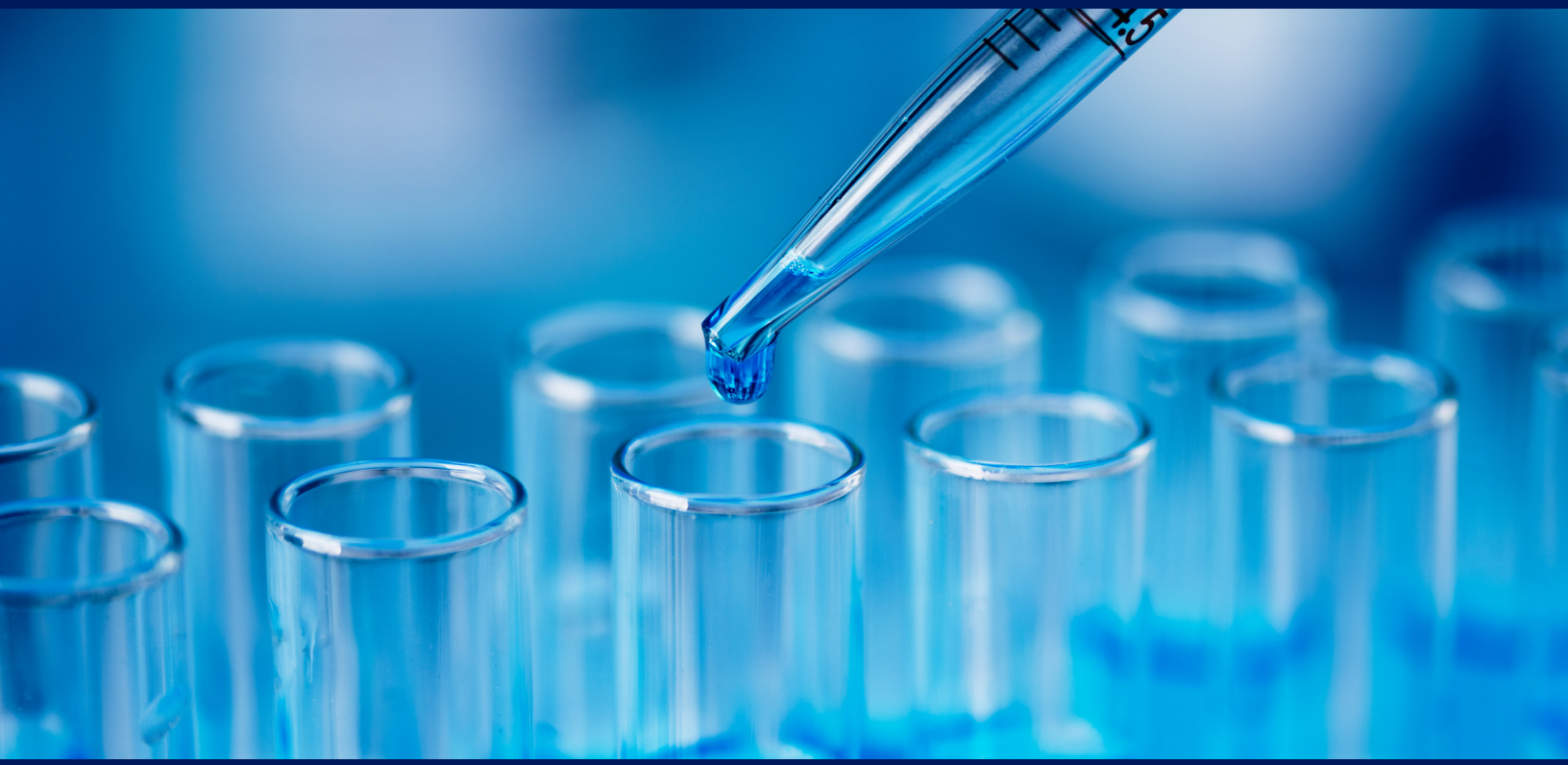
Final Audit Report of Star Laboratory Corporation's Medicaid Billing Practices

MEDICAID FRAUD DIVISION REPORT



Kevin D. Walsh
Acting State Comptroller

Issued March 19, 2025

NEW JERSEY
OFFICE OF THE STATE
COMPTROLLER

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* Exhibits B, C, D, and E were omitted to maintain confidentiality.

I. Executive Summary

As part of its oversight of the Medicaid program (Medicaid), the New Jersey Office of the State Comptroller, Medicaid Fraud Division (OSC) conducted this audit to determine whether Star Laboratory Corporation (Star), an independent clinical laboratory, billed for drug tests in accordance with applicable requirements. For the period from July 1, 2017 through March 31, 2021 (audit period), OSC selected a probability sample of Star's claims comprised of 148 episodes with 296 unique paid claims for one presumptive and one definitive drug test for which the Medicaid program paid Star a total of $19,420. OSC selected the sample from a population of 56,871 episodes with 113,742 paid claims for presumptive and definitive drug tests for which the Medicaid program paid Star a total of $7,538,640.

OSC found that for 81 of 148 (54.7 percent) sample episodes, Star's documentation failed to comply with legal requirements. Specifically, OSC found that in 79 episodes, Star performed and billed for drug tests that lacked required signatures from the referring physician or licensed practitioner. In addition, OSC found that in five episodes, Star performed and billed for a higher level of testing than what was included on the test requisition, with three of these episodes having both deficiencies. By performing drug tests in these instances, each of which failed to meet one or more regulatory requirements, Star lacked assurance that referring providers authorized these tests or that the tests were medically necessary, resulting in potentially unnecessary drug tests, and the waste and abuse of Medicaid program resources. Notwithstanding those obvious bases for rejecting these test requests, Star improperly accepted and processed them, then billed and accepted Medicaid program payments for these tests, as well as for higher-level tests than requested. OSC extrapolated the sample error dollars, $9,615 of $19,420, to the sample universe of 56,871 episodes (113,742 claims) totaling $7,538,640. OSC calculated that Star received an overpayment of at least $3,332,626,[1] which Star must repay to the Medicaid program.

Additionally, OSC found that for 51 of 148 (34.5 percent) sample episodes in OSC's sample, Star did not perform at least one specific drug test that the physician or licensed practitioner ordered. While OSC is not seeking a monetary recovery for these deficiencies because they did not cause economic harm to the Medicaid program, OSC highlights these actions because Star's failure to perform requested tests may have had an adverse impact on patient care. Such adverse impacts may include, but are not limited to, establishing a less than accurate and comprehensive medical history, which may lead to inaccurate diagnoses, missed treatment decisions, and missed opportunities for further testing.

Finally, separate from the claims in its sample universe, OSC identified seven instances during the audit period in which Star billed for presumptive and definitive testing when the test requisitions lacked a signature from the ordering physician or licensed practitioner. For one of these seven instances, Star also billed for definitive testing even though the test results did not document that Star had performed any definitive testing. In addition, separate from these seven instances, OSC identified one instance in which Star improperly billed for two definitive testing procedure codes on the same date of service for the same beneficiary, and, in this instance, the test requisition also lacked a signature from the ordering physician or licensed practitioner. For

[1] OSC can reasonably assert, with 90% confidence, that the total overpayment in the universe is greater than $3,332,626.35 (9.8% precision) with the error point estimate as $3,694,878.13.

these eight deficient outlier episodes, OSC found that Star received an additional non-extrapolated overpayment of $1,208 that it must repay to the Medicaid program.

II. Background

Star Laboratory Corporation (Star), located in Piscataway, New Jersey, has participated as an independent clinical laboratory in the New Jersey Medicaid program since November 7, 2012. Pursuant to N.J.A.C. 10:61-1.2, "'[c]linical laboratory services' means professional and technical laboratory services provided by an independent clinical laboratory when ordered by a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by the laws of the state in which he or she practices." During the audit period, Star was one of the New Jersey Medicaid program's highest-paid providers of independent clinical laboratory services.

Star submitted claims to the Medicaid program primarily for presumptive and definitive drug tests. Presumptive drug tests screen for the possible use or non-use of a drug or drug class. Definitive drug tests identify specific drugs or metabolites (byproducts of a drug).

III. Audit Objective, Scope, and Methodology

The objective of this audit was to evaluate claims for services that Star billed and received payment from the Medicaid program to determine whether Star complied with applicable state and federal laws, regulations, and guidance.

The scope of this audit was for the period from July 1, 2017 to March 31, 2021. This audit was conducted pursuant to the authority of the Office of the State Comptroller (OSC) as set forth in N.J.S.A. 52:15C-1 to -23 and the Medicaid Program Integrity and Protection Act, N.J.S.A. 30:4D-53 to -64.

To accomplish the audit objectives, OSC reviewed a probability sample of 148 sample episodes comprised of 296 unique paid claims for one presumptive drug test and one definitive drug test, both on the same date of service, for which the Medicaid program paid Star a total of $19,420. OSC selected the audit sample from a population of 56,871 episodes with 113,742 unique paid claims for presumptive and definitive drug tests for which the Medicaid program paid Star a total of $7,538,640. Separate from the claims in its sample universe, OSC also separately reviewed eight outlier episodes comprised of 17 claims totaling $1,208 for presumptive and definitive testing. (See Exhibit A for code descriptions.)

OSC reviewed Star's service agreements with its referring providers, test requisitions, and test results to determine whether Star possessed the necessary documentation to substantiate the claims for these drug tests.

IV. Compliance Framework

Medicaid regulations for clinical laboratories establish safeguards to ensure program integrity, and to prevent fraud, waste, and abuse. These rules establish clear requirements for medical necessity, documentation, and financial arrangements. Understanding the broader compliance framework provides essential context to understand these regulations. The following discussion outlines key provisions that regulate laboratory services to protect the integrity of the program.

The relevant regulations, N.J.A.C. 10:61, impose multiple requirements on clinical laboratories as part of a comprehensive regulatory approach that was constructed to safeguard the integrity of Medicaid and prevent fraud, waste, and abuse in an industry with a history of corruption in New Jersey. The longstanding rules, which supplement other generally applicable rules that apply to all Medicaid providers, establish clear guidelines to ensure the integrity of public funds. Laboratories are required to maintain detailed records of all test orders, results, and associated billing information. N.J.A.C. 10:61-1.6. The rules further mandate that standing orders must be patient-specific, medically necessary, and effective for no longer than 12 months. N.J.A.C. 10:61-2.4 prohibits reference laboratories, service laboratories, physicians, or other providers from offering rebates, discounts, or kickbacks in any form, including money, supplies, or equipment. Moreover, laboratories cannot engage in arrangements in which they rent space or provide personnel to referring physicians, closing potential loopholes that could be exploited for financial gain. These rules directly target conflicts of interest and protect taxpayer funds by ensuring ethical conduct at every step of the process.

N.J.A.C. 10:61-1.6(a) further protects Medicaid by establishing strict requirements for the authorization of clinical laboratory services to ensure that tests are medically necessary and properly documented. That regulation states:

> All orders for clinical laboratory services shall be in the form of an explicit order personally signed by the physician or other licensed practitioner requesting the services, or be in an alternative form of order specifically authorized in (b)1 through 3 below. The written order shall contain the specific clinical laboratory test(s) requested, shall be on file with the billing laboratory and shall be available for review by Medicaid/NJ FamilyCare representatives upon request.

This provision not only guards against fraudulent billing practices, unnecessary testing, and financial arrangements that could improperly influence when and which tests are ordered but also establishes an audit trail that allows for retrospective reviews. By requiring a physician's signature, the regulation ensures that laboratory services are only provided when deemed medically necessary by a qualified professional. Requiring this explicit professional approval prevents referring providers from ordering medically unnecessary tests and drug testing laboratories from processing such unauthorized requests. Without this or a similarly effective safeguard, unscrupulous providers could generate excessive or unnecessary test orders to inflate billing, leading to wasteful Medicaid expenditures. Requiring the signed order to be maintained on file and available for review provides the Medicaid program with a crucial ability to verify the legitimacy of claims and identify potential abuses.

