
21	80301	$ 16.80	80353	$ 22.05	$ 38.85	X											$ -
22	80301	$ 16.80	-	-	$ 16.80	X											$ -
23	G0434	$ 15.87	-	-	$ 15.87	X											$ -
24	G0434	$ 15.87	-	-	$ 15.87	X											$ -
25	G0434	$ 15.83	-	-	$ 15.83	X											$ -
26	80302	$ 28.00	-	-	$ 28.00	X	X							X	80301, 80302	$ 44.80	$ (16.80)
27	G0434	$ 15.83	-	-	$ 15.83	X											$ -
28	80301	$ 16.80	-	-	$ 16.80	X											$ -
29	G0434	$ 15.87	82055	$ 4.50	$ 20.37	X	X						X		G0434, 80349	$ 37.92	$ (17.55)
30	G0434	$ 15.87	-	-	$ 15.87	X											$ -
31	80307	$ 86.28	-	-	$ 86.28	X											$ -
32	G0479	$ 63.40	-	-	$ 63.40	X											$ -
33	G0479	$ 63.40	-	-	$ 63.40	X											$ -
34	-	-	80324 80347 80359	$ 17.62 $ 20.96 $ 22.05	$ 60.63	X	X							X	G0479, 80324, 80347, 80359	$ 124.03	$ (63.40)
35	G0479	$ 63.40	-	-	$ 63.40	X											$ -
36	G0479	$ 63.40	-	-	$ 63.40	X											$ -
37	G0479	$ 63.40	-	-	$ 63.40	X											$ -
38	G0479	$ 63.40	-	-	$ 63.40	X											$ -
39	80307	$ 86.28	-	-	$ 86.28	X											$ -
40	80307	$ 86.28	-	-	$ 86.28	X											$ -
41	G0479	$ 63.40	-	-	$ 63.40	X											$ -
42	80307	$ 86.28	-	-	$ 86.28	X											$ -
43	G0434	$ 15.87	80102 80154 82742	$ 15.00 $ 21.50 $ 21.73	$ 74.10	X	X						X		G0434, 80154	$ 37.37	$ 36.73
44	G0434	$ 15.87	82646 82649 83925	$ 25.30 $ 31.00 $ 22.00	$ 94.17	X	X		X								$ 94.17
45	80307	$ 86.28	-	-	$ 86.28	X											$ -
46	80307	$ 86.28	-	-	$ 86.28	X											$ -
47	80307	$ 86.28	-	-	$ 86.28	X											$ -
48	G0479	$ 63.40	-	-	$ 63.40	X											$ -
49	80307	$ 86.28	-	-	$ 86.28	X											$ -
50	G0479	$ 63.40	-	-	$ 63.40	X											$ -

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
51	G0479	$ 63.40	-	-	$ 63.40	X											$ -
52	G0434	$ 15.87	80152 80160 80166 80174 80182	$ 15.00 $ 15.00 $ 15.00 $ 15.00 $ 12.00	$ 87.87	X											$ -
53	80301	$ 16.80	80349 80358	$ 22.05 $ 16.48	$ 55.33	X											$ -
54	G0479	$ 63.40	-	-	$ 63.40	X											$ -
55	80307	$ 86.28	-	-	$ 86.28	X											$ -
56	80307	$ 86.28	-	-	$ 86.28	X											$ -
57	G0479	$ 63.40	-	-	$ 63.40	X											$ -
58	80307	$ 86.28	-	-	$ 86.28	X											$ -
59	80307	$ 86.28	-	-	$ 86.28	X											$ -
60	80301	$ 16.80	80324 80353 80359	$ 17.62 $ 22.05 $ 22.05	$ 78.52	X	X						X		80301, 80353	$ 38.85	$ 39.67
61	80301	$ 16.80	80347 80368	$ 20.96 $ 22.05	$ 59.81	X	X						X		80301, 80347	$ 37.76	$ 22.05
62	G0479	$ 63.40	-	-	$ 63.40	X											$ -
63	-	-	80154 82742	$ 21.50 $ 21.73	$ 43.23	X	X						X		G0434, 80154	$ 37.37	$ 5.90
64	80307	$ 86.28	-	-	$ 86.28	X											$ -
65	G0434	$ 15.83	80102 80154 82055 82742	$ 15.00 $ 21.50 $ 4.50 $ 21.73	$ 78.56	X	X						X		G0434, 80154	$ 37.33	$ 41.23
66	80307	$ 86.28	-	-	$ 86.28	X											$ -
67	80307	$ 86.28	-	-	$ 86.28	X											$ -
68	80307	$ 86.28	-	-	$ 86.28	X											$ -
69	80302	$ 28.00	80321	$ 16.66	$ 44.66	X	X							X	80301, 80302, 80321	$ 61.46	$ (16.80)
70	G0479	$ 63.40	-	-	$ 63.40	X											$ -
71	G0479	$ 63.40	-	-	$ 63.40	X											$ -
72	80307	$ 86.28	-	-	$ 86.28	X											$ -
73	80307	$ 86.28	-	-	$ 86.28	X											$ -
74	G0479	$ 63.40	-	-	$ 63.40	X											$ -
75	G0479	$ 63.40	-	-	$ 63.40	X											$ -
76	G0479	$ 63.40	-	-	$ 63.40	X											$ -
77	80307	$ 86.28	-	-	$ 86.28	X											$ -
78	G0479	$ 63.40	-	-	$ 63.40	X											$ -
79	80307	$ 86.28	-	-	$ 86.28	X											$ -
80	G0479	$ 63.40	-	-	$ 63.40	X											$ -
81	80307	$ 86.28	-	-	$ 86.28	X											$ -
82	80307	$ 86.28	-	-	$ 86.28	X											$ -
83	80307	$ 86.28	-	-	$ 86.28	X											$ -
84	G0479	$ 63.40	-	-	$ 63.40	X											$ -
85	80307	$ 86.28	-	-	$ 86.28	X											$ -
86	80307	$ 86.28	-	-	$ 86.28	X											$ -
87	G0479	$ 63.40	-	-	$ 63.40	X	X		X								$ 63.40
88	G0479	$ 63.40	-	-	$ 63.40	X											$ -
89	80307	$ 86.28	-	-	$ 86.28	X											
90	80307	$ 86.28	-	-	$ 86.28	X											
91	80307	$ 86.28	-	-	$ 86.28	X											
92	80307	$ 86.28	-	-	$ 86.28	X											
93	80307	$ 86.28	-	-	$ 86.28	X											
94	G0479	$ 63.40	-	-	$ 63.40	X											

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
95	G0479	$ 63.40	-	-	$ 63.40	X											
96	G0479	$ 63.40	-	-	$ 63.40	X											
97	80307	$ 86.28	-	-	$ 86.28	X											
98	80307	$ 86.28	-	-	$ 86.28	X											
99	G0479	$ 63.40	-	-	$ 63.40	X											
100	G0479	$ 63.40	-	-	$ 63.40	X											
101	G0479	$ 63.40	-	-	$ 63.40	X											
102	G0434	$ 15.83	80347 80368	$ 20.96 $ 22.05	$ 58.84	X	X						X		G0434, 80347	$ 36.79	$ 22.05
103	80307	$ 86.28	-	-	$ 86.28	X	X		X								$ 86.28
104	80307	$ 86.28	-	-	$ 86.28	X											$ -
105	G0434	$ 15.87	80102 80154 82742	$ 15.00 $ 21.50 $ 21.73	$ 74.10	X	X						X		G0434, 80154	$ 37.37	$ 36.73
106	G0479	$ 63.40	-	-	$ 63.40	X											$ -
107	G0434	$ 15.87	80102 80154 82742	$ 15.00 $ 21.50 $ 21.73	$ 74.10	X	X						X		G0434, 80154	$ 37.37	$ 36.73
108	-	-	80154 82742	$ 21.50 $ 21.73	$ 43.23	X	X						X		80301, 80154	$ 38.30	$ 4.93
109	80307	$ 86.28	-	-	$ 86.28	X											$ -
110	80302	$ 28.00	80349 80358	$ 22.05 $ 16.48	$ 66.53	X	X						X		80301, 80349	$ 38.85	$ 27.68
111	80307	$ 86.28	-	-	$ 86.28	X											$ -
112	80307	$ 86.28	-	-	$ 86.28	X											$ -
113	G0479	$ 63.40	-	-	$ 63.40	X											$ -
114	80307	$ 86.28	-	-	$ 86.28	X											$ -
115	G0479	$ 63.40	-	-	$ 63.40	X											$ -
116	G0434	$ 15.87	80102 80154 82742	$ 15.00 $ 21.50 $ 21.73	$ 74.10	X	X						X		G0434, 80154	$ 37.37	$ 36.73
117	80307	$ 86.28	-	-	$ 86.28	X											$ -
118	G0479	$ 63.40	-	-	$ 63.40	X											$ -
119	G0479	$ 63.40	-	-	$ 63.40	X											$ -
120	G0479	$ 63.40	-	-	$ 63.40	X											$ -
121	G0479	$ 63.40	-	-	$ 63.40	X											$ -
122	80307	$ 86.28	-	-	$ 86.28	X											$ -
123	G0479	$ 63.40	-	-	$ 63.40	X											$ -
124	-	-	80347 80354 80356 80361 80363 80365	$ 20.96 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05	$ 120.07	X	X						X		G0479, 80347, 80361	$ 106.41	$ 13.66
125	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
126	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
127	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
128	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
129	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
130	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
131	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
132	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
133	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
134	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
135	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
136	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
137	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
138	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
139	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
140	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
141	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X	X		X								$ 127.35
142	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
143	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
144	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
145	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
146	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
147	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
148	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
149	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
150	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
151	G0434	$ 15.87	80102 82055 82520 82646 82649 83805 83925	$ 15.00 $ 4.50 $ 17.00 $ 25.30 $ 31.00 $ 23.00 $ 22.00	$ 153.67	X	X		X								$ 153.67
152	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
153	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
154	80307	$ 86.28	G0480	$ 63.95	$ 150.23	X											$ -
155	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
156	80301	$ 16.80	80354 80356 80361 80363 80365 80369 80373	$ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 20.96 $ 16.66	$ 153.53	X	X						X		80301, 80361	$ 38.85	$ 114.68
157	G0434	$ 15.87	80102 82055 82520 82646 82649 83805 83925	$ 15.00 $ 4.50 $ 17.00 $ 25.30 $ 31.00 $ 23.00 $ 22.00	$ 153.67	X	X						X		G0434, 82520, 83925	$ 54.87	$ 98.80
158	G0479	$ 63.40	G0480	$ 63.95	$ 127.35	X											$ -
159	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
160	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
161	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
162	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
163	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
164	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
165	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
166	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
167	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
168	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
169	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
170	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
171	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
172	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
173	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
174	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
175	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
176	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
177	G0434	$ 15.87	80102 80154 82101 82520 82646 82649 82742 83805 83840 83925	$ 15.00 $ 21.50 $ 16.30 $ 17.00 $ 25.30 $ 31.00 $ 21.73 $ 23.00 $ 4.50 $ 22.00	$ 213.20	X	X						X		G0434, 80154, 80348, 80349, 82520, 83840, 83925	$ 120.30	$ 92.90
178	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
179	80301	$ 16.80	80347 80354 80356 80361 80363 80365 80368 80369 80373	$ 20.96 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 22.05 $ 20.96 $ 16.66	$ 196.54	X	X		X								$ 196.54
180	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
181	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
182	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
183	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
184	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
185	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
186	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
187	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
188	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
189	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
190	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
191	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
192	80301	$ 16.80	80347 80353 80354 80356 80361 80363 80365	$ 20.96 $ 22.05 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05	$ 158.92	X	X						X		80301, 80347, 80353, 80361	$ 81.86	$ 77.06
193	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
194	80301	$ 16.80	80347 80353 80354 80356 80361 80363 80365	$ 20.96 $ 22.05 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05	$ 158.92	X	X						X		80301, 80347 80353, 80361	$ 81.86	$ 77.06
195	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
196	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 157.52	$ 4.27
197	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
198	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
199	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
200	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
201	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
202	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
203	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
204	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 157.52	$ 4.27

