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

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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 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

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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.