The signature requirement also ensures providers comply with other program integrity requirements imposed by N.J.A.C. 10:61. It functions as a direct check on financial arrangements that would violate anti-kickback laws prohibited by the rules. The regulation's requirement that all test orders be explicitly documented and retained by the billing laboratory creates a clear audit trail, reinforcing accountability at every stage of service delivery. Physicians and licensed practitioners bear direct responsibility for ordering tests, reducing the risk of abuse by ensuring that clinical decisions remain within the purview of medical professionals rather than financially motivated entities. Without this safeguard, improper financial incentives could undermine the integrity of laboratory services.

N.J.A.C. 10:61-1.6(a) authorizes additional ways to authenticate the validity of testing orders that are similarly designed to ensure the physician is the one who authorizes the order. N.J.A.C. 10:61-1.6(b)(1) and (3) permit laboratories to rely on properly documented chart documentation and verbal orders followed by written or electronic confirmation within 30 days. This flexibility allows for efficient ordering while maintaining regulatory safeguards. N.J.A.C. 10:61-1.6(b)2 states:

> A test request also may be submitted to the laboratory electronically, if the system used to generate and transmit the electronic order has adequate security and system safeguards to prevent and detect fraud and abuse and to protect patient confidentiality. The system shall be designed to prevent and detect unauthorized access and modification or manipulation of records, and shall include, at a minimum, electronic encryption.

The four approaches to conveying testing orders (signature, chart documentation, electronic with safeguards to prevent and detect fraud and abuse, and verbal orders with written or electronic confirmation) permitted by N.J.A.C. 10:61-1.6, provide flexibility to providers while preventing fraud, waste, and abuse. All of the permitted approaches to authenticating testing orders ensure that physicians or other licensed practitioners make the decision to order tests and that the order is explicitly approved by them. Further, each method ensures a direct link between the test order and responsible practitioner, reinforcing accountability.

The importance of these policies and the overarching goals of N.J.A.C. 10:61 are clear from the rulemaking proceedings that led to the adoption of these rules. The regulatory history shows that the Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) was focused on preventing abuses by clinical laboratories and other providers. In response to a request to relax the physician signature requirement, DMAHS in 1996 stated:

> The requirement that all requests for laboratory services include a definitive order personally signed by the physician requesting services is a continuation of current policy (see N.J.A.C. 10:61-1.4(b)). <u>The ordering practitioner, when signing for the laboratory test, is attesting to the medical necessity of the test. This requirement is pivotal to curtailing fraud and abuse.</u> The current policy is valid and should remain unchanged.
>
> [28 N.J.R. 1054(a) (Feb. 5, 1996) (emphasis added).]

In 2010 to 2011, DMAHS amended N.J.A.C. 10:61-1.6 and again responded to concerns about physicians and licensed professionals being the only ones authorized to order laboratory tests. In response to a request to "reconsider the requirement for each paper order to be personally signed by the ordering practitioner," which was said to "'significantly detract[ ]' from the practitioner's time caring for patients," DMAHS responded:

> The Department does not believe that signing the order for a clinical laboratory service is so time consuming as to significantly detract from the time a practitioner is caring for a patient; however if that does become an issue for an individual practitioner, the Department maintains that the new alternatives to the submission of a signed order proposed at N.J.A.C. 10:61-1.6(b) are sufficient to ensure the efficient ordering of the services. All services reimbursed by the New Jersey Medicaid/NJ FamilyCare program must be certified as medically necessary. With regard to these specific rules, the authorization of orders for clinical laboratory services by a licensed practitioner is an integral part of ensuring that only medically necessary clinical laboratory services are provided to the beneficiaries and reimbursed by the program. For these reasons, no change will be made in response to the comment.
>
> [43 N.J.R. 423(a) (Feb. 22, 2011) (emphasis added).]

Similarly, in response to a comment that providers should be permitted to rely on an "'authorized representative' of the ordering licensed practitioner to sign the order" given that "the licensed practitioner would retain the ultimate responsibility for the authenticity of the order because they are responsible for the actions of their staff," which would "increase office efficiency," DMAHS responded that:

> the supervision of an 'authorized representative' would not necessarily be the responsibility of the individual licensed practitioner ordering the clinical laboratory services, for example, if the licensed practitioner provides services in a clinic or other setting in which multiple practitioners practice. Under the scenario suggested by the commenter, this could potentially result in the responsibility of the authenticity of the order being that of someone that has no knowledge of a beneficiary's individual medical needs. Ensuring that the licensed practitioner requesting the laboratory services is the individual responsible for attesting to its authenticity ensures that the care and treatment of the beneficiary remains the ultimate responsibility of the practitioner familiar with the medical needs of the beneficiary. For these reasons, no change will be made in response to the comment.
>
> [Id. at 423-24.]

In addition to N.J.A.C. 10:61, providers must comply with N.J.A.C. 10:49-9.8, which requires providers to certify the accuracy of claims, maintain comprehensive records for at least five years,

and ensure that all billed services were actually provided, thereby preventing fraudulent billing, enforcing accountability, and safeguarding Medicaid funds. Overall, these regulations reinforce program integrity and serve as a deterrent against improper billing practices.

Providers must also comply with N.J.A.C. 10:49-5.5(a)(13), which prohibits reimbursement for services when the corresponding medical records fail to adequately and legibly reflect the procedural requirements associated with the billed procedure code. Specifically, N.J.A.C. 10:49-5.5(a)(13)(i) states that "[f]inal payment shall be made in accordance with a review of those services actually documented in the provider's health care record." This rule ensures that Medicaid only pays for services that are properly recorded, medically justified, and compliant with professional standards. This provision serves as a safeguard against fraud, waste, and abuse by preventing providers from billing for undocumented, incomplete, or exaggerated services. By ensuring providers comply with rigorous documentation requirements, N.J.A.C. 10:49-5.5(a)(13) helps protect public funds from fraudulent claims, ensures that beneficiaries receive appropriate care, and promotes accountability among healthcare providers participating in Medicaid.

V. Discussion of Auditee Comments

The release of this Final Audit Report concludes a process during which OSC afforded Star multiple opportunities to provide input regarding OSC's audit findings. Specifically, OSC provided Star a Summary of Findings (SOF) and offered Star an opportunity to discuss the findings at an exit conference. OSC and Star, represented by counsel, held an exit conference during which the parties discussed OSC's findings in the SOF. After the exit conference, Star's counsel provided OSC a written response that disputed the missing signatures on the testing requisitions (See Appendix A.) After considering Star's response, OSC conducted a sworn interview of the ordering physician. Subsequently, OSC provided Star a Draft Audit Report (DAR) with recommendations and instructed Star to provide a Corrective Action Plan (CAP) as part of its formal response to the DAR. Star submitted a formal response to the DAR; however, Star failed to submit a CAP. (Star's response to the DAR is attached as Appendix B.)

OSC addresses each argument raised by Star in more detail in Appendix C to this report. After reviewing Star's submission, OSC determined that there was no basis to revise any of its findings presented in this audit report.

A. Auditee Comments Post Summary of Findings

Following the exit conference, Star's counsel submitted a written response to the SOF in which Star disputed the missing signatures on the testing requisitions, asserting that labels bearing the ordering physician's initials were affixed to the requisitions in place of signatures in conjunction with having yearly facility-wide standing order forms. Star's response further explained that, rather than signing the testing requisitions, the physician associated with these missing signatures "printed an electronic label generated from [the referring providers'] Methasoft EMR [electronic medical record] system. The printed label was affixed to the paper requisition form and evidenced [the physician's] intent and request for the applicable drug tests." Star also stated that "[t]here is no dispute that [the physician] intended and requested the lab tests by printing and affixing the label on the requisition forms as agreed." In sum, Star claimed that the labels, generated from the

Methasoft EMR system that included the physician's printed initials, served as evidence of the physician's intent and request for the relevant drug tests. See Appendix A.

B. Summary of the Referring Provider's Sworn Interview

To verify Star's claims regarding the ordering physician's level of involvement and knowledge of the testing requisition forms, OSC conducted a sworn interview of the ordering physician. From this interview, OSC confirmed that, contrary to Star's assertions, the ordering physician neither printed nor affixed any labels to the testing requisition forms during the audit period. Rather, the physician explained that he was not involved in the drug test ordering and submission process. Under oath, the physician stated as follows: "I had no involvement. There was a written form with my signature that gave permission to run the test." Furthermore, in response to being asked whether he reviewed the drug test orders prior to submission to Star, the ordering physician stated, "No, it's impossible" due to the high volume of patients at the clinic and further stated that "I can't be checking every form." The physician also disclosed that the responsibility for printing and affixing labels to drug requisition forms rested with the Director of Nursing: "The DON, Director of Nursing will print out the label with my initials on it and all the standard labs will be done." The physician also advised that he was not aware of any instances when Star did not perform drug tests that were included on the testing requisition forms. Despite that statement, OSC found that in 51 out of 148 sample episodes, Star did not perform at least one specific drug test included on the drug test order. The physician's apparent failure to recognize that Star performed fewer tests than the physician had ordered raises a troubling question as to whether referring providers are reviewing drug test results for their patients. Out of concern for patient care and program integrity, OSC highlights this point in the event that this referring provider's apparent lack of due diligence in reviewing test results is emblematic of a broader problem in this area.

Star claimed that the ordering physician reviewed all testing requisitions, but the sworn interview revealed that the physician did not follow the signature protocol as asserted. Star's documented failure to perform requested tests and its acceptance of test requisitions that obviously lacked required signatures raise serious concerns about Star's potential waste and abuse of Medicaid program resources.

C. Additional Auditee Comments Post Sworn Interview

After the sworn interview, Star's counsel submitted a supplemental response. This response requested that OSC rescind its SOF report, alleging that OSC relied upon insufficient evidence to support the audit findings. OSC found no reason to withdraw its SOF. OSC conducted the sworn interview of the referring provider to test the veracity of claims made by Star, through its counsel. Through this process, OSC found that the information provided by Star was unsupported and contradicted by the referring provider's sworn testimony. In sum, Star did not present any evidence that would compel OSC to rescind these findings.

VI. Audit Findings

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

OSC reviewed Star's documentation to assess whether it properly documented the services billed to the Medicaid program. OSC found that in 81 of the 148 sample episodes (54.7 percent), Star failed to properly document services it provided, with three sample episodes including multiple deficiencies. OSC extrapolated the error dollars, $9,615 of $19,420, to the sample universe of 56,871 sample episodes (113,742 claims) totaling $7,538,640. Applying this process, OSC calculated that Star received an overpayment of at least $3,332,626[2] from the sample universe. Set forth below is a discussion of each type of deficiency that OSC found.

1. Missing Signatures

OSC found that test requisitions for 79 of the 148 sample episodes (53.4 percent) failed to include the signature of the ordering physician or other licensed practitioner requesting drug testing services in a written requisition. Star should have rejected test requisitions that lacked a physician or other licensed practitioner's signature because without a signature from a physician or licensed practitioner, Star lacked assurance that there was sufficient medical necessity to perform the requested tests. Star ignored the glaring omission of signed requisitions, performed the tests, then billed and received payment from the Medicaid program for these tests.

