BUTTACI LEARDI & WERNER
ATTORNEYS AT LAW

BUTTACI LEARDI & WERNER LLC
212 Carnegie Center, Suite 202
Princeton, NJ 08540
609-799-5150
609-799-5180 FAX
www.buttacilaw.com

JOHN W. LEARDI, ESQ.
MEMBER, NJ, NY, & MI BARS
DIRECT EXTENSION: 115
E-MAIL: JWLEARDI@BUTTACILAW.COM

March 10, 2021

VIA ELECTRONIC MAIL ONLY
Michael Morgese, Audit Supervisor
Office of the State Comptroller
Medicaid Fraud Division
20 West State Street, 4th Floor
P.O. Box. 025
Trenton, NJ 08625-0025
[redacted]

Re: Truetox Laboratories, LLC
MFD File No. 2016-00318

Dear Mr. Morgese:

As you know, this firm is legal counsel to Truetox Laboratories, LLC ("Truetox"). We are in receipt of the Draft Audit Report ("DAR") prepared by the Medicaid Fraud Division ("MFD") dated February 24, 2021, which purported to identify an overpayment of $24,089,938.00 relative payments previously made to Truetox based on claims it submitted to the New Jersey Medicaid and FamilyCare programs ("NJ Medicaid") between January 1, 2015 to June 30, 2018 (the "Overpayment"). Please accept this letter as our client's formal response thereto.

I. Preliminary Statement.

We are disappointed, but frankly not surprised, that MFD makes no attempt to address the numerous concerns we detailed: (i) in my letter to you dated April 6, 2020, in response to MFD's Summary of Findings ("SOF") (the "SOF Rebuttal"); (ii) during the Exit Conference conducted on April 13, 2020; and (iii) in my letter to [redacted] dated May 6, 2020, sent as a follow-up to our discussion during the Exit Conference (the "EC Rebuttal"). It is rather astounding that MFD's response to 20 pages of legal objections to its findings and 330 pages of additional documents to rebut its factual findings was merely this:

> MFD considered all of Truetox's arguments, including its supplemental documentation. MFD determined that Truetox's explanations and supplemental documentation did not provide any supportable justification to modify MFD's

preliminary audit findings. Accordingly, the findings in this DAR conform to the findings contained in the SOF.

DAR at 12-13. After 11 months, this is the best MFD do; either that, or you and your "cracker jack" team have decided to pervert the audit process by "saving" your response to our various arguments for the Final Audit Report, knowing full well MFD's responsive arguments could then be published without a corresponding response from Truetox. Either way, the conduct of this audit smacks of bad faith: you and your team have no interest in a true "audit" of Truetox's claims to NJ Medicaid. Instead, you are trying to shake Truetox down for as much as you can; perhaps hoping its staff will remember you like the NY Mets apparently do.

II. MFD's "Audit" of Truetox.

MFD's audit of Truetox began in October 2018. MFD initiated the audit to "determine if [Truetox's] claims for services are billed in accordance with the American Medical Association (AMA) guidelines, state law, and federal regulations." The purpose of the audit was initially described by MFD as "to ensure proper documentation exists to substantiate the claims." The scope of the audit, nevertheless, increased significantly.

MFD then went "on-site" to Truetox and collected documentation relating to 103 claims submitted to Medicaid for review. Curiously, however, only 82 claims were part of MFD's ultimate sample. The MFD also never presented its "audit plan" or whether and to what extent it would review Truetox's contracts or relationships with referring providers and facilities. Nevertheless, Truetox complied with all MFD's requests, including after our engagement by Truetox in December 2018. Indeed, there were several subpoenas needlessly issued during the audit that were unnecessary; Truetox would have (and, in fact, did) comply with less formal requests. There is not a single request of MFD that was denied.

On March 10, 2020, MFD issued its SOF. The SOF was allegedly based on the review of a "statistically valid random sample comprised of 82 episodes with 198 unique paid claims totaling $12,810 in payments selected from a population of 140,772 episodes with 302,326 paid claims totaling $24,382,684." So, based on a review of less than one-tenth of one-percent of the claims Truetox submitted to NJ Medicaid, MFD seeks to recover approximately 99% of the corresponding payments NJ Medicaid made to Truetox. The Overpayment is based upon three distinct issues: (i) Truetox's contractual discounts to uninsured patients and/or referring facilities who agree to pay for testing provided to uninsured patients; (ii) documentation deficiencies identified by MFD with respect to the documentation maintained by Truetox regarding testing orders; and (iii) Truetox's billing NJ Medicaid for specimen validity tests on samples utilized for drug testing. MFD also identified "other systemic or regulatory issues" not associated with a repayment demand, including: (i) "use of provider-specific blanket requests;" and (ii) "laboratory rebates."

In response to the SOF, I wrote to you on April 6, 2020. In our SOF Rebuttal, we noted that the SOF was both legally and factually baseless. First, we demanded information sufficient to determine whether the probability sample MFD utilized was properly executed (i.e., define the

universe, the frame, the sampling units, the randomization, how the variables of interest were measured, and any formulas used for estimation). *See, e.g., Maxmed Healthcare, Inc. v. Price,* 2017 U.S. App. LEXIS 11115, *2 (5th Cir. 2017) (stating that following an overpayment determination based on extrapolation, the burden shifts to the provider, who could attack the statistical validity of the sample, or challenge the correctness of the determination in specific cases identified by the sample) (internal citation omitted). Second, we noted that MFD's invocation of N.J.A.C. 10:61-1.7 was ludicrous because that regulation does not prohibit Truetox from offering and accepting contractual discounts. Third, we objected to MFD's audit including claims that were the subject of a comprehensive self-disclosure made 15 months earlier because Truetox had not failed "to cooperate in good faith with MFD to resolve the disclosure." And finally, we explained that most of the documentation deficiencies identified in the SOF are simply wrong and provided a significant supplemental production of documents directed to same.

