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.