The use of initials, stamps, and/or machine-generated signatures on non-electronic media claims violates N.J.A.C. 10:49-9.8(a), which states that providers shall "certify that the information furnished on the claim is true, accurate, and complete." In addition, this also violates N.J.A.C. 10:49-9.8(b)(1) and (4), which state that providers shall "keep such records as are necessary to disclose fully the extent of services provided" and that such services are "in accordance with the requirements of the . . . program." Further, Star failed to ensure that the test requisitions were signed by the ordering physician in compliance with N.J.A.C. 10:61-1.6(a), which states that "orders for clinical laboratory services shall be in the form of an explicit order personally signed by the physician or other licensed practitioner requesting the services." Star similarly did not comply with the alternatives to providing a signature permitted under N.J.A.C. 10:61-1.6(b): chart documentation, electronic with safeguards to prevent and detect fraud and abuse, or verbal orders with written or electronic confirmation.

2. Presumptive and Definitive Testing Not Ordered

Additionally, OSC found that in 5 of the 148 sample episodes, Star performed and billed for presumptive or definitive drug testing that was not requested in the corresponding test requisition or billed for a greater level of service from what was ordered, with three of these sample episodes also failing to contain the necessary ordering physician or licensed practitioner signature.

[2] See footnote 1.

Referring providers submitted test requisitions to Star either electronically or manually. When a referring provider submitted a manual requisition, the requisition listed the drug tests ordered, including the type of testing (i.e., presumptive, definitive) and the specific drugs to be tested. Because these manual requisitions provided a clear description of what the referring provider ordered, OSC did not have to perform any additional steps to validate the testing ordered. When a referring provider submitted a requisition electronically, however, the requisition did not specify the type of testing or the specific drugs to be tested but instead listed a test code that corresponded to a pre-determined list of drugs to be tested. After finding that the electronic requisitions did not contain enough information to validate these claims, OSC reviewed additional documentation to ascertain whether Star properly submitted each claim. Star provided drug screening agreements with its primary referring provider that listed the type of drug test ordered for specified drugs or drug classes. Star also provided a test compendium of the unique test codes that the physician or licensed practitioner would select when ordering a drug test following the drug screening agreement. OSC found, however, that despite this documentation, the testing performed and billed in these five sample episodes was not consistent with the respective drug screening agreements or test compendium.

The American Medical Association's Healthcare Common Procedure Coding System codes recognize multiple levels of definitive drug testing. The definitive codes identify drugs or metabolites (byproducts of a drug) that will be tested, with billing categories that increase in cost based on the number of drug classes that will be tested. The lowest level of definitive testing, which has the lowest Medicaid reimbursement rate, covers 1 to 7 drug classes, with progressively higher reimbursement levels for 8 to 14 drug classes, 15 to 21 drug classes, and, finally, 22 or more drug classes, which has the highest Medicaid reimbursement rate.

In one of these five sample episodes, the referring provider did not request either presumptive or definitive testing, but Star billed both for both types of testing. In three of these five sample episodes, the referring provider did not request definitive testing, but Star performed and billed for it. For the remaining one of these five sample episodes, Star billed for a greater level of definitive testing than what the referring provider had ordered.

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

Pursuant to N.J.A.C. 10:49-9.8(a), "all providers shall certify that the information furnished on the claim is true, accurate, and complete."

3. Requested Testing Not Performed

In addition to downcoding claims when Star billed for more drug tests than its documentation supported, OSC also found that Star did not perform all drug testing that referring providers ordered. OSC determined that in 51 of the 148 sample episodes (34.5 percent), Star did not perform at least one drug test included on the drug test order. For example, a referring provider's test requisition instructed Star to perform definitive testing of cocaine following a positive presumptive test, but Star failed to test for cocaine. OSC is not seeking a monetary recovery for

these omissions because they did not cause economic harm to the Medicaid program, but OSC highlights this finding because Star's lack of oversight may have had an adverse effect on patient care. Such adverse impacts may include, but are not limited to, establishing a less than accurate and comprehensive medical history, which may lead to inaccurate diagnoses, missed treatment decisions, and missed opportunities for further testing.

B. Direct Review of Outlier Claims for Presumptive and Definitive Drug Testing

During the audit period, but not within OSC's sample universe of episodes, OSC identified seven outlier episodes in which Star improperly billed an outdated procedure code for presumptive testing. For each of these seven episodes, Star billed for presumptive and definitive testing when the test requisitions lacked a signature from the ordering physician or licensed practitioner. For one of these seven instances, Star also billed for a definitive test even though the test results did not document that Star had performed a definitive test. OSC also identified an additional instance when Star improperly billed for two definitive testing procedure codes on the same date of service for the same beneficiary, and, in this instance, the test requisition also lacked a signature from the ordering physician or licensed practitioner. Since OSC had not reviewed these eight episodes as part of its sample universe, OSC separated these episodes, comprised of 17 claims totaling $1,208, from the sample claims in its analysis. From this analysis, OSC found that Star received an additional non-extrapolated overpayment of $1,208 for these eight episodes.

Pursuant to N.J.A.C. 10:61-1.6(a), " [a]ll orders for clinical laboratory services shall be in the form of an explicit order personally signed by the physician or other licensed practitioner requesting the services." (N.J.A.C. 10:61-1.6(b)(1), (2), and (3) provide alternative approaches to the signature requirement of N.J.A.C. 10:61-1.6(a) with which Star did not comply.) Pursuant to N.J.A.C. 10:49-9.8(a), "all providers shall certify that the information furnished on the claim is true, accurate, and complete."

VII. Summary of Medicaid Overpayment

OSC determined that Star improperly billed and received payment for 81 of the 148 sample episodes due to deficient documentation and billing irregularities related to presumptive and definitive drug testing. OSC extrapolated the sample error dollars, $9,615 of $19,420, to the sample universe of 56,871 episodes (113,742 claims) totaling $7,538,640. Applying this process, OSC calculated that Star received an extrapolated overpayment of at least $3,332,626.

OSC also found that Star improperly billed for eight outlier episodes comprised of 17 claims totaling $1,208 for deficient documentation and billing irregularities for presumptive and definitive testing. OSC determined that Star received an additional overpayment of $1,208 for these eight episodes for which OSC seeks a direct recovery.

In sum, OSC seeks to recover a total overpayment of $3,333,834 ($3,332,626 + $1,208).

VIII. Recommendations

Star shall:

1. Reimburse the Medicaid program the overpayment amount of $3,333,834.

2. Ensure that it properly maintains all orders for clinical laboratory services and all records and documentation supporting its claims in a manner that complies with applicable state and federal laws, regulations, and guidance.

3. Maintain the necessary documentation and ensure that it only performs and bills for those drug tests ordered by the physician or other licensed practitioner requesting such services.

4. Ensure all test orders indicate the test(s) to be performed, including the specific drugs and class of drugs as defined by the American Medical Association.

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

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

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

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

Star Laboratory Corporation
HCPCS and CPT Code Descriptions for Presumptive and Definitive Drug Testing
July 1, 2017 to March 31, 2021

Exhibit A

AMA CPT Code Descriptions - Presumptive

Code	Code Descriptor
80307	Drug test(s), presumptive, any number of drug classes, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.

AMA HCPCS Code Descriptions - Presumptive

Code	Code Descriptor
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analysers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.

AMA HCPCS Code Descriptions - Definitive

Code	Code Descriptor
G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.
G0481	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.
G0482	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.
G0483	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.

BALDASSARE & MARA, LLC

VIA EMAIL [redacted]

January 19, 2024

[redacted],
Assistant Division Director (Audit)
Medicaid Fraud Division
New Jersey Office of the State Comptroller
Trenton, NJ 08625-0025

Re: Star Laboratory Corporation – Response to Summary of Findings

Dear Mr. [redacted]:

We represent Star Laboratory Corporation ("Star Lab"). Please allow this letter and attachments to serve as Star Lab's response to the summary of findings report, dated November 21, 2023, issued by the New Jersey Office of the State Comptroller, Medicaid Fraud Division ("OSC"). The report alleges that Star Lab lacked sufficient documentation to support its claims for drug test reimbursement such that the OSC seeks an extrapolated overpayment in the amount of $3,332,626. For at least the following three reasons, the OSC's findings, and extrapolated and demanded overpayment, are erroneous.

First, the OSC's primary allegation is that Star Lab failed to ensure that drug test requisition forms were signed by the ordering practitioner. We disagree. Drug tests were indeed requested and signed by Dr. [redacted], the medical director for [redacted], an outpatient substance use disorder treatment facility. During the audit period prior to March 2020, there was no software interface between Star Lab's Labgen LIS and [redacted]'s Methasoft EMR system to allow for electronic requisitions, processing, and test results. Accordingly, Dr. [redacted] ordered drug tests by using a paper requisition form. To order the drug tests and link it and the subsequent test results to the applicable patient's substance use disorder treatment records, Dr. [redacted] printed an electronic label generated from [redacted]'s Methasoft EMR system. The printed label was affixed to the paper requisition form and evidenced Dr. [redacted]'s intent and request for the applicable drug tests. *See* Exhibit A.

To that end, Dr. [redacted] entered into agreements with Star Lab so that Star Lab understood and could rely on the fact that the phrase "Requested by [redacted]" on Dr. [redacted]'s printed label "represents my digital signature" and "reaffirms my intent for medical testing and supplements as my signature." *See* Exhibit B. Star Lab relied on these agreements and relied on the fact that the printed label constituted Dr. [redacted]'s intent and personal signature. There was a clear and unambiguous understanding between Dr. [redacted] and Star Lab to that effect.

N.J.A.C. 10:61-1.6 sets forth the requirements for lab orders; that regulation does not state, imply or in any way indicate that the phrase "personally signed" requires a wet, handwritten signature. If that were the case, the OSC would not accept PDFs "signed" via DocuSign. Because the OSC accepts such documents with full knowledge that the "signature" is electronic and can be "signed" by anyone, there is simply no basis in reason (other than an arbitrary decision now imposed on Star Lab after the fact with no notice) to conclude that the labels are inappropriate.[1] By way of example, documents electronically signed via DocuSign are legally binding, and the OSC accepts documents signed in this electronic manner, even though there is the potential someone other than the "signatory" actually effectuated the "signing" of the DocuSign document.

As discussed during the OSC exit conference, the purpose for requiring a signed order is to ensure that the ordering practitioner intended and actually requested the lab test. In this case, that is exactly what happened. There is no dispute that Dr. [redacted] intended and requested the lab tests by printing and affixing the label on the requisition forms as agreed. The printed label on the requisition forms constitutes Dr. [redacted]'s "personal signature" just as a thumbprint, seal, or marker constituted a person's signature years ago. Thus, the labels clearly and without dispute vindicated the regulation's purpose.

The OSC has offered no legal basis (statutory, regulatory, decisional or otherwise) for its finding, other than simply saying the labels are insufficient. The OSC's allegation that there were overpayments relating to the claims associated with the labeling issue is untethered to its mission to "detect and recover funds that are improperly used."[2] For these reasons, the record contains sufficient documentation of signed requisition orders such that reimbursement for the ordered drug tests is appropriate and that the OSC's demand for over $3,000,000.00 lacks legal and factual support.

Second, the OSC alleges that, in a few instances, Star Lab billed an expired procedure code for presumptive drug testing. It appears Medicaid reimbursed Star Lab for these drug tests even though the codes were outdated or by updating them to the correct codes and providing reimbursement. In any case, there is no dispute that the lab tests were in fact ordered and processed. (This, of course, demonstrates the fact that this finding is the epitome of form over

[1] A review of the recently posted settlement agreements by MFD establishes that, in fact, the OSC regularly accepts DocuSign "signatures" to execute such agreements. *See, e.g.*, Settlement Agreement and Mutual Release with All 4 Kidz Pediatrics, LLC, at p. 6 (*available at* nj.gov/comptroller/news/docs/all4kidz_settlement_agreement.pdf), Settlement Agreement and Mutual Release with Campus Pharmacy, at p. 6 (*available at* www.nj.gov/comptroller/news/docs/campus_pharmacy_settlement_agreement2.pdf), Settlement Agreement and Mutual Release with RDx Bioscience, Inc., at (PDF) p. 8 (*available at* www.nj.gov/comptroller /news/docs/rdx_settlement_agreement.pdf).