Then, on April 13, 2020, the parties held the Exit Conference. The Exit Conference began rather auspiciously, however, with you bragging to your colleagues and Truetox's staff members how as an auditor for another agency you almost "took down" the New York Mets. Transcript of Exit Conference conducted on April 13, 2020 ("Exit Conf. Tr.") ("it was a great audit. They definitely remember me 15 years later.") Regardless, you and your team were inexplicably unprepared to address any of the issues raised in my April 6 letter at the Exit Conference. On the two legal issues raised, i.e., the "charge" issue under N.J.A.C. 10:61-1.7 and the inclusion of previously self-reported claims in the SOF, [redacted] claimed to be taking copious notes, and assured us that MFD was "reviewing" the issues we had raised and understood specifically with the charge issue that MFD was required to provide further feedback. And with respect to our supplemental production of documents, the overall feedback was simply that MFD would review whatever materials we provided.

After the Exit Conference, I wrote to [redacted] on May 6. In the EC Rebuttal, we provided additional authority: (i) rebutting MFD's warped interpretation of N.J.A.C. 10:61-1.7; (ii) explaining why claims included in Truetox's self-disclosure 15 months earlier could not be included in MFD's audit findings. Additionally, the EC Rebuttal included a substantial production of documents dispelling MFD's allegations that Truetox provided improper rebates to any of its referring facilities by providing updated agreements and/addenda to its service agreements—removing the language MFD deemed concerning, as well as signed attestations from Truetox's facility clients confirming that no such rebates were ever provided; with the exception of one educational grant that was provided to a referring provider to send a member of its staff to attend the International Nurses Society on Addiction Conference.[1] And finally, the EC Rebuttal clarified the circumstances underlying certain charitable donations made between 2017-2020 to another

[1] This grant, of course, was (i) based on objective criteria that did not consider the volume or value of referral the recipient; (ii) did not constitute an inducement to do business with Truetox; (iii)was appropriately documented; and (iv) not made to a private account or individual. As such, there was no risks of (i) interfering with clinical decision-making; (ii) increasing the cost to a federal healthcare program; (iii) increasing overutilization or inappropriate utilization; or (iv)raising patient safety of quality-of-care concerns. 68 Fed. Reg. 23731, 23736 (May 5, 2003).

referring provider. These *bona fide* charitable contributions fall outside of the OIG's definition of remuneration under the Anti-Kickback Statute (AKS), and thus fall outside of the scope of what qualifies as a rebate under N.J.A.C. 10:61-2.4.[2]

In all, Truetox submitted 20 pages of argument and 330 pages of supplemental documentation to MFD in response to the SOF. MFD has yet to respond at all; despite the assurances of [redacted] at the Exit Conference. In fact, the only communication with MFD we had since the Exit Conference was a request for clarification related to one date of service in November 2020. As part of our supplemental documentation, we apparently provided documentation for a date of service outside the sample. To correct this error (the dates in question were mere days apart), we pulled the requisition and test results for the samples date of service and contacted the referring facility to obtain a corroborating attestation. But when we contacted the facility (who gladly cooperated with us previously), they refused to discuss this matter, citing their direct communication with MFD and the "tenor" of those discussions.

Yet, the DAR is identical in all material respects to the SOF. MFD failed to address, let alone respond to, every argument raised by Truetox in its various rebuttals. MFD very plainly refused to consider any of the voluminous corroborating documents we provided to rebut the audit's documentation findings. And MFD apparently went so far as to interfere with Truetox's efforts to obtain information and documents from its referring facilities to support the billing it submitted to NJ Medicaid for services rendered to patients of those facilities.

In all, MFD's audit was a farce—both in substance and in process. What follows in this response in merely to ensure the record is complete when the "results" of this farce are published. We will address each of Truetox's objections in turn. And we look forward to further testing the validity of MFD's "findings" before the Office of Administrative Law.

III. Truetox's Contractual Discounts for Uninsured Patients.

The DAR maintains MFD's untenable interpretation of N.J.A.C. 10:61-1.7; an interpretation you concede was made by members of your audit team as opposed to any supervising attorneys. Specifically, the DAR states that for 70 of the 82 samples reviewed (85.4%), Truetox improperly charged Medicaid an amount that exceeded Truetox's charge for identical services to other groups. MFD claims to have reached this conclusion by reviewing, among other things, Truetox's clinical account agreements and monthly invoices to its clinical account clients. MFD contends that Truetox's contractual agreement to accept a reduced fee from its clinical account clients relative to uninsured patients violates N.J.A.C. 10:61-1.7, which states, in relevant part, that "[i]n no event shall the charge to the Medicaid/NJ FamilyCare program exceed the providers charge for identical services to other groups or individuals."

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[2] The OIG has a notably favorable disposition towards charitable donations. As such, the OIG considers a donation made by a vendor is response to a fund-raising campaign in which community-wide contributions are solicited as a *bona fide* charitable donation.

