



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.

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.

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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:



Star Laboratory Corporation (via email)

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