[2] *See* www.nj.gov/comptroller/about/work/medicaid.

substance that has nothing to do with "ensuring that providers properly deliver care for which they bill the Medicaid program").[3] This is not a case where a provider received funds "for claims for the same services for the same patients on the same service dates[.]"[4] Rather, Star Lab inadvertently used outdated codes. Had Medicaid denied the claim at the time of submission for this reason, there is no question that Star Lab would have re-submitted the claim with the correct codes and received reimbursement. The OSC has certainly never argued to the contrary.

Medicaid is not permitted to reimburse a claim, wait until the time expires for Star Lab to correct and resubmit the claim, and then seek an overpayment to the detriment of Star Lab. The OSC has not justified providing Medicaid with a financial windfall, particularly where Medicaid took no steps to notify Star Lab of this error. Aside from a legal defense of laches,[5] such an interpretation defies reason, due process and any sense of fair play. This audit is subject to legal standards and, even though the auditors are not attorneys and this is not litigation, the law matters and must guide the decisions made at every step of the way. Deploying State regulations to collect a windfall of money is simply contrary to law. For this reason, the inadvertent use of expired procedure codes should not be included as part of the OSC's overpayment demand. Excluding this portion of the OSC's demand reduces the amount sought from Star Lab by $1,208.00.

Third, it is significant that, around March 2020, Star Lab and [redacted] implemented a software interface between their systems. Going forward, Dr. [redacted] logged into Star Lab's website portal and electronically submitted requisition orders for lab tests. This included an electronic image of his signature consistent with N.J.A.C. 10:61-1.6(b)(2). All requisition forms were received electronically by Star Lab and all test results were electronically transmitted to [redacted]. In its report, OSC concluded that, after about March 2020, Star Lab was fully compliant with having electronically signed requisition forms (that is, from that point forward there was a 0.0% error rate on the reviewed claims), with three exceptions: in one instance, the finding resulted from Star Lab's use of the old requisition form, and in two instances, OSC denied payment for other reasons.[6]

Further, based on the available information, OSC's audit period of July 1, 2017 to March 31, 2021, is arbitrary and untethered to the facts and circumstances of this case or regulatory guidance. In light of Star Lab's implementation of a software interface in March 2020 (of which OSC was aware), it is clear that had the audit period been selected for a timeframe closer in time to OSC's findings in November 2023 (from January 2019 to July 2022, for example), it is likely that the probability sample would have contained more compliant test requisitions than the sample upon which OSC based its findings. That, in turn, would have resulted in a lower demand from OSC, possibly even to a demand for $0.00 if, for example, the random sample from a different time period contained only compliant claims.

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[3] *See* www.nj.gov/comptroller/about/work/medicaid.

[4] *See* Settlement Agreement and Mutual Release with Jefferson Cherry Hill Hospital, at p.1 (*available at* www.nj.gov/comptroller/news/docs/kennedy_memorial_hospital_settlement_agreement.pdf); Settlement Agreement and Mutual Release with All 4 Kidz Pediatrics, LLC, at p. 1 (*available at* nj.gov/comptroller/news/docs/all4kidz_settlement_agreement.pdf).

[5] As noted, the law has to matter at every turn as the OSC discharges its obligation.

[6] Star Lab's good faith throughout the analyzed period is not surprising given that the OSC's report did not find any indicia of intentional misconduct or fraud.

* * * *

We acknowledge that a written response to an exit interview is not technically the forum for legal argument, but just as the audit division demands millions of dollars based upon its interpretation of the law, so too must the audit division be guided by controlling legal principles. For all these reasons, the OSC has not demonstrated a right to repayment as claimed in the draft audit report. The OSC should amend its findings accordingly in its final report. Star Lab reserves all rights on all issues.

Sincerely,

Michael Baldassare

Sincerely,

Edward J. Yun

cc: [redacted]
Star Laboratory Corporation (via email)

Exhibits attached to the provider's response have been omitted to maintain confidentiality.

BALDASSARE & MARA, LLC

VIA EMAIL

November 19, 2024

[redacted], Senior Auditor
Office of the State Comptroller
Medicaid Fraud Division
20 West State Street, 4th Floor
Trenton, NJ 08625

Re: Star Laboratory Corporation
Medicaid Provider Number [redacted]
Response to Draft Audit Report dated October 8, 2024

Dear Mr. [redacted]:

This firm, along with Brach Eichler, LLC, represents Star Laboratory Corporation ("Star"). This submission responds to the Medicaid Fraud Division's October 8, 2024 Draft Audit Report ("DAR"). For the following reasons, MFD should demand no repayment from Star.

I. EXECUTIVE SUMMARY

MFD's conduct in this case establishes one broad and troubling point with certainty: MFD is not interested in merit. Rather, MFD has become a bureaucracy driven by inertia and the need to collect money to justify its own budget. MFD has transformed "form over substance" into a profitable policy.

For example, MFD ignores that the testing at issue in this matter *was not only medically necessary but required as a matter of law.* *See, e.g.*, N.J.A.C. 10:161B-11.4, 11.6, 11.7, 11.8 & 11.9. As discussed herein, MFD is well aware of, but completely ignores, those legal requirements.

Further, MFD seeks to put a small business (that is important to the health care of many) out of business based upon a regulation that was never properly enacted in the first place and, therefore, carries no legal force. In sum, MFD's "signature" regulation, N.J.A.C. 10:61-1.6, was enacted contrary to the mandate of the New Jersey Administrative Procedure Act. Given MFD's penchant for demanding perfection, it should be cognizant of its own deficiencies before manufacturing a $3,000,000.00 demand *based on a regulation that does not carry the force of law.*

Moreover, MFD demands a level of compliance with arcane and esoteric rules and regulations that it does not exhibit itself. Despite the requirement that the N.J.A.C. be updated every seven years, MFD's regulations contain errors that should have been corrected decades ago; moreover, those N.J.A.C. provisions are replete with erroneous references to federal regulations, as well as regulations that do not exist:

> N.J.A.C. 10:49-1.1, 1.3. Those subsections cite 42 C.F.R. § 412.30. That federal regulation has not been in effect since August 5, 2011, having been "removed" on that date.
>
> N.J.A.C. 10:49-5.5(a)(9)(i). This regulation refers to "Retroactive Eligibility at N.J.A.C. 10:49-2.7(c)." Section 10:49-2.7 has no subsection (c). Further, § 10:49-2.7 no longer deals with "Retroactive Eligibility." Section 10:49-2.7 now covers "Applying for Medicaid eligibility for a newborn infant or for an inpatient upon admission to a hospital."
>
> N.J.A.C. 10:49-5.5(a)(11). This regulation cites "N.J.A.C. 10:49-6," but there is no such regulation. It is possible that the operative regulation is now § 10:49-6.1, but MFD is charged with an error here given its demands for perfection from providers.
>
> N.J.A.C. 10:49-5.5(a)(13)(ii). This regulation cites "N.J.A.C. 10:49-9.5, Provider Certification and Recordkeeping." That regulation has nothing to do with certifications or recordkeeping. Rather, it addresses "Observance of religious belief." That regulation changed topics 26 years ago in 1998.
>
> N.J.A.C. 10:49-5.5(a)(14). This regulation refers to "N.J.A.C. 10:49-2.13(e)(2), Special Status Program." Subsection (e)(2) does not exist. Further, § 2.13 now deals with "Forms that validate Medicaid eligibility."

One can easily imagine MFD's outrage if the federal government threatened to withhold funding or support based on those errors.

Fortunately, we do not need to imagine. We know precisely how the State reacts when called to account for such errors. Earlier this year when the federal government audited the New Jersey Department of Human Services, the federal government demanded a repayment of $94,000,000.00. Ex. DD. In response to that demand, the DHS advanced some of the very same arguments presented here by Star (which MFD will likely completely ignore):

> DHS does not concur with this recommendation and stands behind its original response to this audit. Please see our response to the original audit for more detail, but DHS generally contends that a disallowance is unwarranted due to:
>
> 1. The OIG's significant recoupment recommendation is based on a limited sample size and five findings from its review of 100 of

> the more than 3.8 million partial care claims for services rendered during the four-year audit period, calendar years 2009 through 2012.
>
> 2. The audit report imposes unreasonable standards on entities providing dynamic and comprehensive services to individuals with serious mental illness.
>
> 3. Noncompliance with State law is not appropriate grounds for a disallowance.
>
> 4. OIG should not recommend recoupment based on missing documentation of claims submitted more than three years before the start of the audit period.

Ex. DD. The State's recent response only supports Star's observation that MFD holds everyone to a different standard than it holds itself; moreover, the State's response establishes the validity of Star's positions here because they are some of the same arguments.

And, MFD has failed and continues to fail to provide adequate notice of how it will conduct audits and how it will engage in the extrapolation that enables it to demand millions of dollars from small businesses. Once again, the law imposes such notice requirements, but MFD is never called to account for those failures.

Further, this case provides a stark example of why MFD's blind allegiance to its own draft audit reports is particularly troubling: MFD found no violations for the vast majority of its investigative goals. MFD conducted the audit "to determine whether Star billed for drug tests during the Audit Period in accordance with applicable state and federal laws, regulations, and guidance." DAR p. 1. The DAR found no violation of any federal law, any federal regulation or any federal guidance. Further, the DAR found no violation of any state law or state guidance. The DAR rests on a violation of a single state regulation that is not properly on the books in the first place. MFD's determination that there were no violations for the vast expanse of its years-long investigation (with which Star complied during site visits and numerous document productions) speaks volumes about MFD's elevation of form over substance and extrapolating minor errors into multi-million dollar demands.

Ultimately, the draft audit process is ineffective. Even a cursory review of recent audits published by the Office of the State Comptroller reveals that the back and forth between MFD and a provider is a waste of resources for all sides. MFD does not change its findings with any meaningful regularity. With stunning consistency, MFD does little except change the word "Draft" to "Final." Thus, giving the provider an opportunity to respond to a draft audit may have the appearance of due process; however, in reality, it provides no such protections.

* * * *

Fortunately for Star, changes in the law provide paths to challenge MFD's operating ethos. The time has come for MFD to be challenged as far as the Court system provides. Star's response to the DAR is the first step of what promises to be a long process.

II. FACTUAL AND PROCEDURAL BACKGROUND

This saga began nearly five years ago, when on December 2, 2019, MFD issued an audit notice to Star. In connection with the audit, MFD conducted a site visit on January 9, 2020. During this site visit, MFD staff members employed overly aggressive and bullying tactics that have been its hallmark and endured by Star and other providers. Indeed, MFD staff members commandeered Star's copy machine, barked orders at Star personnel and counsel, and generally disrupted Star's business operations. Notwithstanding this inappropriate and unprofessional behavior, Star remained cooperative throughout the site visit. Star also made four document productions relating to this audit, with the last one occurring on March 23, 2020.

Following an inexplicable two-year period of silence from MFD, Star received a second audit notice on April 13, 2022. On July 6, 2022, MFD conducted another site visit. And Star ultimately made an additional seven document productions.