Notably, N.J.A.C. 10:61-1.7 has never been interpreted by any court or agency in any published case or decision. The specific clause referenced by MFD was added to the regulation on February 5, 1996, and in enacting the clause, the Department of Human Services responded to multiple comments from industry on the scope of the new language:

> COMMENT: Both commenters requested clarification of the changed implementation language in N.J.A.C. 10:61-1.7, Basis for reimbursement.
>
> RESPONSE: The language does not change existing reimbursement standards at N.J.A.C. 10:61-1.5(a). It was changed to: one, include a reference to N.J.A.C. 10:61-3 and, two, to make clear that the charge to Medicaid shall not exceed the provider's lowest charge for the service.

28 N.J.R. 1054(a). So, the clear and unambiguous focus of the regulation is on the word ***charge***, and its mandate is very straightforward. If a provider has multiple or tiered charges for a service or supply, its ***charge*** to Medicaid shall not exceed that provider's lowest ***charge*** for the same service. The regulation does not mention, let alone prohibit, contractual discounts.

MFD's error, then, is its conflation of Truetox's charges with its negotiation of contractual discounts, which include not only the clinical account agreements it enters with referring facilities to address the pervasive issue of receiving samples from uninsured patients, but also managed care agreements, which similarly provide for Truetox to accept contractually-agreed upon discounts. Neither type of agreement alters, let alone reduces, Truetox's standard charges for the testing it provides. Instead, Truetox merely agrees to accept a reduced fee as payment for its services. In case of its clinical account agreements, this discount of its full charge is accepted only when the clinical account client agrees to accept financial responsibility for the payment of testing services provided to uninsured patients, an overwhelmingly vulnerable demographic, i.e., homeless addicts, for whom a bill is likely both impossible to deliver and an excuse to leave treatment entirely. The discount is accepted by Truetox in consideration of the time and expense it will save by not having to pursue these uninsured patients directly—which is rarely successful anyway.

A fee for service discount in exchange for prompt payment or in response to a financial hardship is not a novel concept. And while there is no authority discussing such discounts in the specific context of N.J.A.C. 10:61-1.7, there is in the context of CMS's substantively analogous exclusion authority for "excessive charges" to Medicare or the Medicaid programs under § 1128(b)(6)(A) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(6)(A), which prohibits a provider from charging Medicare or Medicaid substantially in excess of the company's usual charges. In interpreting § 1128(b)(6)(A), the OIG has conceded that this is not a blanket prohibition on offering discounts to private pay patients, but instead addresses a much narrower issue of tiered charge structures that set one price for Medicare or Medicaid and a substantially lower price for ***most*** other customers. *See* Letter from Kevin G. McAnaney, Chief, Industry Guidance Branch, Office of Inspector General (Apr. 26, 2000), available at https://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm (last visited March 7, 2021). Section 1128(b)(6)(A) is not implicated then unless the provider's charge to Medicare/Medicaid is discounting "close to half of

its non-Medicare/Medicaid business." *Id.* And "***providers are free to negotiate discounts***" so long as they are not tied to unlawful referrals. *Id.* (emphasis added).

As such, a clinical laboratory may agree to accept a discount to its usual and customary charge if the discount has a rational basis. As noted above, Truetox's acceptance of a discount relative to testing provided to uninsured patients is rooted in its desire to avoid the time and expense associated with invoicing uninsured patients directly—and usually unsuccessfully—while at the same time recovering its costs. Indeed, the $8 discount referenced in the DAR comes directly from two data-points. First, it is the fee schedule for treatment providers who are reimbursed directly from the State of New Jersey for services rendered to under/uninsured patients who participate in programs like Drug Court ("DC") or Driving Under the Influence Initiative ("DUII"), which were created to provide adequate Substance Abuse/Mental Health coverage for patients that are underinsured or uninsured. And second, it is Truetox's cost per sample—as opposed to its fully-loaded costs. There is nothing under either federal or New Jersey law that prohibits Truetox from offering such discounts. After all, "there are reasons why a company might agree to sell services below its average fully loaded costs." *See* Letter from Kevin G. McAnaney.

In OIG Advisory Opinion No. 15-04, the OIG again confirmed that: (i) § 1128(b)(6)(A) of the Social Security Act does not provide a basis to exclude or attempt to exclude any provider or supplier that provides discounts or free services to uninsured or underinsured patients; (ii) "a provider need not even worry about section 1128(b)(6)(A), unless it is discounting close to half of its non-Medicare or non-Medicaid business"; and (iii) the substantially in excess provision is not designed to prevent providers and suppliers from negotiating their rates with other payers. *See* OIG Advisory Opinion No. 15-04 (March 25, 2015), available at https://oig.hhs.gov /fraud/docs/advisoryopinions /2015/AdvOpn15-04.pdf (last visited March 7, 2021). In doing so, the OIG pointed to its own prior guidance to hospitals who discount their services for uninsured patients. *See* "Hospital Discounts Offered to Patients Who Cannot Pay Their Hospital Bills," (February 2004). The Advisory Opinion emphasized that so long as the services are not offered as *free,* the "substantially in excess provision is not designed to prevent providers and suppliers from negotiating their rates with private plans." available at https://oig.hhs.gov/ fraud/docs/alertsandbulletins/2004/fa021904hospitaldiscounts.pdf ("it will continue to be the OIG's enforcement policy that, when calculating their 'usual charges' for purposes of section 1128(b)(6)(A), individuals and entities do not need to consider free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying patients for the items or services furnished") (last visited March 30, 2020); *see also* "Addendum to Hospital Discounts Offered to Patients Who Cannot Pay Their Hospital Bills," (June 2007), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2007/revised%20addendum%20to%20uninsured %20guidance%20_4_%20_2_%20_2_.pdf (last visited March 7, 2021).