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
205	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 157.52	$ 4.27
206	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X	X	X									$ 180.40
207	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 157.52	$ 4.27
208	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
209	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
210	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
211	G0479	$ 63.40	G0482	$ 132.82	$ 196.22	X	X						X		G0479, G0481	$ 161.79	$ 34.43
212	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X	X		X								$ 180.40
213	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
214	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
215	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
216	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
217	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
218	80301	$ 16.80	80154 80354 80356 80361 80363 80365 82742	$ 21.50 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 21.73	$ 159.14	X	X						X		80301, 80154, 80361	$ 60.35	$ 98.79
219	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
220	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
221	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
222	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
223	80301	$ 16.80	80332 80336 80342 80353 80354 80356 80358 80361 80363 80365 80369 80373 80375	$ 16.66 $ 16.66 $ 16.48 $ 22.05 $ 16.48 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 20.96 $ 16.66 $ 16.48	$ 258.34	X	X						X		80301, 80336, 80353, 80361	$ 77.56	$ 180.78
224	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
225	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 157.52	$ 4.27
226	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
227	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
228	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
229	80307	$ 86.28	G0481	$ 98.39	$ 184.67	X	X						X		80307, G0480	$ 180.40	$ 4.27
230	80301	$ 16.80	80347 80353 80354 80356 80361 80363 80365 80368 80369 80373	$ 20.96 $ 22.05 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 22.05 $ 20.96 $ 16.66	$ 218.59	X	X						X		80301, 80347, 80353, 80361	$ 81.86	$ 136.73
231	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
232	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
233	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
234	G0434	$ 15.87	80102 80154 82055 82646 82649 82742 83805 83925	$ 15.00 $ 21.50 $ 4.50 $ 25.30 $ 31.00 $ 21.73 $ 23.00 $ 22.00	$ 179.90	X	X						X		G0434, 80102, 80154, 83925	$ 74.37	$ 105.53
235	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X	X					X					$ 94.12
236	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
237	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
238	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
239	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
240	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
241	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
242	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
243	80301	$ 16.80	80332 80336 80342 80347 80353 80354 80356 80358 80361 80363 80365 80368 80369 80373 80375	$ 16.66 $ 16.66 $ 16.48 $ 20.96 $ 22.05 $ 16.48 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 22.05 $ 20.96 $ 16.66 $ 16.48	$ 301.35	X	X						X		80301, 80336, 80347, 80353, 80361	$ 98.52	$ 202.83
244	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
245	80301	$ 16.80	80354 80356 80358 80361 80363 80365 80369 80373	$ 16.48 $ 16.48 $ 16.48 $ 22.05 $ 22.05 $ 22.05 $ 20.96 $ 16.66	$ 170.01	X	X						X		80301, 80358, 80361	$ 55.33	$ 114.68
246	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
247	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
248	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
249	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
250	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
251	80307	$ 86.28	G0481	$ 128.79	$ 215.07	X	X						X		80307, G0480	$ 180.40	$ 34.67
252	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
253	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
254	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
255	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
256	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
257	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -

Atlantic Diagnostic Laboratories, LLC
Summary of Noncompliant Presumptive and Definitive Testing
January 1, 2015 to June 30, 2018

Sample Claim Data						Audit Findings		Deficient Documentation and Billing Irregularities*							Incorrect Procedure Code(s) Billed**		Deficient Documentation and Billing Irregularities Overpayment (Underpayment)
Sample Number	Presumptive Procedure Code(s) Billed	Presumptive Claim Amount	Definitive Procedure Code(s) Billed	Definitive Claim Amount	Total Claim Amount	1. Basis of Reimbursement	2. Deficient Documentation and Billing Irregularities*	Missing Order	Standing Order Date Range Does Not Cover Requisition	Missing Physician's Signature	Definitive Testing Billed but Not Performed	Definitive Test(s) Not Supported by Physician or Licensed Practitioner	Incorrect Procedure Code(s) Billed**	Underbilled Claim	Correct Procedure Code(s) Per Audit**	Claim Payment Amount Per Audit**	
258	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
259	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 127.35	$ 34.44
260	G0479	$ 63.40	G0481	$ 98.39	$ 161.79	X	X						X		G0479, G0480	$ 157.52	$ 4.27
261	80307	$ 86.28	G0480	$ 94.12	$ 180.40	X											$ -
						261	**88**	**1**	**7**	**1**	**4**	**1**	**71**	**3**			**$ 3,997.47**
								88 Exceptions									

Sample Dollars	Universe Claims	Universe Dollars
$31,167.11	615,648	$31,200,171.65

ADL Atlantic Diagnostic Laboratories

The Clinician's Choice

RESPONSE BY ATLANTIC DIAGNOSTIC LABS, LLC
TO THE DRAFT AUDIT REPORT
OF THE OFFICE OF THE STATE COMPTROLLER, MEDICAID FRAUD DIVISION
DATED NOVEMBER 23, 2023

Please accept this response by Atlantic Diagnostic Labs, LLC ("ADL") to the second Draft Audit Report ("2023 DAR") of the Medicaid Fraud Division ("MFD") issued on November 29, 2023. Previously, on October 11, 2022, MFD issued a draft audit report to ADL ("2022 DAR"), and ADL timely submitted a response to that draft audit report on November 23, 2022. Over a year later, MFD re-issued its proposed findings in the form of the 2023 DAR. While ADL appreciates MFD having reconsidered some of its conclusions in light of our response, the 2023 DAR continues to contain findings that are wholly unfounded.

ADL is a family-owned, independent laboratory that performs vitally important toxicology screening and other testing for the Medicaid population in New Jersey and other states. Unlike the large, institutional labs such as Quest and Labcorp, we do not have the financial support or resources of a big company to help us defend against this audit. Nonetheless, we feel compelled to provide a detailed response to the findings in the 2023 DAR, which we can only conclude are the product of auditors who are skilled in their primary areas of expertise, but are in this case acting from a lack of awareness of laboratory procedures and documentation.

We respectfully submit this response to the 2023 DAR and provide additional documentation where applicable. We truly hope that MFD will review our arguments in good faith and reconsider its puzzling determination that every single sampled claim failed to meet legal requirements. ADL has been audited in multiple states, on many occasions, over many years, and has never seen anything like the approach taken by MFD in this audit.

Audit Findings Response:

1. First, MFD found that for 89 of 261 (34.1 percent) sample episodes, ADL's documentation failed to comply with the requirements of N.J.A.C. 10:49-9.8, N.J.A.C. 10:61-1.6, and/or N.J.A.C. 10:49-5.5. MFD found that: *(a) ADL could not provide OSC with a test requisition for 1 of the 261 sample episodes; (b) in 7 of the 261 sample episodes, ADL processed standing orders that failed to comply with N.J.A.C. 10:61-1.6 and N.J.A.C. 10:49-9.8(a) and (b) because the dates of service for the drug tests were outside the effective date range of each of the standing orders; and (c) 2 of the 261 sample episodes failed to include the signature of the physician or other licensed practitioner who ordered the services in a written requisition.*

   ADL Response: ADL does not dispute that 10 of the 261 samples that MFD reviewed contained minor clerical errors – 9 of which occurred at the provider level. Since the audit

3520 Progress Drive, Suite C • Bensalem, Pa 19020
Ph (866) 465-6763 • Ph (267) 525-2470 • Fax (267) 525-2488 • www.adllab.net

was conducted, ADL has implemented various technological fixes that have largely eliminated the likelihood of these types of human error. As such, ADL strongly disagrees with MFD's decision to extrapolate to a multi-million-dollar finding based off of these isolated errors.

First, with respect to the single failure to provide a test requisition, that error occurred because the provider gave ADL the incorrect Medicaid Recipient ID. When ADL's billing department billed for the testing on the sample, it input that Medicaid Recipient ID, causing the sample to be billed under the wrong patient's name. ADL's computer system now employs an automated rule that will prevent such errors from occurring in the future. The automated rule does not allow for a billing clerk to change the name of the patient on the order without a manager override. Further, ADL's computer system now automatically performs an eligibility check to confirm that the Medicaid Recipient ID is correct.

Second, the 7 sample episodes (Sample Numbers 44, 87, 103, 141, 151, 179, 212) with an incorrect date range for the standing order also arose out of a provider error. All 7 samples originated from the same provider and contained minor typos in the date range. Since all seven episodes arose from the same client, ADL does not believe this should be included in the extrapolation, or at most, all 7 episodes should be considered a single episode for purposes of the extrapolation.

Third, with respect to MFD's finding that ADL failed to ensure that 2 requisitions contained the signature of the ordering physician or licensed practitioner, this finding is inaccurate with respect to at least one of the two samples. The two samples identified by MFD are Sample Number 4 and Sample Number 62. Sample 62, does, in fact contain the ordering provider's signature. The signature is on the requisition form above the signature line. *See* Ex. 1, Sample 62 Requisition Form. This should be reviewed by MFD and taken off the findings list. As to Sample Number 4, ADL is unable to respond to this finding due to MFD's significant delay in managing this audit. ADL has been unable to locate the requisition form from October 9, 2015 – more than 7 years ago – in our warehouse by the deadline for this response. However, ADL does not – and would not have – performed the requested testing unless it received a requisition form.

All of the errors in this category are minor human errors that are now obviated due to changes to ADL's technology. None of these findings should be extrapolated against the entire claim pool.

(d) In 4 of the 261 sample episodes, ADL billed and was reimbursed for a definitive test even though the physician or licensed practitioner had not ordered a definitive test and ADL had not performed one.

ADL Response: The samples at issue in this finding are Sample Numbers 6, 7, 13 and 14. ADL did not bill for definitive testing on any of these samples. On all four samples, ADL billed codes G0434 and 82055. G0434 is defined as "Drug screen, other than

chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter" and 82055 is defined as "Alcohol (ethanol); any specimen except breath." G0434 does not specify that Alcohol (ethanol) is included in the code. ADL performed an Alcohol (ethanol) presumptive test and billed code 82055 appropriately. The definition for 82055 does not specify whether the code is for a definitive or presumptive test and the American Medical Association ("AMA") and Centers for Medicare & Medicaid Services ("CMS") both eliminated this code effective December 31, 2014, but the New Jersey Department of Human Services, Medicaid Division ("NJ Medicaid" or "DMAHS") still used this code in 2015. During the time period at issue, ADL was in regular communication with NJ Medicaid, which was changing the requisite coding on a quarterly basis. MFD's finding on this issue likely stems from NJ Medicaid's confusion during 2015 and 2016 as to the correct AMA and/or CMS billing codes being listed on the NJ Medicaid Fee Schedule. A review of the relevant quarterly fee schedule will reveal that ADL billed the correct codes for the tests at issue. MFD should reevaluate this finding.

(e) For 1 of the 261 sample episodes, ADL failed to provide documentation to support that the referring physician or licensed practitioner had ordered the definitive drug testing that was performed by ADL.

ADL Response: According to the records provided by MFD, this finding is on Sample Number 235. Line 235 states ADL billed code 80307, which is a presumptive test. ADL also billed for code G0480 – which is a definitive test – due to the negative methadone metabolite test for a patient that was prescribed methadone. The methadone definitive test only picked up raw methadone, which means the patient was diverting/selling their methadone and spiking their sample with methadone. This is the correct way to perform a reflex test for a negative prescribed medication and human error occurred on the order. The order was misprinted and should have read, "All positive drug classes and negative prescribed medication auto confirmed by LC/MS/MS." While the order did not state this, the doctor wanted this test and ADL would be willing to obtain an affidavit from the doctor confirming this request if MFD requires.