Further, MFD conducted an interview with Dr. [redacted], who is employed by [redacted], not Star, on May 10, 2023. On November 21, 2023, MFD issued its summary of findings. On January 4, 2024, MFD held an exit conference with Star's counsel, and two weeks later, Star provided its response to the summary of findings. *See* Ex. AA. Approximately two months later, in an apparent attempt to intimidate Dr. [redacted], MFD conducted a sworn interview with him, presumably covering the same topics addressed in his first interview almost a year earlier. On March 18, 2024, Star submitted a supplemental response to the summary of findings, in which it demanded that it be provided with the transcript of the sworn interview. *See* Ex. BB. MFD ignored that response and failed to provide the transcript to Star, only disclosing it when MFD issued its draft audit report on October 8, 2024.

MFD's years-long investigation culminated in the issuance of a DAR on October 8, 2024. That report states that the audit was searching for violations of "state and federal laws, regulations, and guidance." DAR p. 1. MFD found no violations of federal statutes, federal regulations or federal guidance. MFD does not identify any violations of state statutes or state guidance. Nor, for that matter, does the DAR find any actual harm to Medicaid or a patient. Of course, the DAR never acknowledges that Star was in compliance with all federal laws, regulations and guidance, as well as all state statutes and guidance. As is typical, the DAR simply elevates form-over-substance and conjures a demand for over $3,000,000.00 on a technical error with a state regulation.

Most importantly, MFD has long known that Star corrected these issues *well over four years ago*. Yet here we are, expending taxpayer money, not to protect patients or Medicaid funds, but to ensure that MFD appears effective.

III. "DEFICIENT DOCUMENTATION AND BILLING IRREGULARITIES FOR PRESUMPTIVE & DEFINITIVE DRUG TESTING"

A. MFD audit procedures violate due process.

Medicaid investigations and audits must be conducted in a manner that affords the providers with the due process of law. That bedrock principle is codified with respect to MFD in 42 C.F.R. § 455.13:

> The Medicaid agency must have … (b) Methods for investigating these cases that – (1) Do not infringe on the legal rights of persons involved; and (2) Afford due process of law ….

Demonstrating the importance of MFD's obligation to comply with that provision, the federal government regularly audits MFD for compliance with that federal law.[1] In fact, the federal government audited MFD in 2019 and found deficiencies because MFD failed to account for changes in federal law in a timely fashion. Ex. CC. (As discussed below, had MFD found those deficiencies in a provider, it would certainly result in a large monetary demand even if no harm had been visited on any party.)

One glaring violation of Star's right to due process is based on MFD's selection of an audit period. To start with, there is no public notice, guidance or disclosure as to how MFD selects its audit period. MFD does not publish any manual on its auditing process. There is no guidance on how an audit is conducted. MFD uses the RAT-STATS extrapolation, a method that is not disclosed, described or explained in any New Jersey statute or regulation. Indeed, one could comb New Jersey statutes, the New Jersey Administrative Code, MFD's website, and all other state resources and come away with no information regarding how the audit or the subsequent extrapolation will be conducted. Of course, extrapolation is particularly important given that is how MFD can find some mistakes and spin them out into a multi-million-dollar demand.

Based on the lack of accountability or standards, MFD is free to select an audit period that is (at best) arbitrary and capricious and (at worst) selected to generate a large monetary demand. Indeed, that is precisely what happened in this case. On or about April 13, 2022, MFD selected an audit period of 7/1/2017 – 3/31/2021. MFD has never explained why or how it selected that audit period. Worse, MFD has long known that, as of March 2020, Star corrected the issue upon which the DAR focuses: the signature on lab requests.

The selection of that audit period violates due process because it is contrary to the only available *published guidance* for the government's most analogous federal program: Medicare. CMS instructs that an incorrectly made payment should not be sought

> if the payment was made to an individual who was 'without fault,' or its recovery would be contrary to Medicare purposes or would be against 'equity and good conscience.'

[1] The MFD is certainly aware of its obligation to comply with this federal law because the MFD has been audited pursuant to it.

J. Health Care Compl. September-October 2018 at 8 (quoting 42 U.S.C. §§ 1395pp(a)(2) and 1395gg(c)). Further, CMS' *published* Program Integrity Manual expressly limits the use of statistical sampling … until after educational intervention has been implemented and failed to correct the error. In other words, agencies like MFD are precluded from using statistical sampling for claims that occurred before or during its educational intervention audits.

Here, however, MFD conducted no educational intervention and, far more troubling, MFD never acknowledges that Star self-corrected the potential signature issue. Not only did *MFD fail* to follow such guidance, it selected an audit period that is directly contrary to the only published and relevant guidance. MFD improperly defined its universe in a manner to ensure a large monetary demand and to penalize Star notwithstanding its self-correction.

Had MFD selected an audit period starting in March 2020, the demand in this case would be nominal. Rather, MFD looked back to 2017 and then generated a demand of over $3,000,000.00. By selecting the audit period pursuant to an unidentified method (if there is even a method to MFD's actions on this issue), MFD violated Star's right to due process because the selection process is untethered to any policy and/or the facts of this case; further, MFD deprived Star of the protection afforded by due process by ensuring that the selected audit period manufactured a headline-grabbing and unjust demand for millions of dollars.

MFD also ignores a basic legal requirement that mitigates, if not wholly negates, any error underlying MFD's demand for recoupment. As Dr. [redacted] *told* MFD, methadone clinics are required by State regulations to conduct the very testing at issue in the DAR. *Accordingly, it is clear that the testing was not only medically necessary but required as a matter of law. See, e.g.*, N.J.A.C. 10:161B-11.4, 11.6, 11.7, 11.8 & 11.9.

And, as discussed in the following Section, MFD tries to put Star out of business based on a regulation *that has no force of law*. The operative regulation, N.J.A.C. 10:61-1.6, was not enacted according to state mandates. If anything violates due process, it is a demand for $3,000,000.00 and the taking of a small business based on a regulation that lacks the force of law.

B. "Missing Signatures"

1. The lack of due process rendered MFD's evaluation of "missing signatures" fundamentally flawed.

Star incorporates the preceding discussion of MFD's due process violations into its response on this issue. The due process deficiencies are particularly stark because MFD's conclusions regarding missing signatures is the basis for essentially its entire demand for over $3,000,000.00. As the United States Supreme Court has stated in a matter involving federal benefits:

> Procedural due process imposes constraints on governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.

Mathews v. Eldridge, 424 U.S. 319, 332 (1976) (considering whether procedures in place were sufficient to satisfy due process in an administrative social security disability benefits termination).

Regarding MFD's erroneous and inadequate N.J.A.C. provisions, the New Jersey Supreme Court has provided a directly relevant conclusion that favors Star's argument regarding due process:

> Administrative rulemaking serves the interests of fairness and due process. Administrative agencies should inform the public and, through rules, 'articulate the standards and principles that govern their discretionary decision in as much detail as possible.'

Holmdel Builders Ass'n v. Holmdel, 121 N.J. 550, 578 (1990) (quoting *Crema v. DEP*, 94 N.J. 286, 301 (1983)). The Appellate Division is, not surprisingly, in accord:

> An agency's ability to select procedures it deems appropriate to accomplish its statutory mission is limited by 'the strictures of due process and of the [APA].'

Grimes v. New Jersey Dept. of Corrections, 452 N.J. Super. 396, 404 (App. Div. 2017) (citing *In re Solid Waste Util. Cus. Lists*, 106 N.J. 508, 519 (1987)) (finding that the Department of Corrections calling policy violated the APA).

And, the New Jersey Supreme Court stated:

> We have, moreover, not hesitated (as a matter of judicial policy) to impose principles of fundamental procedural fairness on administrative agencies and trial tribunals beyond constitutional demands.

In re Arndt, 67 N.J. 432, 436 (1975) (citing *Monks v. N.J. State Parole Board*, 58 N.J. 238 (1971) and *Rodriguez v. Rosenblatt et al.*, 58 N.J. 281, 294 (1971) (a 32-month delay in activating a license suspension was violative of procedural rights in an administrative procedure)). *See also Richardson v. Perales*, 402 U.S. 389 (1971) (citing *Goldberg v. Kelly*, 397 U.S. 254, 262-263 (1970)) (allowing physician reports to be used as evidence in an administrative social security disability hearing to support a disability benefits determination).

This decisional law, binding on MFD, supplements and further establishes precisely how MFD's audit of Star failed to provide protections afforded by well-settled and non-controversial legal principles.

Further, the signature requirement under N.J.A.C. 10:61-1.6 violates the New Jersey Administrative Procedure Act ("NJAPA"), because there was no Federal Standards Statement, which is required when a state regulation is more restrictive than the federal regulation. The NJAPA requires agencies to:

> include as part of the initial publication and *all subsequent publications of such rule or regulation*, a statement as to whether the rule or regulation in question contains any standards or

> requirements which exceed the standards or requirements imposed by federal law. Such statement shall include a discussion of the policy reasons and a cost-benefit analysis that supports the agency's decision to impose the standards or requirements and also supports the fact that the State standard or requirement to be imposed is achievable under current technology, notwithstanding the federal government's determination that lesser standards or requirements are appropriate.

N.J.S.A. § 52:14B-23 (emphasis added).

There is no such statement in N.J.A.C. 10:61-1.6's regulatory history. There is no requirement that an order be personally signed under federal law. *See* 42 CFR 493.1241. The failure to include such a statement is unsurprising, as discussed *supra*. The personal signature requirement appears in New Jersey Register as far back as 1975. Meanwhile, the prevailing federal regulation, CLIA, was enacted in 1988 and has been amended multiple times. Clearly, the New Jersey regulatory scheme fails to account for decades worth of changes in controlling federal regulation.[2]

2. MFD did not find that Medicaid paid for medically unnecessary tests.

In this case, MFD has concluded that there was a ***potential*** expenditure of Medicaid money based on the ***possibility*** that tests were not medically necessary because certain lab orders did not contain a hand written signature of a physician. Thus, MFD did not find any ***real*** harm as the basis for its $3,000,000.00 demand.

With only minor exceptions, MFD has no evidence that tests were not run or that they were actually medically unnecessary (other than the lack of a hand-written signature). As discussed elsewhere, MFD knows that the tests are medically necessary and required as a matter of law. *See, e.g.*, N.J.A.C. 10:161B-11.4, 11.6, 11.7, 11.8 & 11.9. MFD cannot fathom or credit the notion that the tests at issue are required by state law. As is typical with MFD, the physician who authorized the tests told MFD this during his interviews, yet MFD ignores that statement.

3. MFD's interpretation of statutes and regulations is entitled to little or no deference.

In issuing its Draft Audit Report, MFD stated that it conducted the audit "to determine whether Star billed for drug tests during the Audit Period in accordance with applicable state and federal laws, regulations, and guidance." For the reasons discussed herein, MFD's interpretation of "state and federal laws" is entitled to little deference and, accordingly, so are its conclusions regarding Star's compliance with those laws.

[2] In addition, issues regarding the signature requirement were brought to the attention of the Department of Human Services. *See* 43 N.J.R. 423(a) Cmt. 2,3. Of course, the comments were dismissed.

In *Loper Bright Enterprises v. Raimondo*, the Supreme Court overruled the *Chevron* deference doctrine. 144 S. Ct. 2244, 2273 (2024). Under *Chevron*, courts were required to defer to an agency's reasonable interpretation of an ambiguous statute that the agency administered. In overruling *Chevron*, the *Loper Bright* Court held that the Administrative Procedure Act (APA) requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, and courts may not defer to an agency's legal interpretation simply because a statute is ambiguous. *Id.*

Therefore, under *Loper Bright*, federal agencies interpreting Medicaid statutes are not entitled to deference where a provision is ambiguous. And, of course, state agencies such as MFD are likewise entitled to no deference at all. Indeed, that has long been the law, even under *Chevron*. *See In re RCN of N.Y.*, 186 N.J. 83, 92-93 (2006) (stating that "we will not afford to the BPU the deference that *Chevron* provides to federal agencies interpreting federal law").