N.J.A.C. 10:61-1.7 only makes sense from an enforcement perspective if it is interpreted in line with its federal counterpart, § 1128(b)(6)(A), as prohibiting tiered pricing whereby Medicaid is subject to one standard charge while most of a provider's non-Medicaid business is subjected to a lesser charge. First, the plain language of the regulation itself refers to charges, and does not mention, let alone prohibit, contractually-negotiated discounts. Second, the Department

of Human Services explicitly confirmed that the enactment of N.J.A.C. 10:61-1.7 was not intended to "change existing reimbursement standards," including of course, those standards applicable to both Medicare and Medicaid claims under the Social Security Act. Third, to accept that unlike § 1128(b)(6)(A), N.J.A.C. 10:61-1.7 broadly prohibits Medicaid providers in New Jersey from negotiating discounts below the Medicaid fee schedule would turn the entire managed care industry in the state on its ear; including the administration of Medicaid benefits through the five health plans that participate in New Jersey's NJ FamilyCare program. And finally, because MFD is not the agency responsible for promulgating or enforcing N.J.A.C. 10:61-1.7, its interpretation of the regulation is not entitled to any deference. *Cf. Bedford v. Riello*, 195 N.J. 210, 222 (2008) ("Among the sources that inform us is the long-standing meaning ascribed to the language by the agency charged with its enforcement."); *see also National Loans v. Tennessee Dep't of Fin. Insts.*, 1997 Tenn. App. LEXIS 276 at *19 (Ct. App. 1997) (citing to *Baltimore Gas & Elec. Co. v. Heintz*, 760 F.2d 1408, 1419 (4th Cir. 1985) (stating "a regulatory agency's decision to enforce a statute or regulation in some cases but not others may entitle the person subjected to formal enforcement proceedings to an explanation from the agency").

The MFD's motives as it relates to the "charge" issue were made clear in your August 1, 2019 phone call to Mr. Bohan to discuss a purely legal issue despite his knowledge that Truetox was represented by counsel.[3] Indeed, during that phone call, you explicitly characterized the charge issue as one of first impression, apparently just unearthed by your "cracker jack staff." Transcript of August 1, 2019 Phone Call Between [redacted] and Pat Bohan ("Aug. 1 Tr.") at 3:15. After querying whether Mr. Bohan was familiar with the regulation, you described your "layman's understanding" as being that "although there is a Medicaid charge schedule, if the lab is charging other clients and/or individuals a lower rate, then that rate should also be applied to the state's charges." Aug. 1 Tr. at 4:7-11. You proceeded to explain how an application of his layman's understanding would apply to Truetox: "I'm sure at $2 or $3 a lab test, you guys wouldn't survive until 6:00 today." Aug. 1 Tr. at 9:5-6. Incredibly, you then tried to cast yourself as a white knight who could save Truetox from being "put out of business" by "management." Tr. 13:8. Specifically, you stated that his audit team was "looking in terms of if you have contracts with Horizon outside of Medicaid or AT&T [sic] that you're charging them to the going Medicaid rate. I might be able to say, hey, yeah, talk to management here and say, look this is really what it's costing them. Do we want to really charge them $2 and take all our money back and put them out of business?" Aug. 1 Tr. 13:1-8. Yet minutes later, you conceded that your tactics were pure gamesmanship:

> So I think I really want to give you an opportunity to share with us, and again – and I'm not going to go cutthroat, not use the $2 rate because I mean, I'm sure the $2 rate might be negotiated because of the other – I guess the frequency of specimens

[3] Your call to Mr. Bohan to discuss a purely legal issue was entirely inappropriate. I assume MFD audits are conducted with appropriate legal oversight. Under RPC 4.2., a lawyer (or an agent thereof) may not communicate with a person known to be represented by another lawyer. While our letter of representation requested that all further MFD communications be directed to my attention, we permitted MFD to communicate directly with Truetox to facilitate document collection—not for you to impermissibly interrogate its CEO on purely legal issues.

> coming in from a particular behavioral health, you know, can offset business. It's going to be competitive.

Aug. 1 Transcript, 18:2-9.

Notably, we attempted to preemptively engage you on this issue immediately. After your phone call with Mr. Bohan raising this issue for the first time, I responded to you by email. In that email I: (i) referenced N.J.A.C. 10:61-1.7's prohibition on tiered charges not having any impact on contractually-negotiated discounts; (ii) expressed my availability to discuss the issue with you "at your convenience;" and (iii) indicated Truetox's willingness to produce whatever corroborative documentation you might require. Instead of taking me up on that offer, MFD issued a series of subpoenas on Truetox and several of its clinical account clients to unearth facts that our client would have gladly stipulated to. Surely MFD would not have undertaken such extensive and time-consuming efforts based solely on a non-attorney's "theory" as to the applicability of N.J.A.C. 10:61-1.7 to Truetox's clinical account agreements.