(g) OSC also found that in 71 of the 261 sample episodes, ADL billed and was paid for a greater level of definitive drug testing than ordered by the referring physician or licensed practitioner or, billed for an incorrect procedure code.

ADL Response: MFD defined definitive testing by drug classes: Opiates are one drug class, Benzodiazepines are another drug class, etc., which is correct. However, when presumptive testing is performed, Opiates, Benzodiazepines, and other drugs cross react to more than the drugs listed in the AMA defined Opiates or Benzodiazepines drug classes. For example, Opiate presumptive testing cross reacts to nine substances that are not all defined in the AMA Opiate definitive test definition. When an Opiate presumptive test is positive, ADL then tests all nine cross reactive substances by definitive methodology and

bills accordingly, based on the AMA defined drug classes for each cross reactive substance. ADL has submitted the cross-reactivity data to MFD for all presumptive immunoassay drug tests. The scientific and medically necessary way to bill this one presumptive drug assay for definitive testing is nine drug classes, but MFD says this is only one drug class. Since all 71 sample episodes include multiple presumptive positive drug assays, ADL billed the proper level of definitive drug testing based off the order listed on the requisition form.

Following the exit conference, ADL provided MFD with an explanation from ADL's forensic toxicologist, [redacted], detailing how ADL performs both presumptive screening and confirmatory testing on the samples it receives, along with scientific publications supporting the same. ADL recommended MFD consult a laboratory expert to help them understand the exhibits ADL presented, but apparently this never happened. ADL also disputes that the Physician Acknowledgments and Agreements ordered are inconsistent with the testing that was ordered and performed. ADL's online ordering system has pop-up windows listing the testing components and reflexes for the drug panel that was chosen by the provider. Space limitations on the paper requisition forms render it impossible for the components and reflexes to be included on the drug. However, ADL receives the full electronic order in its Lab Information System (LIS) and performs the testing based off the components and reflexes in the electronic order. All drug panels and reflex definitive testing are set forth in the ADL/Client Lab Services Agreement, Physician Acknowledgment and Standing Order process. ADL disputes that all 71 of these samples were not properly documented.[1]

There are some other purported errors in this category that are not correct. These issues all arose during 2015 and 2016 when NJ Medicaid's coding and fee schedules were, simply put, a mess. ADL was in communication with NJ Medicaid about the coding issue, was told by NJ Medicaid to bill the codes utilized, and can provide numerous emails to support the codes billed. For example, MFD flagged Sample Numbers 29, 107 and 177 as samples where ADL billed the wrong codes. However, all three samples were performed before November 1, 2015. ADL billed the correct codes for this date of service as the codes (80321 thru 80375) were not in effect or priced on the NJ Fee Schedule at the time the samples were received. These codes did not go into effect until November 1, 2015. Furthermore, when NJ Medicaid placed the codes on the NJ fees schedule in November 2015 the price was listed as "BR." This means ADL would not have been paid for using those codes, as they were not yet priced. ADL billed the older codes which were still active and priced on the NJ Fee Schedule. Other purported errors in this category similarly arose from coding issues. MFD should review the 2015 and 2016 NJ Fee Schedules by each quarter to see what codes were in effect and priced.

[1] ADL does not dispute that the definitive testing performed on Sample Number 60 was the result of human error. The wrong definitive test was performed by our definitive laboratory technician and should not have been billed.

(h) MFD's review also found that for 195 of 261 sample episodes (74.7 percent), ADL did not perform at least one specific drug test included on the drug test requisition that was ordered by the physician or licensed practitioner. For example, ADL often failed to perform definitive tests ordered following positive and/or negative methadone presumptive test results. OSC notes this because it highlights the inconsistencies among the test services ordered, the tests that ADL performed, and the tests for which ADL billed the Medicaid program. OSC is not seeking a monetary recovery for these omissions because they did not lead to any economic harm to the Medicaid program but highlights this finding because ADL's lack of oversight of its testing was improper and may have had an adverse effect on patient care.

ADL Response: All of these patients were in a Methadone clinic and were taking methadone. As a result, all of the 195 samples had a presumptive positive test for Methadone/EDDP, which indicates that the patients were taking their medication as directed by the physician. In methadone programs, a physician would want a definitive test performed only if Methadone/EDDP, which is the methadone metabolite and indicates ingestion of methadone, came up negative. Since the presumptive test was positive, a definitive test is deemed medically unnecessary in this situation. The proper testing from a medical perspective was performed. Citing this in this audit is another example of MFD not understanding the real-world services provided to patients. We have little doubt that if ADL did perform this testing as indicated on the form, MFD would be citing us for performing non-medically necessary testing and would be taking back the dollars paid.

2. Second, MFD found that ADL violated N.J.A.C. 10:49-9.8 and failed to adhere to the AMA's Current Procedural Terminology ("CPT") guidelines, the AMA's Healthcare Common Procedure Coding System ("HCPCS") guidelines, and the Centers for Medicare & Medicaid Services National Correct Coding Initiative Policy Manual for Medicaid Services regarding specimen validity/sample validation testing and presumptive and definitive drug testing in 2015 and 2016. Because ADL unbundled 231,091 specimen validity tests, MFD seeks direct recovery of $1,140,043 in improper Medicaid reimbursements that ADL received for these validity test claims.

ADL Response: At the time that ADL billed the claims at issue, the CPT codes – which is what NJ Medicaid used for Medicaid billing at the time – did not bundle presumptive and validity testing. In 2015, the federal Centers for Medicare & Medicaid Services changed its guidance to no longer have validity testing as a separate claim, but New Jersey was not following CMS's HCPCS codes at the time. As a result, ADL continued to bill for validity testing until it received notice of a change. Indeed, in 2015, ADL affirmatively reached out to DMAHS for clarity on the appropriate billing codes, which led to a series of in-person and telephone discussions on these issues. *See, e.g.,* Ex. 2, Email Chain between ADL and DMAHS.

Critically, if DMAHS wanted labs to follow the new CMS coding guidance, state law required that any such change be published in the New Jersey Register. *See* N.J.A.C. 10:61-3.1(a) ("[R]evisions to the CPT codes and the Healthcare Common Procedure Coding System (code additions, code deletions and replacement codes) will be reflected in this chapter through publication of a notice of administrative change in the New Jersey Register."). At the time these claims were billed, DMAHS had not published any change in the NJ Register notifying laboratories that validity testing was now included in the presumptive drug testing codes. Nor did NJ Medicaid even issue a Newsletter update on the njmmis.com website. NJ Medicaid also could have placed a block in their system that blocked the validity testing codes from being paid when drug testing codes are billed on the same date of service. It did not do so.

The purported "unbundling" by ADL is simply not true. Any error here was on the part of NJ Medicaid by using AMA codes. ADL alerted NJ Medicaid to the coding issue and was told by NJ Medicaid to continue billing the AMA codes. Since ADL alerted NJ Medicaid to this issue, and made a good faith effort to try and ascertain the appropriate coding, it should not be penalized for NJ Medicaid's error.

3. Third, MFD found that for all 261 sample episodes, ADL charged Medicaid an amount that exceeded its charge to other groups for identical services. Pursuant to N.J.A.C. 10:61-1.7, an independent clinical laboratory is prohibited from charging the Medicaid program more for a test or service than the laboratory charges another payer for an "identical" test or service (the "BOR regulation"). MFD states that it is imposing a civil penalty of $3,269,332 pursuant to its authority under N.J.S.A. 30:4D-57(d)(2), N.J.S.A. 30:4D-17(e)(3), and N.J.S.A. 2A:32C-3.

ADL Response: As an initial matter, MFD's novel interpretation of N.J.A.C. 10:61-1.7 is based on a misunderstanding of the services at issue. All of the referring providers that MFD used as a comparator for the audit are all either Medication Assisted Treatment ("MAT") Providers or drug-free clinics. Although MFD contends that the providers were charged a lower price for an identical service, the services provided to those entities are not, in fact, identical. The non-Medicaid funded services that ADL renders to the identified providers involve two types of clientele: 1) patients who participate in the New Jersey Department of Health ("NJDOH") Substance Abuse Prevention & Treatment Initiative ("SAPTI"), are referred by the Division of Child Protection and Permanency, or are participants in the New Jersey Drug Court program; and 2) patients who are wholly uninsured. For the first category of patients, the State reimburses the drug treatment providers a flat rate of $8.00; for the second category of patients, the drug treatment providers generally receive no payment. *See* Ex. 3, SAPT Fee Schedule. NJDOH requires all New Jersey drug treatment providers to accept all patients that apply for services, regardless of insurance status or the patient's ability to pay – known as "charity care." As a result, these providers – who receive either $8 or $0 for the services they provide – negotiate with ADL in order to obtain an appropriate rate. ADL, like other labs in the state,

has made an effort to charge a rate that would accommodate the provider's services under these state programs and charity care and negotiates a blended rate with those service providers. The blended rate ADL charges considers the differences for the Client/Charity Care patients and NJ Medicaid patients. These differences include lower presumptive positive rates for Court-Ordered patients, no front end checking for criteria outlined in N.J.A.C. 10:61-1.6, and minimal billing steps. A step-by-step comparison of the different services provided to NJ Medicaid clients and these client bill accounts demonstrates that the services provided to NJ Medicaid clients require at least 20 different, additional steps when compared to the client laboratory services used as comparators. *See* Ex. 4, Comparison of Client Laboratory Services and NJ Medicaid Laboratory Services.

Tellingly, the State itself pays labs, including ADL, less than the Medicaid rate for laboratory services. For example, when the State solicits bids for drug testing services for state programs, such as Drug Court, Probation, and Intensive Supervision Programs ("ISP"), labs including ADL respond to the requests for production with bids at rates that are often lower than the price charged to the Medicaid program. For example, in Exhibit 5, ADL responded to an RFP with a rate of $16.50 for certain testing; for the same time period, the New Jersey Medicaid Program would have reimbursed ADL $63.95 for the same testing. Ex. 5, Request for Proposal 15-x-23545/Winning Bids. Like the charges to the MAT providers and drug-free clinics, the lower rate is only feasible for ADL due to the different billing and regulatory requirements for the services.

The BOR regulation, N.J.A.C. 10:61-1.7, has been in place since approximately February 1996. Since that time, ADL and other labs had never been informed of MFD's novel interpretation of this provision. There are not any published court or agency decisions related to the enforcement of N.J.A.C. 10:61-1.7 – let alone any that would have warned ADL of MFD's intent to enforce a new interpretation of the regulation. After reviewing the reports on New Jersey Office of the State Comptroller's website dating back to 2018, ADL could not find any lab audits that had findings citing this clause until well after this audit began. Due process would preclude MFD from suddenly enforcing the BOR regulation in this manner with no warning.

Moreover, in these circumstances MFD does not have the authority to impose the civil penalty it is seeking here. Under the applicable statutes, MFD must show that ADL's violations were knowing and willful. *See* N.J.S.A. 30:4D-17(b) (providing that an entity violates the False Claims Act when it "[k]nowingly and willfully made or caused to be made a false statement or representation of material fact: (i) in a document required to apply for or receive a NJ Medicaid benefit or payment; or (ii) for use in determining rights to the NJ Medicaid benefit or payment"); N.J.S.A. 2A:32C-3(1-2) (providing that an entity violates the False Claims Act when it [k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval" or "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim"). As outlined, above, ADL did not – and does not – believe that the services it provides to NJ

Medicaid are "identical" to the services provided to non-Medicaid payers. Even assuming for the sake of argument that ADL committed a technical violation of the regulation, ADL was not aware that this conduct would violate the BOR regulation. In short, there is zero evidence of any knowing or intentional misconduct here. The absence of such evidence is demonstrated, among other things, by this penalty not being included in the 2022 DAR, even though MFD had before it at that time the very same evidence it has before it now. MFD has not demonstrated that ADL's purported violations of the BOR regulation were knowing or willful. Therefore, the imposition of a False Claims Act penalty is inappropriate.