Moreover, MFD's interpretation of New Jersey's Medicaid statutes is likewise entitled to no deference. The parallel state doctrine of deference was based on the *Chevron* doctrine, *see Matturri v. Bd. of Trs. of the Judicial Ret. Sys.*, 173 N.J. 368, 381-82 (2002), which has now been struck down. Accordingly, without its guiding principle, New Jersey's doctrine of deference for its agencies interpreting ambiguous state statutes has been gutted. This is particularly true where, as here, the state statutes are so heavily interconnected with a federal statutory regime.

In light of the foregoing and for the reasons discussed herein, MFD's interpretation of a wet signature requirement for lab orders is baseless and entitled to no deference. First, there is no federal statutory requirement that lab orders be "personally signed" in order for them to be properly paid under Medicaid. Nor is there a New Jersey Medicaid statute requiring a hand-written signature as MFD has demanded. Rather, there is only a state regulation, which MFD interprets as requiring a "wet signature" and upon which it relies in demanding over three million dollars from Star.

Nor are MFD's extrapolation techniques entitled to any deference. There are no federal or state statutes setting forth the appropriate statistical methods to be used in this context, nor are there any federal or state regulations prescribing such methods. Rather, MFD simply states that it follows GAO guidelines in conducting audits and then employs its own statistical techniques (RAT-STATS) to use a small sample to extrapolate and conclude, in this case, that Star was overpaid by millions of dollars.

Even under the pre-*Loper Bright* case law, MFD's auditing techniques are fatally flawed because, as discussed, *supra*, its selection of the "audit period" is arbitrary and capricious. Indeed, as discussed in our January 19, 2024 submission to MFD, the audit period selected by MFD overrepresented claims made before Star implemented the software interface, which streamlined the requisition process and resulted in claims deemed compliant by MFD.

C. "Presumptive & Definitive Testing Not Ordered"

In addition to the preceding arguments, which apply with full force to many of the claims related to this alleged deficiency, Star submits that any instance in which it performed and billed for certain drug testing that was not requested in the test requisition was the product of human

error. Thus, just as the DHS made sufficient errors to fail a federal audit to the tune of $94,000,000.00, Star had human error.

D. "Requested Testing Not Performed"

On this issue, MFD seeks no monetary recovery. Further, with respect to patient harm, MFD does not identify anything more than a *possibility*. MFD does not even come close to claiming – let alone supporting – any actual patient harm. Indeed, the prescribing physician never contacted Star or wrote a follow-up lab order to correct this issue on the patient's behalf.

IV. "DIRECT REVIEW OF OUTLIER CLAIMS FOR PRESUMPTIVE & DEFINITIVE DRUG TESTING"

For all the reasons discussed in the preceding Sections, MFD should seek no payment from Star in connection with the outlier claims.

V. IN THIS AREA OF THE LAW, FEDERALLY RECOGNIZED PRINCIPLES OF EQUITY AND GOOD CONSCIENCE PRECLUDE MFD'S DEMAND FOR OVER $3,000,000.00.

As noted, *supra*, federal statutes governing Medicare recognize principles of "equity and good conscience." Those concepts should be at the forefront in this case. MFD seeks over $3,000,000.00 because of statements made by a physician who was not Star's employee. As Star told MFD, that physician assured Star that he was reviewing every lab order and that his signature was represented by his initials on the requisition form. *See* Ex. AA. Indeed, Star had a signed standing order from that physician stating as much. MFD harassed and interviewed that physician with two interviews until he said what they wanted to hear: that what he told Star was not entirely accurate and that he was not reviewing every lab order. Significantly, that physician did not say that Star had any reason to know of his inaccurate statements to them. Nor did he say that the lab tests were not medically necessary. To the contrary, he told MFD that they were required by New Jersey regulations.

MFD never grapples with the fact that the physician was not employed by Star. What is worse, MFD never challenges Star's assertion that the physician made those statements and that Star's reasonably relied on them.

As noted herein, MFD does not, and could never, live up to the technical perfection it demands of small businesses that provide a critical function for the health of New Jersey residents. For example, the *N.J.A.C.* Title and Chapters that govern MFD often refer to federal regulations that do not exist. One can only imagine the hue and cry that would issue from MFD if the federal government pulled funding or support based on those errors. Suddenly, form over substance errors would not matter if MFD was on the losing end.

As MFD knows, Star performed drug testing for needy patients of a methadone clinic in Newark during what can only be described as an overwhelming opioid crisis in our State. It should be commended, not penalized for doing that work. Further, while MFD was shut down and/or working from home during the pandemic, Star employees were on-site and performed

tens of thousands of COVID tests to help stop the spread of the virus and keep people informed during an unprecedented and terrifying health care crisis for the citizens of New Jersey.

VI. CONCLUSION

For all these reasons, the Final Audit Report should demand no repayment from Star. And, of course, this submission and its exhibits must be appended to the Final Audit Report and all public filings related to this audit. Star reserves all rights.

Sincerely,

Michael Baldassare

cc: Lani M. Dornfeld, Esq.
Edward J. Yun, Esq.

Exhibits attached to the provider's response have been omitted to maintain confidentiality.

Star's Comments and OSC's Responses

In response to the Draft Audit Report (DAR) issued by the Office of the State Comptroller, Medicaid Fraud Division (OSC or MFD), Star Laboratory Corporation (Star), through counsel, submitted a response that takes issue with OSC's audit findings. In general, Star states that its documentation adequately supported its claims and it further asserts that OSC cited inapplicable regulations and regulations that contained improper citations.

As part of the DAR, OSC instructed Star to submit a Corrective Action Plan to address OSC's audit findings, but Star failed to do so.

Set forth below are Star's specific objections to the audit findings and OSC's responses to each. After reviewing Star's submission, OSC determined that there was no basis to revise any of its original audit findings. Star's full response is attached to the Final Audit Report as Appendix B.

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

a. Star's Objection: MFD audit procedures violate due process

Excerpt of Star's Comments

Medicaid investigations and audits must be conducted in a manner that affords the providers with the due process of law. That bedrock principle is codified with respect to MFD in 42 C.F.R. § 455.13:

> The Medicaid agency must have … (b) Methods for investigating these cases that – (1) Do not infringe on the legal rights of persons involved; and (2) Afford due process of law ….

Demonstrating the importance of MFD's obligation to comply with that provision, the federal government regularly audits MFD for compliance with that federal law.[1] In fact, the federal government audited MFD in 2019 and found deficiencies because MFD failed to account for changes in federal law in a timely fashion. Ex. CC. (As discussed below, had MFD found those deficiencies in a provider, it would certainly result in a large monetary demand even if no harm had been visited on any party.)

One glaring violation of Star's right to due process is based on MFD's selection of an audit period. To start with, there is no public notice, guidance or disclosure as to how MFD selects its audit period. MFD does not publish any manual on its auditing process. There is no guidance on how an audit is conducted. MFD uses the RAT-STATS extrapolation, a method that is not disclosed, described or explained in any New Jersey statute or regulation. Indeed, one could comb New Jersey statutes, the New Jersey Administrative Code, MFD's website, and all other state resources and come away with no information regarding how the audit or the subsequent

[1] The MFD is certainly aware of its obligation to comply with this federal law because the MFD has been audited pursuant to it.

extrapolation will be conducted. Of course, extrapolation is particularly important given that is how MFD can find some mistakes and spin them out into a multi-million-dollar demand.

Based on the lack of accountability or standards, MFD is free to select an audit period that is (at best) arbitrary and capricious and (at worst) selected to generate a large monetary demand. Indeed, that is precisely what happened in this case. On or about April 13, 2022, MFD selected an audit period of 7/1/2017 – 3/31/2021. MFD has never explained why or how it selected that audit period. Worse, MFD has long known that, as of March 2020, Star corrected the issue upon which the DAR focuses: the signature on lab requests.

The selection of that audit period violates due process because it is contrary to the only available *published guidance* for the government's most analogous federal program: Medicare. CMS instructs that an incorrectly made payment should not be sought

> if the payment was made to an individual who was 'without fault,' or its recovery would be contrary to Medicare purposes or would be against 'equity and good conscience.'

J. Health Care Compl. September-October 2018 at 8 (quoting 42 U.S.C. §§ 1395pp(a)(2) and 1395gg(c)). Further, CMS' *published* Program Integrity Manual expressly limits the use of statistical sampling … until <u>after educational intervention has been implemented and failed to correct the error</u>. In other words, agencies like MFD are precluded from using statistical sampling for claims that occurred before or during its educational intervention audits.

Here, however, MFD conducted no educational intervention and, far more troubling, MFD never acknowledges that Star self-corrected the potential signature issue. Not only did <u>*MFD fail*</u> to follow such guidance, it selected an audit period that is directly contrary to the only published and relevant guidance. MFD improperly defined its universe in a manner to ensure a large monetary demand and to penalize Star notwithstanding its self-correction.

Had MFD selected an audit period starting in March 2020, the demand in this case would be nominal. Rather, MFD looked back to 2017 and then generated a demand of over $3,000,000.00. By selecting the audit period pursuant to an unidentified method (if there is even a method to MFD's actions on this issue), MFD violated Star's right to due process because the selection process is untethered to any policy and/or the facts of this case; further, MFD deprived Star of the protection afforded by due process by ensuring that the selected audit period manufactured a headline-grabbing and unjust demand for millions of dollars.

MFD also ignores a basic legal requirement that mitigates, if not wholly negates, any error underlying MFD's demand for recoupment. As Dr. [redacted] <u>*told*</u> MFD, methadone clinics are required by State regulations to conduct the very testing at issue in the DAR. <u>*Accordingly, it is clear that the testing was not only medically necessary but required as a matter of law.*</u> *See, e.g.*, N.J.A.C. 10:161B-11.4, 11.6, 11.7, 11.8 & 11.9.

And, as discussed in the following Section, MFD tries to put Star out of business based on a regulation <u>*that has no force of law*</u>. The operative regulation, N.J.A.C. 10:61-1.6, was not enacted according to state mandates. If anything violates due process, it is a demand for $3,000,000.00 and the taking of a small business based on a regulation that lacks the force of

law.

OSC's Response

In its response, Star alleges that the OSC violated its due process rights by arbitrarily selecting the audit period without offering public notice, guidance, or transparency regarding the criteria used. Star further asserts that OSC does not publish a manual or provide clear guidelines detailing its audit process. Additionally, it claims that the OSC knowingly selected an audit period that included a resolved issue—specifically, the lack of signatures on drug test requisition forms, which Star states it had already corrected. Lastly, Star contends that the testing in question was legally mandated, thereby mitigating any alleged errors.

As a Medicaid provider, Star is required to maintain documentation supporting the services it bills to the program for at least five years from the date the service was rendered. The assertion that OSC had "long known" about changes to the way Star processes drug test requisitions and OSC knowingly selected an audit period is unfounded. OSC neither knew, nor could it have known, of any changes to Star's business processes prior to conducting a review of Star's operations. Furthermore, Star's acknowledgment that it amended its processes to address the lack of signatures confirms that the "issue" existed during the audit period. Further, Star's assertion that it corrected the signature issue in March 2020 does not negate its responsibility to comply with documentation requirements for services billed during the audit period. Medicaid regulations require providers to maintain compliance at all times, and a provider's subsequent corrections do not absolve the provider from findings of non-compliance for earlier violations.

