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.