Because of your refusal to engage on this issue during the audit, I demanded during the Exit Conference that MFD articulate its position on the applicability of N.J.A.C. 10:61-1.7 to contractually-negotiated discounts, and to provide either: (i) corresponding ***legal*** analysis; or (ii) a position statement from the Department of Human Services regarding same. Indeed, at the Exit Conference, [redacted] confirmed she was "taking notes" when confronted with the "charge issue" and that she understood that there needed to be an explanation as to why and how this regulation was being utilized in this fashion since the Department of Human Services never rendered any opinion as to the scope and breadth of the regulation. *See* Exit Conference Tr. 12:21-14:5. Of course, MFD did not supplement its "analysis" in the nine months it took to issue the same exact audit findings sent a year ago today. Not a single word.

There is no published court or agency decision related to the enforcement of N.J.A.C. 10:61-1.7. And our review of all publicly-available Final Audit Reports posted on the Office of the Comptroller's website relative to audits completed between October 6, 2010 to February 25, 2021, indicates that not one single audit even references N.J.A.C. 10:61-1.7, let alone purports to opine as to its scope and breadth. So, it appears that MFD's interpretation of N.J.A.C. 10:61-1.7 in the DAR is an enforcement position it has never taken before.

MFD's novel (and apparently selective) enforcement of N.J.A.C. 10:61-1.7 is very clearly nothing short of a baseless money grab. You conceded the egregiousness of using the "$2 rate" and your understanding of the business rationale behind accepting contractual discounts, precisely what is contemplated as lawful under authority interpreting the scope and breadth of N.J.A.C. 10:61-1.7's federal counterpart, 42 U.S.C. § 1320a-7(b)(6)(A). So, MFD's interpretation of N.J.A.C. 10:61-1.7: (i) is legally incorrect; and (ii) represents an attempt by MFD, for the first time, to enforce a layman's reading of the regulation without any underlying enforcement position from the Department of Human Services.

IV. Inclusion of Self-Disclosed Claims in the DAR.

On January 31, 2019, Truetox made a self-disclosure to the Office of the State Comptroller pursuant to its obligation as a Medicaid provider. Specifically, pursuant to Sec. 6402 of the Patient Protection and Affordable Care Act, 42 U.S.C. Sec. 1320a-7k(d)(2), N.J.A.C. §10:49-1.5 (b)(1), Truetox was obligated to disclose certain overpayments it received from the New Jersey Medicaid program. The MFD's attempt to include 16 claims that were part of this self-disclosure within its audit findings is patently improper. Specifically, MFD is improperly depriving Truetox of the benefits of self-disclosure, including and most importantly, anonymity.

To encourage self-disclosure, MFD offers incentives for providers to investigate, and report matters that involve possible fraud, waste, abuse, or inappropriate payments—whether intentional or unintentional—under the state's Medicaid program. To that end, MFD extends the following benefits to providers who, in good-faith, participate in a self-disclosure: (i) avoidance of False Claims penalties if reported within 60 days of identification; (ii) forgiveness or reduction of interest payments (for up to two years); (iii) extended repayment terms; (iv) waiver of penalties and/or sanctions; (v) timely resolution of the overpayment; and (vi) in most circumstances, the avoidance of a MFD Corporate Integrity Program. Self-disclosures are also not published on MFD's website, nor are settlements of those Self-Disclosures.

Assuming a provider completely cooperates and responds promptly to information requests, MFD expects that most self-disclosures will be completed within six months of submission of this information. The MFD will consider the provider's involvement and level of cooperation throughout the disclosure process in determining the most appropriate resolution and the best mechanism to achieve that resolution. Only if a provider and MFD cannot reach agreement on the amount of the overpayment identified, or if a provider fails to cooperate in good faith with MFD to resolve the disclosure, will MFD pursue the matter through established audit or investigation processes.

Here, MFD has very plainly deviated from its own published guidance. Indeed, in the two years since the Self-Disclosure, MFD has not responded, let alone requested any confirmatory or clarifying documents or information. Truetox, of course, cannot then plausibly be accused of not cooperating with MFD's investigation of the Self-Disclosure. Yet it is clear from the SOF and the DAR that MFD has decided to pursue the *res* of the Self-Disclosure through the audit process; albeit by reviewing a nominal sample of only 16 claims as opposed to considering all the claims included in the Self-Disclosure.

Specifically, MFD defends its inclusion of the self-disclosed claims because,

> MFD performed more robust, comprehensive audit tests than Truetox performed in its internal review. Moreover, MFD's findings, as set forth in this [DAR], largely include Truetox's self-disclosed claims. Accordingly, MFD's findings herein adequately address the claims included in Truetox's self-disclosure for the period corresponding to this audit.

Notwithstanding MFD's "robust" audit, there is nothing in the OIG's Self-Disclosure Protocol ("SDP") that prohibits a self-disclosure from being made during an existing investigation or audit. Nor is there anything that limits or otherwise deprives self-disclosing providers of the benefits of self-disclosure when made during an existing investigation or audit.

