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.
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> 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."
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> 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.