4. Third, MFD found that ADL violated N.J.A.C. 10:61-2.4, a regulation that prohibits providing rebates, including money discounts and other considerations. The regulation at issue provides:

> Rebates by reference laboratories, service laboratories, physicians or other utilizers or providers of laboratory service are prohibited under the Medicaid/NJ FamilyCare program. Rebates shall include refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value. Laboratories shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved.

MFD found that by violating the BOR Regulation, ADL also violated N.J.A.C. 10:61-2.4 because compared to the rate charged to Medicaid, the lower rates that ADL charged referring providers constituted a "discount." Further, MFD found that ADL also violated the regulation at issue by making charitable contributions of $10,000 dollars in May 2017, May 2018, and August 2019 to sponsor a provider's annual golf outings.

Since MFD concluded that the same overall course of conduct that violated the BOR regulation also violated N.J.A.C. 10:61-2.4, ADL incorporates its response above regarding the purported violation of that regulation. As explained above, ADL did not provide a "discount" to other providers, as the services provided were not identical, and therefore ADL did not violate either regulation.

With respect to sponsoring golf outings, those donations also did not violate N.J.A.C. 10:61-2.4. "Other things of Value" is not defined in this regulation and there is an absence of case law interpreting the regulation. Prior to this audit, ADL – like other labs in this state – construed the term consistent with the federal anti-kickback statutes. The Federal Office of the Inspector General (OIG), which rules on rebate violations, has stated that sponsorship for a golf fundraiser for a client of a laboratory is not considered a rebate. OIG

Advisory Opinion No. 01-2, March 20, 2011 found that these sponsorships were "bonafide charitable contributions." That is precisely what occurred here. This regulation was meant to cover kickbacks to clients in the form of money, entertainment, dinners, computers, cars – not these types of charitable contributions for specific fundraisers. ADL has sponsored similar fundraisers for clients and non-clients; for example, ADL sponsored fundraisers for worthy causes like the [redacted] It is a major stretch to construe a charitable golf outing that anyone in the general public can contribute to as a "rebate." If MFD is going to start interpreting this regulation in this new and expansive manner, it needs to provide fair notice of that position. It did not do so.

Summary Statement

From the beginning of this process, the manner in which this audit was handled by MFD has been strange to put it mildly. This audit began in 2018. We are now in the final days of 2023. As a result of the age of the audit, ADL is being asked to answer for records, transactions, and services that in many cases are now over 8 years old. At minimum, ADL's ability to challenge certain of MFD's findings has been hampered by MFD's significant delay, the passage of time, and fading memories regarding the circumstances surrounding certain claims. The audit was marked by lengthy periods during which MFD would be completely silent for months, at times, more than a year. Indeed, ADL's last correspondence with MFD prior to receiving the 2023 DAR was November 23, 2022 – MFD then issued the 2023 DAR over a year later. Yet, when they suddenly emerged (often on the eve of a major holiday), MFD would treat all responsive action by ADL as critically time sensitive, with strict deadlines. For example, we were needlessly and without explanation subpoenaed for documents on 2 occasions, when a simple and typical audit request would have sufficed.

The conduct of the Chief Auditor (the "CA") on the audit team was particularly striking. He apparently is no longer employed at MFD. In the very first meeting with ADL (before the audit had begun), the CA seemingly sought to intimidate ADL when he stated arrogantly, "I already have you for 7 figures." When asked if this was an audit or a fraud investigation, the CA stated threateningly "would you like me make this a fraud investigation?" Throughout this process the CA bragged about his "exploits" of shutting down labs when he was an auditor in New York. In short, from our perspective this process has been result-oriented from day one. Before the audit began, the CA promised us there would be a multi-million dollar finding here and evidently he did everything he could, even if it took six years, to stand by his promise. This is not the way our government is supposed to operate. Even one of the CA's subordinates apologized to an ADL employee for how this audit was conducted.

Then, on August 10, 2021, the exit conference finally took place in this audit. In good faith, ADL explained where MFD was incorrect and provided supporting documents to rebut MFD's claims. Promptly following that meeting, in September and August of 2021, ADL

provided email responses to MFD's post-conference inquiries. Since then, ADL never heard back from MFD regarding our meeting until we received the October 11, 2022 DAR, over a year later. MFD never even bothered to respond to our arguments.

That conducted repeated itself with respect to the 2022 DAR. ADL timely submitted its responses to the 2022 DAR and MFD was silent for over a year. Then, on November 29, 2023, MFD issued the 2023 DAR without substantively acknowledging or ever indicating its answer to many of the arguments raised by ADL.

ADL's COO has been in the laboratory industry for over 55 years and has never seen an audit performed in this manner. This has been by far and without a doubt, the worst audit ADL has ever experienced.

Lest anyone think that ADL misinterpreted or misunderstood some of the above, we note that ADL is not alone in how we were treated. We see from MFD's website and the audit response in particular of True Tox Laboratories, that they had a similar experience to ADL's with the same CA. Perhaps it is no coincidence that True Tox Laboratories is now out of business.

ADL is also questioning the statistical validity of this audit. MFD found an error with each of the 261 samples it looked at. ADL is an experienced lab with over 30 years in the industry and has been audited by numerous state and Federal regulators. MFD's finding thus suggests an error with the sample selection and size and analysis, rather than ADL's conduct. Indeed, the sample utilized by MFD is peculiarly small compared to the pool of claims at issue. MFD selected a probability sample covering the audit period of 261 episodes comprised of 554 unique paid claims for presumptive and/or definitive drug tests for which the Medicaid program paid ADL a total of $31,167. MFD selected the sample from a population of 304,546 episodes with 615,648 paid claims totaling $7,425,159 that the State paid to ADL for presumptive and/or definitive drug testing. This sample constitutes 0.0857% of episodes, 0.08998% of paid claims and 0.09989% of dollars paid. Thus, MFD has identified a handful of human errors in a sample that represents less than 1% of total claims at issue. ADL does not believe that this sample set is a statistically valid sample to extrapolate off of in the manner that MFD is attempting here. Despite multiple requests from ADL over the years, MFD did not provide ADL with the random sample and extrapolation (RS&E) data until November 29, 2023 – when it issued the 2023 DAR. Due to the limited time frame provided to respond to the 2023 DAR, ADL did not have time to engage an independent statistician to provide a report on the problems with the sample and extrapolation here, but will do so if MFD continues to pursue these claims.

In conclusion, ADL hopes that the supervisors at MFD and the Comptroller's Office review the exhibits and arguments ADL has presented and adjusts the findings in the 2023 DAR.

Sincerely,

Darin Domenico
Vice President Client Services

ADL Atlantic Diagnostic Laboratories

The Clinician's Choice

ADL Corrective Action Plan Addressing MFD's Recommendations

1. Reimburse the Medicaid program $7,425,159.

ADL Response: We respectfully request this financial finding be set aside as: (a) extrapolation was not warranted due to the nature of the alleged violations; (b) several of MFD's findings are erroneous; (c) the audit started over 5 years ago on claims that are between 8 and 5.5 years old, and (d) MFD is mistaken in their interpretation of regulations and has employed insufficient scientific expertise to evaluate the claims made against ADL.

2. Ensure that the charge to the Medicaid program does not exceed ADL's charge for identical services to other groups or individuals.

ADL Response: We respectfully disagree that the services that our charges were based upon were/are identical and therefore do not agree with MFD's findings. However, if MFD's current interpretation of N.J.A.C. 10:61-1.7 is upheld, ADL will do and expect the following:

A. ADL will be informing SAPT that all rates paid for lab testing must be at the NJ Medicaid rate or any lab performing this testing will be in violation of MFD's ruling on N.J.A.C. 10:61-1.7.
B. Any RFP or Bid for lab testing in New Jersey for any County or the State of NJ should inform all bidders that pricing for drug testing cannot be less than the NJ Medicaid rates or labs will have to adjust their charges to NJ Medicaid based on MFD's interpretation of N.J.A.C. 10:61-1.7.
C. ADL will immediately raise our client and any charity care patient rates to the NJ Medicaid Rates. ADL fully expects MFD to universally enforce N.J.A.C. 10:61-1.7 as to not allow any laboratory an advantage. This will include not only the NJ Medicaid Fee for Service program but also any NJ Medicaid Managed Care Plans (MCO), as everyone knows that Labcorp and Quest go below NJ Medicaid rates for the MCO plans.
D. ADL will ask for MFD or NJ Medicaid to issue a Bulletin clarifying that N.J.A.C. 10:61-1.7 is now being enforced in this manner so all providers and not just those that were audited will be aware that this dormant and vague regulation is being enforced in this manner.

3. Ensure that all orders for clinical laboratory services and all records and documentation are maintained by ADL and comply with applicable state and federal laws, regulations, and guidance, including the regulations cited above.

ADL Response: We respectfully state that the de minimus human errors associated with the findings can be difficult to eliminate. To the extent that human errors can be eliminated, ADL

3520 Progress Drive, Suite C • Bensalem, Pa 19020
Ph (866) 465-6763 • Ph (267) 525-2470 • Fax (267) 525-2488 • www.adllab.net

has moved to electronic orders for 90% of our accounts, including standing orders from the ordering practitioner. The transition to largely electronic orders has significantly minimized the likelihood of human error. For example, orders are signed using Adobe signs which also checks that the date range is correct. If the date range is incorrect, the standing order goes back to the doctor to fix. ADL does not accept standing orders for more than 1 year.

4. Maintain the necessary documentation and ensure that only those drug tests ordered by the physician or other licensed practitioner requesting services are tested and billed. ADL must contemporaneously document all changes to the tests ordered.

ADL Response: We corrected any paperwork errors before this audit period expired. While some documentation errors occurred, it does not eliminate the fact that the order was given by a licensed practitioner and ADL completed the services. ADL does our best to have all orders comply with the requisition forms at the time of testing. ADL continues to update documentation as needed and complies with the 30-day time limit listed in N.J.A.C. 10.61.

5. Ensure all test orders indicate the test(s) to be performed, including the specific drugs or class of drugs as defined by the AMA.

ADL Response: ADL clearly indicates all drugs and drug classes as defined by the AMA in our Physician Acknowledgements that the ordering practitioner uses to select the wide-ranging drug panels that they require to treat their patients and in our Client Agreements. MFD is misunderstanding how ADL performs our testing and what drugs constitute a drug class based off cross reactivity in the presumptive drug test. Furthermore, in March and April 2021, NJ Medicaid terminated the procedure codes for definitive drug testing involving multiple drug classes and will now only reimburse for a single CPT code. *See* Ex. 5, DMAHS Newsletter, Vol. 31, No. 07 (Mar. 2021); Ex. 6. DMAHS Newsletter, Vol. 31, No. 11 (Apr. 2021). As a result, the listing of drug classes in definitive testing has changed as labs only get paid one fee for definitive testing involving 1 or more drug classes. Since the 80307 presumptive drug tests CPT code pays 1 fee, it does not matter how many drugs ADL lists on an order for all claims going forward. Furthermore, NJ Medicaid Regulations follow not only AMA guidelines (CPT codes) but also CMS guidelines (HCPCS codes), so NJ Medicaid should educate laboratory providers regarding which rules should be followed when the AMA and CMS codes differ.

6. Ensure that all drug testing ordered by a physician or licensed practitioner is performed and reported on the drug test results.