Indeed, SDP was revamped in 1998 to allow providers to work "openly and cooperatively" with the OIG. *See* Office of Inspector General; Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399. "Unlike the previous voluntary disclosure pilot programs" the new SDP "gives detailed guidance to the provider on what information is appropriate to include as part of an investigative report… while setting *no limitations* on the conditions under which a health care provider may disclose information to the OIG." *Id.* (emphasis added). An important update and contrast to the pilot disclosure program states that:

> The fact that a disclosing health care provider is already subject to Government inquiry (including investigations, audits or routine oversight activities) will not automatically preclude a disclosure. The disclosure, however, must be made in good faith. The OIG will not continue to work with a provider that attempts to circumvent an ongoing inquiry or fails to fully cooperate in the self-disclosure process. ***In short, the OIG will continue its practice of working with providers that are the subject of an investigation or audit, provided that the collaboration does not interfere with the efficient and effective resolution of the inquiry***.

Id. (emphasis added). MFD's protocols similarly contemplate a self-disclosure being made, and thus the applicability of the statutory safeguards that accompany same, during an "on-going audit:"

> Matters related to an on-going audit/investigation of the provider are not generally eligible for resolution under the self-disclosure protocol. ***Unrelated matters disclosed during an on-going audit may be eligible for processing under the self-disclosure protocol assuming the matter has received timely attention***. If MFD is already auditing or investigating the provider, and the provider wishes to disclose an issue, in addition to submitting a disclosure under this protocol, the provider should bring the matter to the attention of the on-site audit staff.

MFD Self-Disclosure Protocol, available at https://www.nj.gov/comptroller/divisions/medicaid/disclosure/ (last visited March 7, 2021). Only matters "related" to an on-going audit/investigation are not eligible for resolution under MFD's self-disclosure protocol. Here, at the time that the Self-Disclosure was made, there were no "matters" identified by MFD as being "related" to its audit. In fact, no substantive issues were identified by MFD until your call to Mr. Bohan on August 1, 2019, 8 months ***after*** the Self-Disclosure. And the first mention of certain issues and claims contained in the Self-Disclosure as related to MFD audit was in the SOF, 13 months ***after*** the Self-Disclosure. So, even under a plain reading of MFD's self-disclosure protocol, the Self-Disclosure is eligible for resolution thereunder because it was not related to an on-going audit/investigation ***at the time it was made***. And to characterize the Self-Disclosure as

"related" to an MFD Audit that was, at best, in its infancy at its time, would be to ostensibly rule that all self-disclosures made during the pendency of an audit are not eligible for resolution under the self-disclosure protocol; which runs contrary not only to the above-quoted protocols, but also the policy rationale underlying self-protocols, generally. To adopt such a broad definition of "related matters" will have a chilling effect on provider self-disclosures once made public.

Moreover, MFD has not (and cannot) articulate any facts indicating that: (i) the Self-Disclosure interfered with the efficient and effective resolution of the audit; or (ii) Truetox failed to cooperate in good faith with MFD to resolve the Self-Disclosure. In fact, Truetox's Self-Disclosure is precisely what both the OIG and MFD self-disclosure protocols explicitly contemplate: a provider coming forward with a voluntary disclosure of improper payments, based upon an extensive and complete review and remediation of the underlying issues that gave rise to those overpayments, and a willingness to promptly and amicably tender restitution. Were it up to Truetox, the Self-Disclosure would have been resolved ***and repaid*** already. To deprive Truetox of the benefits of self-disclosure because MFD purports to have identified a few handfuls of "related" findings more than two years after the Self-Disclosure is absurd—and flies in the face of any purported desire of MFD to work "with providers in a cooperative manner."

Moreover, the discussion of this issue at the Exit Conference made clear that to the extent MFD disagreed with Truetox on its position that the self-disclosure should not be included in the FAR, we needed to know why. Specifically, we insisted on MFD explaining why Truetox is being deprived of the procedural framework that is published on MFD's website which applies to these situations. *See* Exit Conference Tr. 14:16-16:12. In response, [redacted] confirmed that MFD was "reviewing" Truetox's position as it relates to the self-disclosure, but seconds later it became apparent that was not the case. *Id*. at 16:13-21. Indeed, you blurted out that because ***you*** knew of MFD's audit plan, the parties should simply "agree to disagree" on the topic. *Id*. at 19:2-3. So, again, it is clear from the tenor your explanation that MFD was never interested in reviewing Truetox's arguments; and the DAR confirmed it.

Nevertheless, because Truetox has always cooperated in good faith during both the audit and self-disclosure process, it is entitled to the benefits of its quick and decisive choice to submit a comprehensive voluntary self-disclosure.

V. Misc. Documentation Issues and Purported Billing Irregularities.

Once stripped of the legally dubious "charge" allegation and the procedurally improper duplication of the Self-Disclosure, the DAR is nothing more than a handful of alleged documentation deficiencies. In both the SOF Rebuttal and EC Rebuttal, Truetox submitted supplemental documentation for all but a few "deficient" claims. The DAR does not discuss, let alone address, *any* of the additional explanations or documentation proffered by Truetox.

A. Documentation Issues.

The MFD alleges that in 15 out of the 82 sample episodes, Truetox failed to "document

properly the services it provided." In all but a few instances, MFD's findings are simply wrong. We will address each alleged documentation deficiency in turn.