While Star cites state regulations applicable to substance use disorder (SUD) treatment facilities, it disregards its own legal requirements as a testing laboratory and Medicaid provider to only process orders that are personally signed by the ordering physician or licensed practitioner. Legal mandates applicable to another provider type for testing do not negate Medicaid's documentation and billing requirements, which are critical to ensuring the integrity of the program.

Star's arguments fail to account for the text and purpose of N.J.A.C. 10:61-1.6. That regulation is part of a comprehensive regulatory approach that was constructed to safeguard the integrity of Medicaid and prevent fraud, waste, and abuse in an industry with a history of corruption in New Jersey.[2] N.J.A.C. 10:61-1.6(a) protects Medicaid by establishing clear requirements for the authorization of clinical laboratory services to ensure that tests are medically necessary and properly documented. This rule guards against fraudulent billing practices, unnecessary testing, and financial arrangements that could improperly influence when and which tests are ordered. By requiring a physician's signature, the regulation ensures that laboratory services are only provided when deemed medically necessary by a qualified professional. Requiring this explicit professional approval prevents referring providers from ordering medically unnecessary tests and drug testing laboratories from processing such unauthorized requests. Without this or a similarly effective safeguard, unscrupulous providers could generate excessive or unnecessary test orders to inflate billing, leading to wasteful Medicaid expenditures. Requiring the signed order to be maintained

[2] *Medicare and Medicaid Frauds: Hearing Before the Subcommittee on Long-Term Care of the Special Committee on Aging*, United States Senate, 94th Congress (February 16, 1976), https://www.aging.senate.gov/imo/media/doc/publications/2161976.pdf.

on file and available for review provides the Medicaid program with a crucial ability to verify the legitimacy of claims and identify potential abuses.

The signature requirement also ensures providers comply with other program integrity requirements imposed by N.J.A.C. 10:61. It functions as a direct check on financial arrangements that would violate anti-kickback laws prohibited by the rules. The regulation's requirement that all test orders be explicitly documented and retained by the billing laboratory creates a clear audit trail, reinforcing accountability at every stage of service delivery. Physicians and licensed practitioners bear direct responsibility for ordering tests, reducing the risk of abuse by ensuring that clinical decisions remain within the purview of medical professionals rather than financially motivated entities.

The four approaches to conveying testing orders (signature, chart documentation, electronic with safeguards to prevent and detect fraud and abuse, and verbal orders with written or electronic confirmation) permitted by N.J.A.C. 10:61-1.6 provide flexibility to providers while preventing fraud, waste, and abuse. All of the permitted approaches to authenticating testing orders ensure that physicians or other licensed practitioners make the decision to order tests and that the order is explicitly approved by them.

The importance of these policies and the overarching goals of N.J.A.C. 10:61 are clear from the rulemaking proceedings that led to the adoption of the N.J.A.C. 10:61 rules, which are discussed fully in the audit report. The Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) notes in its responses to comments that it was focused on preventing abuses by clinical laboratories and other providers. In response to a request to relax the physician signature requirement, DMAHS in 1996 stated that the requirement for "a definitive order personally signed by the physician requesting services" ensure the test is medically necessary and "is pivotal to curtailing fraud and abuse." 28 N.J.R. 1054(a) (Feb. 5, 1996). In 2011, DMAHS again addressed the issue. In response to a request to "reconsider the requirement for each paper order to be personally signed by the ordering practitioner," which was said to "'significantly detract[ ]' from the practitioner's time caring for patients," DMAHS responded that "[a]ll services reimbursed by the New Jersey Medicaid/NJ FamilyCare program must be certified as medically necessary" and stated that "the authorization of orders for clinical laboratory services by a licensed practitioner is an integral part of ensuring that only medically necessary clinical laboratory services are provided to the beneficiaries and reimbursed by the program". 43 N.J.R. 423(a) (Feb. 22, 2011). DMAHS also expressed concern about unauthorized tests being ordered and stated that "[e]nsuring that the licensed practitioner requesting the laboratory services is the individual responsible for attesting to its authenticity ensures that the care and treatment of the beneficiary remains the ultimate responsibility of the practitioner familiar with the medical needs of the beneficiary." Id. at 423-24.

Star's reliance on an approach to receiving tests by using labels instead of one of the approaches permitted by N.J.A.C. 10:61-1.6 undermined New Jersey's interest in protecting the Medicaid program and public funds from fraud, waste, and abuse. These rules were adopted because of a documented history of fraud, waste, and abuse by clinical laboratories in New Jersey. By becoming a Medicaid provider, Star agreed to comply with these rules, but it failed to do so. New Jersey is entitled to expect that a provider that submitted 113,742 claims totaling $7,538,640 during the audit period would have taken the simple steps required by N.J.A.C. 10:61-1.6 to safeguard public funds as a condition of being a Medicaid provider and receiving public funds.

Instead, Star violated applicable rules and thereby exposed the program to a risk of fraud, waste, and abuse.

OSC's selection of the audit period was neither arbitrary nor capricious. OSC selected a standard look back period to ensure a comprehensive review of claims within Medicaid's five-year documentation retention requirement. OSC issued the audit notice to Star on April 14, 2022, with an audit period of July 1, 2017 through March 31, 2021, which is well within the five-year look back period. Further, with regard to the audit period, sample selection, and audit methodology, OSC met with Star at an entrance conference to outline each of these processes, and again provided Star an opportunity to discuss the audit and the audit findings at the Exit Conference following the issuance of the Summary of Findings.

With respect to the extrapolation, OSC provided Star the random sample and extrapolation (RS&E) data to be able to see the extrapolation methodology and recreate it step-by-step, which it appears to have chosen not to do. Extrapolation is a well-supported means to calculate overpayments, and Star did not provide any reason for OSC not to extrapolate its findings in this audit.

OSC finds that Star received due process through the clear regulations and through the process that OSC has conducted to evaluate whether Star complied with the applicable law. Star was on notice of the law, agreed to comply with the law, and has had the opportunity to demonstrate that it did so and to challenge OSC's audit findings. It has provided no evidence of compliance with N.J.A.C. 10:61-1.6 involving the claims for which OSC seeks reimbursement.

Lastly, Star makes additional assertions regarding federal audits or other unrelated matters, which have no relevance to the scope or findings of this audit. These unrelated arguments fail to address the core issues of non-compliance identified during the audit. As such, Star has provided no basis for OSC to amend its extrapolation and audit findings.

b. Star's Objection: Missing Signatures

Excerpt of Star's Comments

1. The lack of due process rendered MFD's evaluation of "missing signatures" fundamentally flawed.

Star incorporates the preceding discussion of MFD's due process violations into its response on this issue. The due process deficiencies are particularly stark because MFD's conclusions regarding missing signatures is the basis for essentially its entire demand for over $3,000,000.00. As the United States Supreme Court has stated in a matter involving federal benefits:

> Procedural due process imposes constraints on governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment.

Mathews v. Eldridge, 424 U.S. 319, 332 (1976) (considering whether procedures in place were sufficient to satisfy due process in an administrative social security disability benefits termination).

Regarding MFD's erroneous and inadequate N.J.A.C. provisions, the New Jersey Supreme Court has provided a directly relevant conclusion that favors Star's argument regarding due process:

> Administrative rulemaking serves the interests of fairness and due process. Administrative agencies should inform the public and, through rules, 'articulate the standards and principles that govern their discretionary decision in as much detail as possible.'

Holmdel Builders Ass'n v. Holmdel, 121 N.J. 550, 578 (1990) (quoting *Crema v. DEP*, 94 N.J. 286, 301 (1983)). The Appellate Division is, not surprisingly, in accord:

> An agency's ability to select procedures it deems appropriate to accomplish its statutory mission is limited by 'the strictures of due process and of the [APA].'

Grimes v. New Jersey Dept. of Corrections, 452 N.J. Super. 396, 404 (App. Div. 2017) (citing *In re Solid Waste Util. Cus. Lists*, 106 N.J. 508, 519 (1987)) (finding that the Department of Corrections calling policy violated the APA).

And, the New Jersey Supreme Court stated:

> We have, moreover, not hesitated (as a matter of judicial policy) to impose principles of fundamental procedural fairness on administrative agencies and trial tribunals beyond constitutional demands.

In re Arndt, 67 N.J. 432, 436 (1975) (citing *Monks v. N.J. State Parole Board*, 58 N.J. 238 (1971) and *Rodriguez v. Rosenblatt et al.*, 58 N.J. 281, 294 (1971) (a 32-month delay in activating a license suspension was violative of procedural rights in an administrative procedure)). *See also Richardson v. Perales*, 402 U.S. 389 (1971) (citing *Goldberg v. Kelly*, 397 U.S. 254, 262-263 (1970)) (allowing physician reports to be used as evidence in an administrative social security disability hearing to support a disability benefits determination).

This decisional law, binding on MFD, supplements and further establishes precisely how MFD's audit of Star failed to provide protections afforded by well-settled and non-controversial legal principles.

Further, the signature requirement under N.J.A.C. 10:61-1.6 violates the New Jersey Administrative Procedure Act ("NJAPA"), because there was no Federal Standards Statement, which is required when a state regulation is more restrictive than the federal regulation. The NJAPA requires agencies to:

> include as part of the initial publication and *all subsequent publications of such rule or regulation*, a statement as to whether the rule or regulation in question contains any standards or requirements which exceed the standards or requirements imposed by federal law. Such statement shall include a discussion of the policy reasons and a cost-benefit analysis that supports the

> agency's decision to impose the standards or requirements and also supports the fact that the State standard or requirement to be imposed is achievable under current technology, notwithstanding the federal government's determination that lesser standards or requirements are appropriate.

N.J.S.A. § 52:14B-23 (emphasis added).

There is no such statement in N.J.A.C. 10:61-1.6's regulatory history. There is no requirement that an order be personally signed under federal law. *See* 42 CFR 493.1241. The failure to include such a statement is unsurprising, as discussed *supra*. The personal signature requirement appears in New Jersey Register as far back as 1975. Meanwhile, the prevailing federal regulation, CLIA, was enacted in 1988 and has been amended multiple times. Clearly, the New Jersey regulatory scheme fails to account for decades worth of changes in controlling federal regulation.[3]

2. MFD did not find that Medicaid paid for medically unnecessary tests.

In this case, MFD has concluded that there was a potential expenditure of Medicaid money based on the possibility that tests were not medically necessary because certain lab orders did not contain a hand written signature of a physician. Thus, MFD did not find any real harm as the basis for its $3,000,000.00 demand.

With only minor exceptions, MFD has no evidence that tests were not run or that they were actually medically unnecessary (other than the lack of a hand-written signature). As discussed elsewhere, MFD knows that the tests are medically necessary and required as a matter of law. *See, e.g.*, N.J.A.C. 10:161B-11.4, 11.6, 11.7, 11.8 & 11.9. MFD cannot fathom or credit the notion that the tests at issue are required by state law. As is typical with MFD, the physician who authorized the tests told MFD this during his interviews, yet MFD ignores that statement.

3. MFD's interpretation of statutes and regulations is entitled to little or no deference.

In issuing its Draft Audit Report, MFD stated that it conducted the audit "to determine whether Star billed for drug tests during the Audit Period in accordance with applicable state and federal laws, regulations, and guidance." For the reasons discussed herein, MFD's interpretation of "state and federal laws" is entitled to little deference and, accordingly, so are its conclusions regarding Star's compliance with those laws.