ADL Response: This was a paperwork error that was corrected before this audit began. ADL performed the testing per the ordering practitioners' wishes and performed the testing based on medical necessity.

7. Ensure that all claims for drug tests comply with all applicable state and federal laws, regulations and guidance.

ADL Response: ADL submitted testing per regulations and guidance as explained above. NJ Medicaid issued multiple codes during 2015 and 2016 and did not follow its own regulations causing the current confusion.

8. Ensure that it refrains from separately submitting claims for specimen validity testing from claims submitted for presumptive and definitive drug tests.

ADL Response: As stated above, ADL stopped billing validity testing for presumptive testing in May of 2016, once NJ Medicaid issued the correct drug testing code that included validity testing. NJ Medicaid never published notice that validity testing was included in the presumptive testing and in fact it was ADL that informed NJ Medicaid that they were using the wrong code, met with NJ Medicaid to discuss this, and helped NJ Medicaid issue the correct codes. ADL never performed or billed for validity testing when just definitive drug testing was performed. NJ Medicaid chose to use AMA codes during 2015 until May of 2016. The AMA did not agree with CMS on bundling of validity testing until January 1, 2017.

9. Refrain from offering rebates, including refunds, discounts, or kickbacks, whether in the form of money, supplies, equipment, or other things of value to its referring providers or to any other entities. ADL shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved.

ADL Response: As explained above, ADL never violated this rule as understood in the available precedents. ADL has never offered rebates or any other items listed in #9. OIG has stated that a golf outing sponsorship is a "bona fide charitable contribution" and not considered remuneration under AKS statutes.

10. Provide training to its staff to foster compliance with Medicaid requirements under applicable state and federal laws and regulations.

ADL Response: ADL provides compliance training for all insurances, including Medicaid. ADL has submitted paperwork to NJ Medicaid and is in compliance with Section 6032 of the Federal Deficit Reduction Act of 2005, 42 U.S.C. §1396a(a)(68).

11. Provide MFD with a Corrective Action Plan (CAP) indicating the steps it will take to implement procedures to correct the deficiencies identified in this report.

ADL Response: As requested by MFD in its cover email, ADL has provided our CAP above under each item. Since ADL disagrees with the findings in this DAR, it is difficult to come up with a CAP in some instances, besides what has already been corrected by ADL or has been changed by NJ Medicaid.

OSC Note: Exhibits 1-7 included in ADL's response have been omitted to maintain confidentiality.

ADL's Comments and OSC's Responses

Atlantic Diagnostic Laboratories, LLC (ADL), through counsel, submitted a response to the Office of the State Comptroller, Medicaid Fraud Division's (OSC or MFD) revised Draft Audit Report (DAR) and took issue with OSC's audit findings. In general, ADL disagreed with OSC's findings that ADL's charges to Medicaid exceeded the lab's charges to other groups or individuals for identical services, ADL's deficient documentation did not adequately support its claims, and that ADL violated the basis of reimbursement and improper rebate regulations. In addition, ADL challenged OSC's qualifications to review laboratory documentation and generally disagreed with OSC's recommendations. Set forth below are excerpts of ADL's objections to the audit findings and OSC's responses to each. Appendix A includes ADL's full response.

1. Deficient Documentation and Billing Irregularities for Presumptive and Definitive Drug Testing

Missing Documentation, Invalid Standing Orders, and Missing Signatures

ADL's Comments

ADL does not dispute that 10 of the 261 samples that MFD reviewed contained minor clerical errors - 9 of which occurred at the provider level. Since the audit was conducted, ADL has implemented various technological fixes that have largely eliminated the likelihood of these types of human error. As such, ADL strongly disagrees with MFD's decision to extrapolate to a multi-million-dollar finding based off of these isolated errors.

First, with respect to the single failure to provide a test requisition, that error occurred because the provider gave ADL the incorrect Medicaid Recipient ID. When ADL's billing department billed for the testing on the sample, it input that Medicaid Recipient ID, causing the sample to be billed under the wrong patient's name. ADL's computer system now employs an automated rule that will prevent such errors from occurring in the future. The automated rule does not allow for a billing clerk to change the name of the patient on the order without a manager override. Further, ADL's computer system now automatically performs an eligibility check to confirm that the Medicaid Recipient ID is correct.

Second, the 7 sample episodes (Sample Numbers 44, 87, 103, 141, 151, 179, 212) with an incorrect date range for the standing order also arose out of a provider error. All 7 samples originated from the same provider and contained minor typos in the date range. Since all seven episodes arose from the same client, ADL does not believe this should be included in the extrapolation, or at most, all 7 episodes should be considered a single episode for purposes of the extrapolation.

Third, with respect to MFD's finding that ADL failed to ensure that 2 requisitions contained the signature of the ordering physician or licensed practitioner, this finding is inaccurate with respect to at least one of the two samples. The two samples identified by MFD are Sample Number 4 and Sample Number 62. Sample 62, does, in fact contain the ordering provider's signature. The signature is on the requisition form above the signature line. See Ex. 1, Sample 62 Requisition Form. This should be reviewed by MFD and taken off the findings list. As to Sample Number 4, ADL is unable to respond to this finding due to MFD's significant delay in managing this audit. ADL has been unable to locate the requisition form from October 9, 2015 - more than 7 years ago-

in our warehouse by the deadline for this response. However, ADL does not- and would not have- performed the requested testing unless it received a requisition form.

All of the errors in this category are minor human errors that are now obviated due to changes to ADL's technology. None of these findings should be extrapolated against the entire claim pool.

OSC's Response

OSC found that for ten sample episodes, ADL failed to provide one requisition, processed seven drug tests that stemmed from an expired or invalid standing order, and processed two requisitions that were not signed by the ordering physician or other licensed practitioner. For 9 of these 10 sample episodes, ADL did not dispute OSC's findings that its supporting documentation did not satisfy relevant regulations. Instead, ADL blamed its referring providers for these failings. ADL failed to recognize that, as the provider that submitted claims to and received payments from the Medicaid program, it was required by Medicaid regulations to maintain true, accurate, and complete supporting documentation for its services and it failed to do so in these nine instances. See N.J.A.C. 10:61-1.6 and N.J.A.C. 10:49-9.8(b).

ADL did not dispute that it failed to maintain supporting documentation for one sample episode, Sample Episode Number 206, and billed for services for a Medicaid beneficiary who did not receive those services. Instead, ADL blamed the referring provider for including the incorrect Medicaid recipient identification number. ADL did not acknowledge that in the claim it submitted for payment, ADL was required to ensure that the services it billed were true, accurate, and complete. Accordingly, ADL's response herein failed to provide any basis for OSC to modify this finding.

For the seven episodes that had invalid standing orders, four orders had a date range of one month, while the remaining three orders had an effective range of one day. ADL blamed the date ranges on the referring provider but did not provide any support to show that these specific dates on the standing orders were the result of an error. Each of these deficiencies were for completely separate sample claims billed by ADL for different beneficiaries, so whether or not the orders were from a single referring provider has no bearing on OSC's ability to extrapolate these distinct deficiencies. Thus, OSC's extrapolation is appropriate. ADL's response herein did not provide any basis for OSC to modify this finding.

For the missing signature in Sample Episode Number 62, the documentation that ADL initially provided to OSC was illegible, making it impossible for OSC to verify the signature. The documentation that ADL submitted as "Ex. 1" in response to the Revised DAR was a more legible copy. Accordingly, OSC removed its finding for Sample Episode Number 62 and adjusted the sample error dollars and extrapolation accordingly. ADL does not dispute that the requisition for the remaining sample episode, Sample Episode Number 4, is unsigned. Besides the one claim (Sample Episode Number 62), which OSC accepted, ADL's response herein did not provide any basis for OSC to modify the finding for Sample Episode Number 4.

Definitive Testing Billed but Not Performed

ADL's Comments

The samples at issue in this finding are Sample Numbers 6, 7, 13 and 14. ADL did not bill for definitive testing on any of these samples. On all four samples, ADL billed codes G0434 and 82055. G0434 is defined as "Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter" and 82055 is defined as "Alcohol (ethanol); any specimen except breath." G0434 does not specify that Alcohol (ethanol) is included in the code. ADL performed an Alcohol (ethanol) presumptive test and billed code 82055 appropriately. The definition for 82055 does not specify whether the code is for a definitive or presumptive test and the American Medical Association ("AMA") and Centers for Medicare & Medicaid Services ("CMS") both eliminated this code effective December 31, 2014, but the New Jersey Department of Human Services, Medicaid Division ("NJ Medicaid" or "DMAHS") still used this code in 2015. During the time period at issue, ADL was in regular communication with NJ Medicaid, which was changing the requisite coding on a quarterly basis. MFD's finding on this issue likely stems from NJ Medicaid's confusion during 2015 and 2016 as to the correct AMA and/or CMS billing codes being listed on the NJ Medicaid Fee Schedule. A review of the relevant quarterly fee schedule will reveal that ADL billed the correct codes for the tests at issue. MFD should reevaluate this finding.

OSC's Response

OSC found that for four sample episodes, ADL billed for definitive testing that was not performed. OSC notes that these findings are related to Sample Episode Numbers 6, 7, 13, and 15 and that Sample Episode Number 14 did not include this finding. Prior to 2015, CPT code 82055 was used to bill for a quantitative (definitive) evaluation of alcohol (ethanol) on any specimen, besides breath. Billing CPT code 82055 in the manner ADL did in these four sample episodes was improper for multiple reasons. First, starting January 1, 2015, prior to when each of these claims were billed, AMA's CPT coding guidelines were revised and CPT code 82055 was deleted. AMA directed providers to use the replacement CPT codes 80320-80322, which are definitive testing procedure codes for alcohol. Despite that, ADL billed this deleted code and, in each of these four sample episodes, ADL did not perform definitive testing for alcohol. If ADL's intent was to bill for presumptive testing for alcohol, then ADL should have only billed HCPCS code G0434, which included presumptive testing for <u>any number</u> of drug classes, including alcohol. By separately billing for another presumptive drug class using CPT code 82055 along with G0434, ADL improperly submitted claims for definitive testing that was not performed. Furthermore, in addition to not performing definitive testing for alcohol in the test results for Sample Episode Number 7, ADL did not perform presumptive testing for alcohol either but billed CPT code 82055. Accordingly, ADL's response herein did not provide any basis for OSC to modify this finding.

Definitive Testing Billed but Not Ordered

ADL's Comments

According to the records provided by MFD, this finding is on Sample Number 235. Line 235 states ADL billed code 80307, which is a presumptive test. ADL also billed for code G0480 - which is a definitive test - due to the negative methadone metabolite test for a patient that was prescribed methadone. The methadone definitive test only picked up raw methadone, which means the

patient was diverting/selling their methadone and spiking their sample with methadone. This is the correct way to perform a reflex test for a negative prescribed medication and human error occurred on the order. The order was misprinted and should have read, "All positive drug classes and negative prescribed medication auto confirmed by LC/MS/MS." While the order did not state this, the doctor wanted this test and ADL would be willing to obtain an affidavit from the doctor confirming this request if MFD requires.

OSC's Response

For Sample Episode Number 235, OSC found that the standing order test requisition pertaining to this sample episode requested definitive testing only for drug classes that had a positive presumptive test result. The test results for this sample episode, however, did not show any positive presumptive test results, which means that the referring provider did not order a definitive test here and ADL should not have performed and billed for a definitive test. ADL did not dispute that the supporting documentation did not include the request for the definitive testing that ADL performed and billed. As a Medicaid provider, ADL is required to ensure that its records fully support the services it bills for, and that supporting documentation is true, accurate, and complete. If ADL believed the order was misprinted, then it should have made a contemporaneous effort to correct and document the error with the referring physician. The intent of the ordering physician was made clear from the test requisition, and ADL improperly performed and billed for tests that were not included on the testing requisition form. Accordingly, ADL's response herein did not provide any basis for OSC to modify this finding.