First, MFD alleges that "test requisitions for 7 of the 82 sample episodes failed to include the signature of the physician or other licensed practitioner who ordered the services in a written requisition." For 2 of those samples ([redacted], date of service [redacted], and Sample Number [redacted], and [redacted], date of service [redacted], and Sample Number [redacted]), the ordering provider's signature is very clearly set forth on the requisition form, each of which is included in the supplemental production of documents provided concurrently herewith at MFD000079-000084. For the remaining 5 of those samples ([redacted], date of service [redacted], and Sample Number [redacted], [redacted], date of service [redacted], and Sample Number [redacted]; [redacted], date of service [redacted], and Sample Number [redacted]; [redacted], date of service [redacted], and Sample Number [redacted]; and [redacted], date of service [redacted] and Sample Number [redacted]), the orders were received verbally by the Truetox Collector onsite at the time the sample was taken and processed. To augment the documentation previously provided, we sought to obtain signed attestations from the ordering providers that the testing orders in question were appropriately made. Unfortunately, two of those ordering providers, accounting for all but one of the remaining five samples, have since passed away, and were therefore unable to confirm their prior verbal orders to Truetox's onsite collectors.

Second, MFD alleges that "in 7 of the 82 sample episodes Truetox accepted and later billed for tests stemming from electronic test requisitions under the name of a physician or other licensed practitioner who no longer engaged in the care of the referring provider's patients on the date the order was submitted." Truetox was admittedly stunned by this finding as it is Truetox's practice to complete onboarding paperwork for every ordering provider. So, to augment MFD's review that led to this purported deficiency, Truetox provided documentation that identified each provider having been onboarded prior to the test being ordered and performed. These were produced with the SOF Rebuttal production at MFD00085-000126.

The SOF, and now the DAR, are devoid of any mention of what documents or information MFD relied upon in concluding that the ordering provider was "no longer employed by the referring provider on the date the service was provided." Nevertheless, because Truetox had no information supporting MFD's allegation, it contacted the referring facilities in question for further elaboration on the matter. Truetox obtained signed attestations from the ordering provider and/or another member of the referring facility's clinical staff regarding that the testing in question was appropriately ordered. Copies of those attestations, along with the underlying requisitions forms were produced with the SOF Rebuttal production at MFD000127-000139.

On November 4, 2020, a member of MFD audit team wrote to request more information as it related to two attestations provided in May of 2020. The wrong dates of service were inadvertently submitted with Truetox's supplemental production. As such, Truetox worked to supplement the record with the corrected dates of service. Truetox did so for one requisition and provided same to MFD. However, for the other date of service, specifically, [redacted], date of service [redacted], sample number: [redacted], Truetox provided a date of service that was two days

earlier than the sampled date of service. Truetox received a sworn attestation from the referring facility that stated the ordering provider was employed on that date of service. However, when contacted again in November of 2020 to sign an attestation for the date of service two days earlier, the clinical director of the facility refused to oblige, stating that MFD had already contacted her and indicated "they had everything they needed."

We, of course, brought this issue immediately to MFD's attention. Specifically, my colleague Nicole Allocca wrote to [redacted]:

> I wanted to reach out directly to you to follow up on your November 4, 2020 request for more information for a particular patient and date of service. Specifically, you requested more information for a date of service that required a physician attestation to verify an order authorization. At your request, Truetox reached out to the provider to obtain a new signed attestation for the correct date of service. However, the provider indicated that MFD had already contacted her and obtained whatever information they needed. The provider also was hesitant to communicate at all with Truetox based on the tenor of MFD's communications. Obviously, this is concerning. Either way, the provider is now unwilling to sign the corrected version of the attestation originally attached to Truetox's post Exit Conference letter. As such, I am not able to provide the clarifying information you originally requested.
>
> Please let me know when you or your team is available to discuss.

Curiously, you first tried to call Ms. Allocca, but when she had our assistant ask when you might be available for a call with both her and I, you responded by email:

> I am responding to your January 28, 2021 email to [redacted]. Before addressing the substance of your letter, I first want to respond to your statement that the referring provider was hesitant to communicate with you based on the tenor of MFD's communications. I assure you that MFD Audit staff's communications with this provider were appropriate and professional.
>
> In terms of the supplemental information you provided to support the claim at issue, just as in any case in which MFD is presented with information that may refute an audit finding, audit staff performed appropriate due diligence to verify the accuracy of such information. Specifically, the claim at issue related to whether a practitioner was on staff in a referring provider's organization on the date that the referring provider generated the test order. You had previously provided attestations for 4/7/2017 and for 7/12/2017 from this referring provider's organization. We had followed up with you because we did not have a claim dated 4/7/2017 in our sample. We did, however, have a claim dated 4/5/2017. MFD staff obtained reasonable assurance that the last day that the physician of record saw patients was in December 2016 and that he was on a leave of absence from that date to when his

> employment formally ceased in July 2017. Since, the physician of record was not actively practicing at the time of the date of service for the claims in question, the referring provider's lab requests containing his name were not valid. Accordingly, based on this due diligence, MFD is reasonably assured that these claims should be denied.
>
> Thank you for your attention to this matter

Your refusal to meaningfully engage on this issue, or to even attempt to explain how MFD's "reasonable assurances" can contradict signed attestations received by the same provider prior to MFD's poisoning of the well, just further belabors our point that MFD's "audit" process here is not about actually validating what services were ordered or performed.

Regardless, this back-and-forth (or lack thereof) resulted in the only substantive change to the SOF manifest in the DAR. This finding was originally "test requisitions for 7 of the 82 sample episodes were electronically submitted under the name of a physician or other licensed practitioner who was no longer employed by the referring provider on the date the order was submitted." Now, MFD has parsed this allegation out into two categories. Specifically, "of the 7 sample episodes, 5 sample episodes were ordered under the name of a physician who no longer was employed by the referring provider, and 2 sample episodes were ordered under the name of a physician who no longer was engaged in patient care, and thus, was not authorized to have ordered such tests." Of course, the DAR does not elaborate on which finding belongs to which sample.