In *Loper Bright Enterprises v. Raimondo*, the Supreme Court overruled the *Chevron* deference doctrine. 144 S. Ct. 2244, 2273 (2024). Under *Chevron*, courts were required to defer to an agency's reasonable interpretation of an ambiguous statute that the agency administered. In overruling *Chevron*, the *Loper Bright* Court held that the Administrative Procedure Act (APA) requires courts to exercise their independent judgment in deciding whether an agency has acted within its statutory authority, and courts may not defer to an agency's legal interpretation simply because a statute is ambiguous. *Id.*

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3 [Footnote 2 in Appendix B] In addition, issues regarding the signature requirement were brought to the attention of the Department of Human Services. *See* 43 N.J.R. 423(a) Cmt. 2,3. Of course, the comments were dismissed.

Therefore, under *Loper Bright*, federal agencies interpreting Medicaid statutes are not entitled to deference where a provision is ambiguous. And, of course, state agencies such as MFD are likewise entitled to no deference at all. Indeed, that has long been the law, even under *Chevron*. *See In re RCN of N.Y.*, 186 N.J. 83, 92-93 (2006) (stating that "we will not afford to the BPU the deference that *Chevron* provides to federal agencies interpreting federal law").

Moreover, MFD's interpretation of New Jersey's Medicaid statutes is likewise entitled to no deference. The parallel state doctrine of deference was based on the *Chevron* doctrine, *see Matturri v. Bd. of Trs. of the Judicial Ret. Sys.*, 173 N.J. 368, 381-82 (2002), which has now been struck down. Accordingly, without its guiding principle, New Jersey's doctrine of deference for its agencies interpreting ambiguous state statutes has been gutted. This is particularly true where, as here, the state statutes are so heavily interconnected with a federal statutory regime.

In light of the foregoing and for the reasons discussed herein, MFD's interpretation of a wet signature requirement for lab orders is baseless and entitled to no deference. First, there is no federal statutory requirement that lab orders be "personally signed" in order for them to be properly paid under Medicaid. Nor is there a New Jersey Medicaid statute requiring a hand-written signature as MFD has demanded. Rather, there is only a state regulation, which MFD interprets as requiring a "wet signature" and upon which it relies in demanding over three million dollars from Star.

Nor are MFD's extrapolation techniques entitled to any deference. There are no federal or state statutes setting forth the appropriate statistical methods to be used in this context, nor are there any federal or state regulations prescribing such methods. Rather, MFD simply states that it follows GAO guidelines in conducting audits and then employs its own statistical techniques (RAT-STATS) to use a small sample to extrapolate and conclude, in this case, that Star was overpaid by millions of dollars.

Even under the pre-*Loper Bright* case law, MFD's auditing techniques are fatally flawed because, as discussed, *supra*, its selection of the "audit period" is arbitrary and capricious. Indeed, as discussed in our January 19, 2024 submission to MFD, the audit period selected by MFD overrepresented claims made before Star implemented the software interface, which streamlined the requisition process and resulted in claims deemed compliant by MFD.

OSC's Response

OSC found that for 79 of the 148 sample episodes, Star failed to ensure that the orders for drug testing services it billed for were signed by the ordering physician or licensed practitioner. OSC, through the sworn interview of the ordering physician, confirmed that the ordering physician had not reviewed the drug test orders prior to those orders having been submitted to Star. Star points to SUD treatment regulations, N.J.A.C. 10:161B, as a basis for claiming that the tests were medically necessary and Star was required to perform these tests as a matter of law. Those regulations are not relevant to this audit because they pertain to SUD treatment facilities, not independent clinical laboratories like Star. Moreover, in pointing to those regulations, Star fails to recognize that these same SUD regulations are predicated on SUD treatment facilities acting under a medical director who oversees the facility's medical services and all physicians employed therein. In short, the SUD regulatory requirements, although not applicable here, do set forth multiple levels of oversight designed to ensure that treatment is provided in a medically

appropriate manner. With respect to the regulations relevant to this audit, a test requisition must contain a signature from the referring physician because that provides assurance that the physician reviewed the order and determined that it was medically necessary. Star's effort to point to irrelevant regulations does not change the fact that the relevant regulations require signatures from ordering physicians or licensed practitioners and such signatures were lacking here.

Star suggests that N.J.A.C. 10:61-1.6(a) is preempted by federal law, but that is not the case. Medicaid is a joint state and federal program. N.J.A.C. 10:61-1.6(a) is a longstanding rule that was adopted and has been maintained in accordance with federal law, which permits states to adopt standards to protect public funds and requires states to guard against fraud, waste, and abuse by providers.

Regarding Star's claim that OSC did not find that Medicaid paid for medically unnecessary tests, OSC notes that N.J.A.C. 10:61-1.6 places the burden on Star to show through appropriate documentation that a physician or other licensed practitioner determined tests were medically necessary. Star does not even attempt to meet that standard, but instead it concedes that it agreed with this physician to a system that, on its face, violates the requirements of N.J.A.C. 10:61-1.6. In response to OSC's Summary of Findings, Star's counsel advised that "[the physician] entered into agreements with Star Lab so that Star Lab understood and could rely on the fact that the phrase 'Requested by [redacted]' on [the physician's] printed label 'represents my digital signature' and 'reaffirms my intent for medical testing and supplements as my signature.'" This was an agreement to violate N.J.A.C. 10:61-1.6. Star's approach does not satisfy the requirements of N.J.A.C. 10:61-1.6(a) because it does not include "an explicit order personally signed by the physician or other licensed practitioner requesting the services," as that rule requires. Star's approach likewise does not satisfy any of the other permitted ways to evidence physician approval of a test requisition that meet the safeguards to ensure medical necessity. A label that can be affixed by any person is not a substitute for a system that assures a physician or other licensed professional has evaluated medical necessity and determined that the expenditure of scarce public funds is appropriate.

In short, Star urges OSC to accept testing orders that have labels on them as an acceptable approach to authentication under N.J.A.C. 10:61-1.6. OSC declines to do so because a label that can be affixed by any person is not a substitute for a system that assures a physician or other licensed professional has evaluated medical necessity and determined that the expenditure of scarce public funds is appropriate.

Regarding Star's argument that OSC denied it due process, Star affirmed its understanding of and willingness to adhere to Medicaid requirements when it enrolled in the Medicaid program and signed the enrollment application, which contained a statement that it would comply with all state and federal laws, policies, rules, and regulations, including those cited within the audit report. Star's failure to comply with these requirements in these instances constitutes a violation of its obligations under the program.

Lastly, while Star presents other arguments regarding unrelated cases and situations, such assertions are not relevant to the findings of this audit. The findings in this audit stand based on the uncontested facts and relevant regulations cited in the report. As such, Star has provided no basis for OSC to modify its audit findings.

c. Star's Objection: Presumptive and Definitive Testing Not Ordered

Excerpt of Star's Comments

In addition to the preceding arguments, which apply with full force to many of the claims related to this alleged deficiency, Star submits that any instance in which it performed and billed for certain drug testing that was not requested in the test requisition was the product of human error. Thus, just as the DHS made sufficient errors to fail a federal audit to the tune of $94,000,000.00, Star had human error.

OSC's Response

OSC found that in 5 of the 148 sample episodes, Star performed and billed for presumptive or definitive drug testing that was not requested in the corresponding test requisition or billed for a greater level of service from what was ordered. Star does not dispute that it billed these claims for a higher level of testing than what was requested and provides no evidence to justify reversing this finding. While Star attributes these discrepancies to human error, those errors resulted in improper payments of Medicaid funds. Medicaid regulations require providers to bill accurately and only for services properly documented and authorized. Regardless of intent, the errors led to improper Medicaid payments that Star was not entitled to receive and must repay to the Medicaid program.

d. Star's Objection: Requested Testing Not Performed

Excerpt of Star's Comments

On this issue, MFD seeks no monetary recovery. Further, with respect to patient harm, MFD does not identify anything more than a *possibility*. MFD does not even come close to claiming – let alone supporting – any actual patient harm. Indeed, the prescribing physician never contacted Star or wrote a follow-up lab order to correct this issue on the patient's behalf.

OSC's Response

OSC found that for 51 of the 148 sample episodes, Star failed to perform at least one specific test included on the test requisition. Star cites the referring physician's lack of due diligence in addition to somehow justify Star's failure to perform requested tests. It is the laboratory's responsibility to ensure that it performs properly requested tests. Star does not dispute that it failed to do that in these instances. As such, Star has not provided any basis for OSC to modify this finding.

2. Star's Objection: Direct Review of Outlier Claims for Presumptive and Definitive Drug Testing

Excerpt of Star's Comments

For all the reasons discussed in the preceding Sections, MFD should seek no payment from Star in connection with the outlier claims.

OSC's Response

During the audit period, but not within OSC's sample universe of episodes, OSC identified seven instances when Star billed and was paid for presumptive and definitive testing when the test requisitions lacked a signature from the ordering physician or licensed practitioner. For one of these seven instances, Star also billed for a definitive test even though the test results did not document that Star had performed a definitive test. In addition, separate from these seven instances, OSC also identified one instance when Star improperly billed for two definitive testing procedure codes on the same date of service for the same beneficiary, and, in this instance, the test requisition also lacked a signature from the ordering physician or licensed practitioner. As discussed in OSC's responses to these findings, Star has not provided any support to warrant adjusting the findings for these outlier claims.

3. Star's Objection: Principles of Equity and Good Conscience

Excerpt of Star's Comments

As noted, *supra*, federal statutes governing Medicare recognize principles of "equity and good conscience." Those concepts should be at the forefront in this case. MFD seeks over $3,000,000.00 because of statements made by a physician who was not Star's employee. As Star told MFD, that physician assured Star that he was reviewing every lab order and that his signature was represented by his initials on the requisition form. *See* Ex. AA. Indeed, Star had a signed standing order from that physician stating as much. MFD harassed and interviewed that physician with two interviews until he said what they wanted to hear: that what he told Star was not entirely accurate and that he was not reviewing every lab order. Significantly, that physician did not say that Star had any reason to know of his inaccurate statements to them. Nor did he say that the lab tests were not medically necessary. To the contrary, he told MFD that they were required by New Jersey regulations.

MFD never grapples with the fact that the physician was not employed by Star. What is worse, MFD never challenges Star's assertion that the physician made those statements and that Star's reasonably relied on them.

As noted herein, MFD does not, and could never, live up to the technical perfection it demands of small businesses that provide a critical function for the health of New Jersey residents. For example, the *N.J.A.C.* Title and Chapters that govern MFD often refer to federal regulations that do not exist. One can only imagine the hue and cry that would issue from MFD if the federal government pulled funding or support based on those errors. Suddenly, form over substance errors would not matter if MFD was on the losing end.

As MFD knows, Star performed drug testing for needy patients of a methadone clinic in Newark during what can only be described as an overwhelming opioid crisis in our State. It should be commended, not penalized for doing that work. Further, while MFD was shut down and/or working from home during the pandemic, Star employees were on-site and performed tens of thousands of COVID tests to help stop the spread of the virus and keep people informed during an unprecedented and terrifying health care crisis for the citizens of New Jersey.

OSC's Response

Star's use of the standing order forms was not in compliance with N.J.A.C. 10:61-1.6, as the forms were not patient specific, but rather constituted non-individualized blanket requests for the entire referring facility. Furthermore, Star has failed to acknowledge its responsibility to maintain requisitions that are personally signed by the ordering physician or licensed practitioner as required under N.J.A.C. 10:61-1.6(a). OSC's sworn interview with the ordering physician confirmed that that he had not reviewed the orders and he did not affix the printed label on the test requisitions. Moreover, those labels do not constitute a signature or other acceptable form of approval. As noted above, Star has acknowledged that it entered into an agreement that on its face violates N.J.A.C. 10:61-1.6 when it agreed to use labels and not to require a personal signature of "a physician or other licensed practitioner requesting the services." Accordingly, Star has provided no basis for OSC to modify its audit findings.