Improper Billing of Presumptive and Definitive Testing

ADL's Comments

MFD defined definitive testing by drug classes: Opiates are one drug class, Benzodiazepines are another drug class, etc., which is correct. However, when presumptive testing is performed, Opiates, Benzodiazepines, and other drugs cross react to more than the drugs listed in the AMA defined Opiates or Benzodiazepines drug classes. For example, Opiate presumptive testing cross reacts to nine substances that are not all defined in the AMA Opiate definitive test definition. When an Opiate presumptive test is positive, ADL then tests all nine cross reactive substances by definitive methodology and bills accordingly, based on the AMA defined drug classes for each cross reactive substance. ADL has submitted the cross-reactivity data to MFD for all presumptive immunoassay drug tests. The scientific and medically necessary way to bill this one presumptive drug assay for definitive testing is nine drug classes, but MFD says this is only one drug class. Since all 71 sample episodes include multiple presumptive positive drug assays, ADL billed the proper level of definitive drug testing based off the order listed on the requisition form.

Following the exit conference, ADL provided MFD with an explanation from ADL's forensic toxicologist, [redacted], detailing how ADL performs both presumptive screening and confirmatory testing on the samples it receives, along with scientific publications supporting the same. ADL recommended MFD consult a laboratory expert to help them understand the exhibits ADL presented, but apparently this never happened. ADL also disputes that the Physician Acknowledgments and Agreements ordered are inconsistent with the testing that was ordered and performed. ADL's online ordering system has pop-up windows listing the testing components and reflexes for the drug panel that was chosen by the provider. Space limitations on the paper requisition forms render it impossible for the components and reflexes to be included on the drug.

However, ADL receives the full electronic order in its Lab Information System (LIS) and performs the testing based off the components and reflexes in the electronic order. All drug panels and reflex definitive testing are set forth in the ADL/Client Lab Services Agreement, Physician Acknowledgment and Standing Order process. ADL disputes that all 71 of these samples were not properly documented.[1]

There are some other purported errors in this category that are not correct. These issues all arose during 2015 and 2016 when NJ Medicaid's coding and fee schedules were, simply put, a mess. ADL was in communication with NJ Medicaid about the coding issue, was told by NJ Medicaid to bill the codes utilized, and can provide numerous emails to support the codes billed. For example, MFD flagged Sample Numbers 29, 107 and 177 as samples where ADL billed the wrong codes. However, all three samples were performed before November 1, 2015. ADL billed the correct codes for this date of service as the codes (80321 thru 80375) were not in effect or priced on the NJ Fee Schedule at the time the samples were received. These codes did not go into effect until November 1, 2015. Furthermore, when NJ Medicaid placed the codes on the NJ fees schedule in November 2015 the price was listed as "BR." This means ADL would not have been paid for using those codes, as they were not yet priced. ADL billed the older codes which were still active and priced on the NJ Fee Schedule. Other purported errors in this category similarly arose from coding issues. MFD should review the 2015 and 2016 NJ Fee Schedules by each quarter to see what codes were in effect and priced.

OSC's Response

In the 71 sample episodes that OSC found ADL billed for a greater level of service than requested, there was no indication that the respective ordering physicians or licensed practitioners requested that ADL test for these cross-reactive drugs as ADL described. For drug testing of New Jersey Medicaid beneficiaries, a drug test must be ordered by a physician or other licensed practitioner. Each drug test order must be medically necessary and contain the exact tests to be performed. In general, a testing laboratory is not responsible for determining the medical necessity of tests it performs nor is it permitted to override the judgment of medical necessity made by the ordering physician or licensed practitioner. In these instances, ADL completed a physician's acknowledgement form with the ordering physician at 6 of the 10 referring facilities that requested testing in these 71 sample episodes. These physician's acknowledgement forms were completed to enable the ordering physician to create customized drug test profiles for future drug test orders. Despite ADL's claim that its cross-reactive tests were all medically necessary, the referring physicians and other medical experts who completed these acknowledgement forms did not list these tests on their forms. ADL faulted the lack of detailed testing to space restrictions on paper requisitions, however, the custom profiles that were pre-populated onto the requisitions were derived from the physician's acknowledgement forms or service agreements, where any testing requested could be detailed without size constraints. The drug testing performed for these cross-reactive drug classes led to an increased level of billing and were not documented on the requisitions, standing orders, laboratory services agreements, or physician's acknowledgement forms. There is nothing to support ADL's claim that the ordering physician or licensed practitioner was aware of or requested these additional drug tests.

[1] ADL does not dispute that the definitive testing performed on Sample Number 60 was the result of human error. The wrong definitive test was performed by our definitive laboratory technician and should not have been billed.

With regard to drug test coding in 2015 and 2016, OSC did not assess findings for ADL not utilizing 2015 procedure codes that had not been put into effect on the date billed. Rather, OSC first reviewed each test requisition to see whether there was sufficient description of the drug testing requested and reviewed the respective test results to determine whether those drug tests were performed. OSC evaluated the procedure codes ADL billed based on the drug testing performed if it was sufficiently documented as being requested by the ordering physician or licensed practitioner. For example in Sample Episode Number 107, which ADL highlights, definitive testing for flurazepam, a type of benzodiazepine, was performed and billed with CPT code 82742. However, the drug test requisition did not specify definitive testing for flurazepam. Instead, only definitive testing for benzodiazepines was specified, which was performed and billed by ADL with CPT code 80154. OSC determined that the CPT code 82742 claim was not appropriate. In another example, in Sample Episode Number 29 which ADL references, CPT code 82055 (Alcohol (ethanol); any specimen except breath) was billed. However, no definitive drug test for alcohol was performed. OSC assessed that CPT code 82055 should not have been billed but CPT code 80349 was appropriate for the cannabinoids definitive test that was ordered and performed. CPT code 80349 was in effect by AMA beginning January 1, 2015.

Additionally, ADL's assertion that all 71 sample episodes included "multiple presumptive positive drug assays" is not correct. For example, test results for Sample Episode Number 110 documented positive results for marijuana only, while all other testing was negative. Additional definitive testing for methadone was not performed but was billed. Accordingly, ADL's response herein did not provide any basis for OSC to modify this finding.

Testing Ordered Not Performed

ADL's Comments

All of these patients were in a Methadone clinic and were taking methadone. As a result, all of the 195 samples had a presumptive positive test for Methadone/EDDP, which indicates that the patients were taking their medication as directed by the physician. In methadone programs, a physician would want a definitive test performed only if Methadone/EDDP, which is the methadone metabolite and indicates ingestion of methadone, came up negative. Since the presumptive test was positive, a definitive test is deemed medically unnecessary in this situation. The proper testing from a medical perspective was performed. Citing this in this audit is another example of MFD not understanding the real-world services provided to patients. We have little doubt that if ADL did perform this testing as indicated on the form, MFD would be citing us for performing non-medically necessary testing and would be taking back the dollars paid.

OSC's Response

OSC reviewed the drug test requisitions and test results for the sample claims to ensure that ADL performed and properly billed for the drug testing requested by the ordering physician. The test requisition details the request by the ordering physician and the laboratory cannot insert its professional judgment in place of that of the ordering physician/licensed practitioner to modify ordered tests. Each of the test requisitions for these 195 sample episodes indicated that ADL should have performed a definitive test for methadone following a positive presumptive test result. For example, many of the drug test requisitions state in the requested testing, "All positive drugs confirmed by LC/MS/MS" which included methadone. In each of the test results for these drug tests, the presumptive test for methadone produced a positive result, which means that ADL

should have performed a definitive test as requested. OSC found some examples of ADL performing definitive tests for methadone following positive presumptive test results (e.g., Sample Episode Number 211), which makes ADL's response that it would only perform a definitive test after a negative presumptive test inconsistent with ADL's own actions. Additionally, although ADL stated that all of these beneficiaries were in a methadone program, OSC found additional requested drug testing, both presumptive and definitive, that ADL performed for drugs other than methadone, such as alcohol and phencyclidine (known as PCP or angel dust). Testing for these drugs was also explicitly requested on the test requisitions but was not performed by ADL. Accordingly, ADL's response herein did not provide any basis for OSC to modify this finding.

2. Improper Billing of Specimen Validity Testing

ADL's Comments

At the time that ADL billed the claims at issue, the CPT codes - which is what NJ Medicaid used for Medicaid billing at the time - did not bundle presumptive and validity testing. In 2015, the federal Centers for Medicare & Medicaid Services changed its guidance to no longer have validity testing as a separate claim, but New Jersey was not following CMS's HCPCS codes at the time. As a result, ADL continued to bill for validity testing until it received notice of a change. Indeed, in 2015, ADL affirmatively reached out to DMAHS for clarity on the appropriate billing codes, which led to a series of in - person and telephone discussions on these issues. *See, e.g.,* Ex. 2, Email Chain between ADL and DMAHS.

Critically, if DMAHS wanted labs to follow the new CMS coding guidance, state law required that any such change be published in the New Jersey Register. See N.J.A.C. 10:61-3.l(a) ("[R]evisions to the CPT codes and the Healthcare Common Procedure Coding System (code additions, code deletions and replacement codes) will be reflected in this chapter through publication of a notice of administrative change in the New Jersey Register."). At the time these claims were billed, DMAHS had not published any change in the NJ Register notifying laboratories that validity testing was now included in the presumptive drug testing codes. Nor did NJ Medicaid even issue a Newsletter update on the njmmis.com website. NJ Medicaid also could have placed a block in their system that blocked the validity testing codes from being paid when drug testing codes are billed on the same date of service. It did not do so.

The purported "unbundling" by ADL is simply not true. Any error here was on the part of NJ Medicaid by using AMA codes. ADL alerted NJ Medicaid to the coding issue and was told by NJ Medicaid to continue billing the AMA codes. Since ADL alerted NJ Medicaid to this issue, and made a good faith effort to try and ascertain the appropriate coding, it should not be penalized for NJ Medicaid's error.

OSC's Response

OSC found that ADL improperly submitted claims for specimen validity testing separately from claims submitted for presumptive and definitive drug tests for the same beneficiary on the same date of service. This inappropriate unbundling of specimen validity claims resulted in an overpayment of $1,140,043. The correspondence between DMAHS and ADL that ADL provided referenced claim denials and discussions of CPT Codes 80300-80377 and did not reference specimen validity testing or the CPT codes used to bill for specimen validity testing (i.e., 82570, 83986, 84311). Thus, that correspondence was not relevant to this finding. Further, ADL did not

dispute that the specimen validity testing it performed and billed was associated with drug testing to determine whether the associated specimens were unadulterated. Pursuant to the Affordable Care Act of 2010, State Medicaid programs are required to follow National Correct Coding Initiative (NCCI) coding rules as specified by the federal Centers for Medicare and Medicaid Services (CMS). See 42 U.S.C. 1396b(r). Additionally, New Jersey Medicaid adopted all Medicaid NCCI guidelines and DMAHS provided notice to Medicaid providers of same on February 20, 2013 in DMAHS Newsletter Volume 23 No. 5, advising providers that they had to follow the Medicaid NCCI manual, including the referenced edits, when submitting Medicaid claims. Effective January 1, 2015, the Medicaid NCCI Manual stated that specimen validity testing should not be separately billed from presumptive or definitive testing. Effective January 1, 2016, the HCPCS code descriptions for presumptive and definitive testing under G0479-G0480 also included language that specimen validity testing was included and should not be separately billed. When providers enroll into the Medicaid program, they agree to comply with all applicable state and federal laws, policies, rules, and regulations for the services they perform and bill for reimbursement. ADL also affirmed this understanding by signing the provider agreement when it enrolled with the Medicaid Program to render services. Simply put, ADL had no basis for unbundling specimen validity claims from presumptive and definitive drug tests for the same beneficiary on the same date of service. Accordingly, ADL's response herein did not provide any basis for OSC to modify this finding.

3. Charge to Medicaid Exceeded Charge to Other Groups or Individuals for Identical Services.

ADL's Comments

As an initial matter, MFD's novel interpretation of N.J.A.C. 10:61-1.7 is based on a misunderstanding of the services at issue. All of the referring providers that MFD used as a comparator for the audit are all either Medication Assisted Treatment ("MAT") Providers or drug-free clinics. Although MFD contends that the providers were charged a lower price for an identical service, the services provided to those entities are not, in fact, identical. The non-Medicaid funded services that ADL renders to the identified providers involve two types of clientele: 1) patients who participate in the New Jersey Department of Health ("NJDOH") Substance Abuse Prevention & Treatment Initiative ("SAPTI"), are referred by the Division of Child Protection and Permanency, or are participants in the New Jersey Drug Court program; and 2) patients who are wholly uninsured. For the first category of patients, the State reimburses the drug treatment providers a flat rate of $8.00; for the second category of patients, the drug treatment providers generally receive no payment. See Ex. 3, SAPT Fee Schedule. NJDOH requires all New Jersey drug treatment providers to accept all patients that apply for services, regardless of insurance status or the patient's ability to pay - known as "charity care." As a result, these providers - who receive either $8 or $0 for the services they provide - negotiate with ADL in order to obtain an appropriate rate. ADL, like other labs in the state, has made an effort to charge a rate that would accommodate the provider's services under these state programs and charity care and negotiates a blended rate with those service providers. The blended rate ADL charges considers the differences for the Client/Charity Care patients and NJ Medicaid patients. These differences include lower presumptive positive rates for Court-Ordered patients, no front end checking for criteria outlined in N.J.A.C. 10:61-1.6, and minimal billing steps. A step-by-step comparison of the different services provided to NJ Medicaid clients and these client bill accounts demonstrates that the services provided to NJ Medicaid clients require at least 20 different, additional steps when compared to the client laboratory services used as comparators. See Ex. 4, Comparison of Client Laboratory Services and NJ Medicaid Laboratory Services.

Tellingly, the State itself pays labs, including ADL, less than the Medicaid rate for laboratory services. For example, when the State solicits bids for drug testing services for state programs, such as Drug Court, Probation, and Intensive Supervision Programs ("ISP"), labs including ADL respond to the requests for production with bids at rates that are often lower than the price charged to the Medicaid program. For example, in Exhibit 5, ADL responded to an RFP with a rate of $16.50 for certain testing; for the same time period, the New Jersey Medicaid Program would have reimbursed ADL $63.95 for the same testing. Ex. 5, Request for Proposal 15-x-23545/Winning Bids. Like the charges to the MAT providers and drug-free clinics, the lower rate is only feasible for ADL due to the different billing and regulatory requirements for the services.

The BOR regulation, N.J.A.C. 10:61-1.7, has been in place since approximately February 1996. Since that time, ADL and other labs had never been informed of MFD's novel interpretation of this provision. There are not any published court or agency decisions related to the enforcement of N.J.A.C. 10:61-1.7 - let alone any that would have warned ADL of MFD's intent to enforce a new interpretation of the regulation. After reviewing the reports on New Jersey Office of the State Comptroller's website dating back to 2018, ADL could not find any lab audits that had findings citing this clause until well after this audit began. Due process would preclude MFD from suddenly enforcing the BOR regulation in this manner with no warning.

Moreover, in these circumstances MFD does not have the authority to impose the civil penalty it is seeking here. Under the applicable statutes, MFD must show that ADL's violations were knowing and willful. See N.J.S.A. 30:4D-17(b) (providing that an entity violates the False Claims Act when it "[k]nowingly and willfully made or caused to be made a false statement or representation of material fact: (i) in a document required to apply for or receive a NJ Medicaid benefit or payment; or (ii) for use in determining rights to the NJ Medicaid benefit or payment"); N.J.S.A. 2A:32C-3(1-2) (providing that an entity violates the False Claims Act when it [k]nowingly presents or causes to be presented a false or fraudulent claim for payment or approval" or "[k]nowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim"). As outlined, above, ADL did not - and does not - believe that the services it provides to NJ Medicaid are "identical" to the services provided to non-Medicaid payers. Even assuming for the sake of argument that ADL committed a technical violation of the regulation, ADL was not aware that this conduct would violate the BOR regulation. In short, there is zero evidence of any knowing or intentional misconduct here. The absence of such evidence is demonstrated, among other things, by this penalty not being included in the 2022 DAR, even though MFD had before it at that time the very same evidence it has before it now. MFD has not demonstrated that ADL's purported violations of the BOR regulation were knowing or willful. Therefore, the imposition of a False Claims Act penalty is inappropriate.

OSC's Response

ADL provided two arguments as to why OSC improperly applied the Basis of Reimbursement rule to its claims. First, ADL contended that, because some of the clientele for whom it provided test services participated in the SAPTI and others were uninsured, the test services it performed for those populations were not identical to the services ADL provided for Medicaid beneficiaries. On that basis, ADL maintained that it was permitted to charge a lower rate for these non-Medicaid services without violating the Basis of Reimbursement rule. Second, ADL stated that because it could not find evidence that any court or agency had enforced the Basis of Reimbursement rule previously, OSC should not enforce this rule in this case.

Before reaching ADL's first claim, it is important to note that ADL is not arguing that the actual drug testing services it provided for Medicaid beneficiaries were different, in any way, from the drug testing services it provided for non-Medicaid clientele. Nor is ADL challenging OSC's finding that it charged the Medicaid program as much as $1,035 and was paid $180 for the same tests that it charged non-Medicaid clients as little as $2.38.

As part of its claim that the testing it performed for SAPTI and uninsured patients was somehow different from tests it performed for Medicaid beneficiaries, ADL stated that services for these populations "include lower presumptive positive rates for Court-Ordered patients…." That statement, however, is inconsistent with the documentation OSC reviewed for these patients, as 9 of the 20 (45 percent) drug test requisitions and results that OSC randomly selected from ADL's non-Medicaid invoices contained evidence that ADL performed definitive (confirmatory) tests.

With respect to ADL's effort to demonstrate that the steps it undertook to perform Medicaid drug testing somehow differed from what it performed for other payer populations, ADL provided a comparative list of steps performed for each population. After reviewing this list, OSC concluded that, even without a comprehensive review of ADL's internal operations, ADL omitted numerous steps that it performed for its non-Medicaid clientele. For example, ADL's list does not include:

- how the samples for non-Medicaid drug tests arrived at the laboratory;
- how ADL assigned an accession number (a unique internal tracking number assigned to samples) and attached it to the samples, which OSC found ADL had done for 20 of the randomly selected drug tests from the invoices for these non-Medicaid drug tests;
- how personnel had to enter patient information data into ADL's laboratory information system (LIS), which OSC found had been done for the 20 randomly selected drug tests from the invoices for non-Medicaid drug tests; and
- how ADL personnel performed eligibility checks for the non-Medicaid patients.

In an effort to distinguish between Medicaid and non-Medicaid payers, ADL cited to different drug testing rates for Drug Court, Probation, and ISP cases and the NJ Medicaid Fee Schedule. This argument reveals a fundamental misunderstanding of the Basis of Reimbursement rule and the NJ Medicaid Fee Schedule. As explained more fully below, N.J.A.C. 10:61-1.7 does not prohibit ADL from negotiating its rates or providing a lower rate to other payers; it only requires that if the laboratory chooses to participate in the NJ Medicaid program, it must also charge Medicaid the same lowest rate. ADL's citation to the Medicaid Fee Schedule is also misplaced, as N.J.A.C. 10:61-1.7 indicates those drug testing rates represent the "maximum" rates paid by NJ Medicaid, not necessarily the set rates for all claim reimbursements.

ADL also objects to OSC's application of the Basis of Reimbursement rule, maintaining that it has not been applied before. In support, ADL states that N.J.A.C. 10:61-1.7 has been in place since 1996. In actuality, this rule has existed since 1971 and the operative language in the rule has existed since 1975. The plain meaning of the text is clear and the history of the rule changes serve to strengthen OSC's plain reading of the rule, which is that independent clinical laboratories must charge the Medicaid program the lowest charge they provide to other payers. See 3 N.J.R. 83(b), see also 7 N.J.R. 420(a), see also 28 N.J.R. 1054(a).

The reimbursement rule for laboratories was originally codified at N.J.A.C. 10:61-1.5, Basis of payment. 3 N.J.R. 83(b). Under this version of the rule, Medicaid reimbursed laboratories based on the "customary charge." The original rule, effective April 21, 1971, stated in part:

> Reimbursement shall be on the basis of the customary charge, not to exceed an allowance determined reasonable by the Commissioner of Institutions and Agencies, and further limited by Federal policy relative to payment of practitioners and other individual providers. In no event shall the payment exceed the customary charge to practitioners for the specific service. [N.J.A.C. 10:61-1.5, Basis of payment. 3 N.J.R. 83(b).]

In 1975, the rule underwent significant changes. The amended rule, effective August 1, 1975, stated in part:

> Reimbursement shall be on the basis of the lowest professional charge, not to exceed an allowance determined reasonable by the Commissioner of Institutions and Agencies, and further limited by Federal policy relative to payment of practitioners and other individual providers. In no event shall the charge to Medicaid for a laboratory functioning as a service laboratory exceed the lowest charge to other providers for the specific service. [N.J.A.C. 10:61-1.5, Basis of laboratory payment. 7 N.J.R. 420(a).]

The 1975 amendment notably changed the basis of Medicaid's reimbursement to laboratories from the "customary charge" to the "lowest professional charge." See 7 N.J.R. 420(a); see also 3 N.J.R. 83(b). Furthermore, the rule was changed so that the laboratory's charge to Medicaid could not "exceed the lowest charge to other providers for the specific service." See 7 N.J.R. 420(a). The 1975 amendments reflect that the Medicaid program would no longer reimburse laboratories based on their "customary charge." See 7 N.J.R. 420(a); see also 3 N.J.R. 83(b). Rather, laboratories were to be reimbursed based on the "lowest professional charge," never to exceed a laboratory's lowest charge to other providers for the service. Ibid. In other words, a laboratory was required to charge Medicaid the laboratory's lowest rate.

The next relevant change occurred in 1996. At that time, the rule was re-codified as N.J.A.C. 10:61-1.7, which contains the current version of the rule. The amended rule, effective February 5, 1996, stated in pertinent part:

> Reimbursement shall be on the basis of the lowest professional charge, not to exceed an allowance determined reasonable by the Commissioner of Human Services, and further limited by Federal policy relative to payment of clinical laboratory services. The maximum fee schedule (allowance) is set forth at N.J.A.C. 10:61-3. In no event shall the charge to the New Jersey Medicaid program exceed the provider's charge for identical services to other groups or individuals. [N.J.A.C. 10:61-1.7. 28 N.J.R. 1054(a).]

During this rulemaking, in response to a comment asking whether the revisions reflected a change in the agency's intent, DMAHS responded:

> RESPONSE: The language does not change existing reimbursement standards at N.J.A.C. 10:61-1.5(a). It was changed to: one, include a reference to N.J.A.C. 10:61-3 and, two, to make clear that the charge to Medicaid shall not exceed the provider's lowest charge for the service. [28 N.J.R. 1054(a)]

The agency specified that the changes were "to make clear that the charge to Medicaid shall not exceed the provider's lowest charge for the service." See 28 N.J.R. 1054(a). DMAHS' response to the inquiry was clear and unambiguous. DMAHS notably did not make any exceptions for laboratories that maintain a multiple or tiered-pricing structure, nor for laboratories offering "discounts" to their referring providers. The regulation does not afford any exemption at all. Plainly, laboratories must not charge Medicaid more than the lowest amount they charge for the same services to any other group or individual, without exception.

Since 1996, DMAHS made one technical amendment in 2006 that did not alter the meaning of this rule. Accordingly, the plain language of the rule, as confirmed by DMAHS in its response to comment in 1996, remains in place today.

With respect to OSC's assessment of a civil monetary penalty for this finding, pursuant to N.J.S.A. 30:4D-57(d)(2), OSC is authorized to assess civil monetary penalties in connection with recovering improperly expended Medicaid funds for violations of Medicaid regulations. Further, pursuant to N.J.SA. 30:4D-7(h), OSC is authorized to "take all necessary action to recover any and all payments incorrectly made to or illegally received by a provider from such provider" and to "assess and collect such penalties as are provided for herein." Additionally, for hundreds of thousands of Medicaid claims that ADL submitted during the audit period, ADL charged the Medicaid program far more than it knowingly charged other payers for identical services, which violated the plain language of N.J.A.C. 10:49-9.8 because, in doing so, ADL submitted Medicaid claims that violated the Basis of Reimbursement and anti-rebate regulations.

ADL's comments do not provide any basis for OSC to modify its Basis of Reimbursement finding, which is anchored in the plain meaning of the laboratory reimbursement rule. OSC found that ADL violated that rule and, thus, is requiring ADL to correct this failing.

4. ADL Provided Improper Rebates

ADL's Comments

Third, MFD found that ADL violated N.J.A.C. 10:61-2.4, a regulation that prohibits providing rebates, including money discounts and other considerations. The regulation at issue provides:

> Rebates by reference laboratories, service laboratories, physicians or other utilizers or providers of laboratory service are prohibited under the Medicaid/NJ FamilyCare program. Rebates shall include refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value. Laboratories shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved.

MFD found that by violating the BOR Regulation, ADL also violated N.J.A.C. 10:61-2.4 because compared to the rate charged to Medicaid, the lower rates that ADL charged referring providers constituted a "discount." Further, MFD found that ADL also violated the regulation at issue by making charitable contributions of $10,000 dollars in May 2017, May 2018, and August 2019 to sponsor a provider's annual golf outings.

Since MFD concluded that the same overall course of conduct that violated the BOR regulation also violated N.J.A.C. 10:61-2.4, ADL incorporates its response above regarding the purported violation of that regulation. As explained above, ADL did not provide a "discount" to other providers, as the services provided were not identical, and therefore ADL did not violate either regulation.

With respect to sponsoring golf outings, those donations also did not violate N.J.A.C. 10:61-2.4. "Other things of Value" is not defined in this regulation and there is an absence of case law interpreting the regulation. Prior to this audit, ADL - like other labs in this state - construed the term consistent with the federal anti-kickback statutes. The Federal Office of the Inspector General (OIG), which rules on rebate violations, has stated that sponsorship for a golf fundraiser for a client of a laboratory is not considered a rebate. OIG Advisory Opinion No. 01-2, March 20, 2011 found that these sponsorships were "bonafide charitable contributions." That is precisely what occurred here. This regulation was meant to cover kickbacks to clients in the form of money, entertainment, dinners, computers, cars - not these types of charitable contributions for specific fundraisers. ADL has sponsored similar fundraisers for clients and non-clients; for example, ADL sponsored fundraisers for worthy causes like the [redacted]. It is a major stretch to construe a charitable golf outing that anyone in the general public can contribute to as a "rebate." If MFD is going to start interpreting this regulation in this new and expansive manner, it needs to provide fair notice of that position. It did not do so.

OSC's Response

OSC found that ADL violated the rebate prohibition, N.J.A.C. 10:61-2.4, in two different ways. First, ADL charged non-Medicaid payers lower amounts than it charged the Medicaid program, which constituted an impermissible "discount" for the non-Medicaid clients. Second, ADL made three $10,000 contributions to a referring provider's annual golf fundraiser. ADL's response did not address either of these findings. Instead, ADL focused on unrelated issues relating to the anti-rebate regulation, including the meaning of "other things of value," which is not relevant here. ADL then defended its financial contributions claiming that these payments would not violate the Federal Anti-Kickback Statute (AKS), citing an OIG Advisory Opinion in support of this position. The AKS and the OIG Opinion are inapplicable here because OSC is interpreting a state regulation, not a federal law or regulation, and the state regulation at issue holds independent clinical laboratories to requirements that are stricter than the AKS. In short, OSC found that ADL failed to comply with N.J.A.C. 10:61-2.4, a state Medicaid regulation that prohibits rebates and other considerations, which notably does not include any exceptions. ADL was required to comply with New Jersey's rules and cannot rely upon inapplicable federal law to justify its noncompliance with a state regulation.

It is important to note that the audit performed by OSC did not exhaustively review ADL's contracts with referring providers, did not obtain a list of all things of value provided by ADL to referring providers, and did not review all of ADL's corporate donations. The limited relevant information available to OSC alone, however, showed that ADL's practices violated N.J.A.C. 10:61-2.4. As a

participant in the Medicaid program, and as an entity that is entrusted to bill Medicaid and to receive public funds in return for the services it provided, ADL is not permitted to give rebates or other considerations to its referring providers. Prohibitions of such practices commonly are imposed on public employees and government contractors to ensure the integrity of government programs and to prevent fraud, waste, and abuse.

5. Summary Statement

ADL's Comments

From the beginning of this process, the manner in which this audit was handled by MFD has been strange to put it mildly. This audit began in 2018. We are now in the final days of 2023. As a result of the age of the audit, ADL is being asked to answer for records, transactions, and services that in many cases are now over 8 years old. At minimum, ADL's ability to challenge certain of MFD's findings has been hampered by MFD's significant delay, the passage of time, and fading memories regarding the circumstances surrounding certain claims. The audit was marked by lengthy periods during which MFD would be completely silent for months, at times, more than a year. Indeed, ADL's last correspondence with MFD prior to receiving the 2023 DAR was November 23, 2022 - MFD then issued the 2023 DAR over a year later. Yet, when they suddenly emerged (often on the eve of a major holiday), MFD would treat all responsive action by ADL as critically time sensitive, with strict deadlines. For example, we were needlessly and without explanation subpoenaed for documents on 2 occasions, when a simple and typical audit request would have sufficed.

The conduct of the Chief Auditor (the "CA") on the audit team was particularly striking. He apparently is no longer employed at MFD. In the very first meeting with ADL (before the audit had begun), the CA seemingly sought to intimidate ADL when he stated arrogantly, "I already have you for 7 figures." When asked if this was an audit or a fraud investigation, the CA stated threateningly "would you like me make this a fraud investigation?" Throughout this process the CA bragged about his "exploits" of shutting down labs when he was an auditor in New York. In short, from our perspective this process has been result-oriented from day one. Before the audit began, the CA promised us there would be a multi-million dollar finding here and evidently he did everything he could, even if it took six years, to stand by his promise. This is not the way our government is supposed to operate. Even one of the CA's subordinates apologized to an ADL employee for how this audit was conducted.

Then, on August 10, 2021, the exit conference finally took place in this audit. In good faith, ADL explained where MFD was incorrect and provided supporting documents to rebut MFD's claims. Promptly following that meeting, in September and August of 2021, ADL provided email responses to MFD's post-conference inquiries. Since then, ADL never heard back from MFD regarding our meeting until we received the October 11, 2022 DAR, over a year later. MFD never even bothered to respond to our arguments.

That conducted repeated itself with respect to the 2022 DAR. ADL timely submitted its responses to the 2022 DAR and MFD was silent for over a year. Then, on November 29, 2023, MFD issued the 2023 DAR without substantively acknowledging or ever indicating its answer to many of the arguments raised by ADL.

ADL's COO has been in the laboratory industry for over 55 years and has never seen an audit performed in this manner. This has been by far and without a doubt, the worst audit ADL has ever experienced.

Lest anyone think that ADL misinterpreted or misunderstood some of the above, we note that ADL is not alone in how we were treated. We see from MFD's website and the audit response in particular of True Tox Laboratories, that they had a similar experience to ADL's with the same CA. Perhaps it is no coincidence that True Tox Laboratories is now out of business.

OSC's Response

In its Summary Statement, ADL objected to the length of the audit, being subpoenaed for documents, the time it was afforded to respond, and the purported actions of OSC's prior Chief Auditor. With respect to the duration of the audit, OSC followed its standard audit plan and, in doing so, afforded ADL multiple opportunities, often with additional time, to respond to requests for information and to provide information and written responses to each written stage of the audit. ADL did not offer any substantive basis to show that either OSC's deadlines or the duration of the audit caused it any harm. In fact, the audit notice was issued to ADL on November 7, 2018 and the scope of the audit was January 1, 2015 through June 30, 2018, which is well within the five-year statutory period which OSC can review. Similarly, despite complaining about OSC's prior Chief Auditor, ADL does not point to anything that he or any other OSC employee did that caused harm to ADL or that would affect OSC's findings. Accordingly, ADL did not provide any basis for OSC to modify its findings.

6. Statistical Sampling

ADL's Comments

ADL is also questioning the statistical validity of this audit. MFD found an error with each of the 261 samples it looked at. ADL is an experienced lab with over 30 years in the industry and has been audited by numerous state and Federal regulators. MFD's finding thus suggests an error with the sample selection and size and analysis, rather than ADL's conduct. Indeed, the sample utilized by MFD is peculiarly small compared to the pool of claims at issue. MFD selected a probability sample covering the audit period of 261 episodes comprised of 554 unique paid claims for presumptive and/or definitive drug tests for which the Medicaid program paid ADL a total of $31,167. MFD selected the sample from a population of 304,546 episodes with 615,648 paid claims totaling $7,425,159 that the State paid to ADL for presumptive and/or definitive drug testing. This sample constitutes 0.0857% of episodes, 0.08998% of paid claims and 0.09989% of dollars paid. Thus, MFD has identified a handful of human errors in a sample that represents less than 1% of total claims at issue. ADL does not believe that this sample set is a statistically valid sample to extrapolate off of in the manner that MFD is attempting here. Despite multiple requests from ADL over the years, MFD did not provide ADL with the random sample and extrapolation (RS&E) data until November 29, 2023 - when it issued the 2023 DAR. Due to the limited time frame provided to respond to the 2023 DAR, ADL did not have time to engage an independent statistician to provide a report on the problems with the sample and extrapolation here, but will do so if MFD continues to pursue these claims.

OSC's Response

ADL questions the validity of OSC's statistical findings based on the size of the sample, but ADL did not provide any statistical argument to support its position. ADL also misstated the total claim payment amount for the audit period as $7,425,159, while ADL was actually paid $31,200,172. While ADL stated that OSC had not done so, OSC, in fact, provided ADL all of the data and tools necessary to analyze every aspect of OSC's random sampling and extrapolation (RS&E) process and to recreate it entirely, step-by-step. Despite ADL's claims, OSC provided ADL with the RS&E data on three separate occasions: July 6, 2021 with the Summary of Findings; October 11, 2022 with the Draft Audit Report; and, November 29, 2023 with the Revised Draft Audit Report. In addition, in each instance that OSC provided ADL the RS&E data, OSC received a read receipt from ADL confirming that ADL accessed the emails with the password-protected RS&E file and emails providing the passwords to the RS&E files. OSC also received emails from ADL's counsel confirming receipt of the password-protected RS&E files and the respective passwords. OSC notes that it has not received a single request from ADL with regard to not having access to the RS&E data for the audit. ADL did not take issue with the substance of OSC's RS&E and, thus, did not provide OSC any basis to modify its RS&E approach or calculations.