In all, Truetox has proffered evidence in the form of (i) account onboarding protocols that demonstrate when the ordering provider began working at the referring facility; (ii) a signed requisition by that provider; and (iii) an attestation by the Medical Director of the facility that the provider was employed and ordered the test in question for each the date of service. As such, Truetox is reasonably assured that MFD's findings on this point are meritless.

B. <u>Presumptive v. Definitive UDT</u>.

MFD found that for 28 of the 82 sample claims, Truetox "failed to provide documentation to support that a referring physician or licensed practitioner had ordered a definitive drug test, which is reimbursed at a higher rate than a presumptive test." The MFD rephrased this "deficiency" from the SOF, which stated, Truetox "failed to maintain documentation that the referring physician actually ordered definitive drug tests on 28 requisitions." MFD originally prefaced the entirety of this finding based on its assertion that "although the test requisitions listed the names of the drugs or drug classes ordered for testing, they failed to specify the type of test (i.e., presumptive and/or definitive) order."

Now, MFD claims that it reviewed Truetox's account set-up forms to help "demonstrate that the referring physician ordered the higher reimbursed definitive tests in 28 sample episodes." However, Truetox did not provide its account set-up forms to refute this purported deficiency. Instead, Truetox provided a different form of requisition for each sampled date which clearly states

whether the test ordered is for a screen or confirmation, formally known as presumptive or definitive drug testing, respectively.

Presumptive drug testing, also known as drug ***screening***, is used when necessary to determine the presence or absence of drugs or a drug class. Results are expressed as negative or positive. The methodology is considered when coding presumptive procedures. Per Current Procedural Terminology ("CPT") guidelines published by the American Medical Association ("AMA"), each presumptive drug testing code (CPT codes 80305, 80306, and 80307) represents all drug and drug class tests performed by the respective methodology per date of service. The test is a single per patient service that should only be reported once irrespective of the number of Drug Class procedures or results on any date of service.

Definitive drug testing, also known as ***confirmation*** testing, is used when it is necessary to identify specific drugs (as opposed to a drug class) that are either prescribed medications or illicit substances and their metabolites. Definitive UDT reports the quantitative results of drugs absent or present in concentrations of ng/ml. These tests identify specific drugs and associated metabolites. A presumptive drug test is not required to be provided prior to a definitive drug test. Definitive UDT is reported under Healthcare Common Procedure Coding System ("HCPCS") codes G0480, G0481, G0482, G0483 and G0659. The HCPCS codes describe a per day service that represents the total number of different drug classes performed.

Every requisition underlying the 28 samples MFD stated lacked documentation that a qualified provider ordered definitive as opposed to presumptive UDT shows clear and unambiguous order choices for both presumptive and definitive drug testing; albeit using the words "screen" and "confirmation" as opposed to "presumptive" and "definitive." For example, the requisition for [redacted], date of service [redacted], and Sample Number [redacted], identifies a (i) validity screen; (ii) opiates confirmation; (iii) fentanyl confirmation; (iv) synthetic opiates confirmation panel; (v) tramadol confirmation panel; (vi) benzodiazepines confirmation panel. The requisition also clearly identifies "[redacted], D.O." as the ordering provider. Each requisition was included in the supplemental production of documents provided before the Exit Conference at MFD000007-000045. The MFD's findings as it relates to insufficient documentation for definitive testing orders is plainly erroneous as the requisitions in question all clearly specify "confirmation" testing, which is definitive UDT.

At the Exit Conference, the parties discussed why the supplemental requisitions appeared differently than the "Copia" requisitions that were originally provided to MFD. Truetox agreed to provide more clarifying information in follow-up correspondence to better explain how Truetox's systems function and the nomenclature change that appeared on the supplemental requisitions. Specifically, Truetox elaborated that on February 6, 2019, Truetox initiated a programming change within its Laboratory Information Management System ("LIMS") to label its confirmation testing panels more precisely. A "panel" has always referred to a definitive test performed on a LCMS instrument, which is better known as a confirmation. To report G0480 to G0483, the requisition must identify the "individual drugs" and the test must "distinguish between structural isomers." *See* AAPC Coder HCPCS for Drug test def 1-7 classes, G0480. Truetox's requisitions always

identified the ordered drug class(es) that needed to be confirmed. However, to create consistent reporting, Truetox updated its LIMS to add "confirmation" to the requisition where indicated that a specific drug class "panel" needed to be tested. So, when MFD originally requested those twenty-eight requisitions, the nomenclature remained at "panel." Because these requisitions were queried again after the SOF for further review, the updated requisition now added the word "confirmation." This series of events is memorialized in Truetox's Chief Information Officer's Certification, previously produced at MFD000271-MFD000272.

So, MFD's assertion that "panel" is not descriptive enough to describe definitive testing is ludicrous. There are only two types of testing — presumptive (screen) and definitive. The older versions of the requisitions clearly specify the tests that are screens, and which specific drug panel needs a definitive test. This is further evident when reviewed with the corresponding test results, identified at MFD000273-MFD000327.

C. Incorrect Procedure Codes.

The MFD found that for 25 of the 82 sample claims, Truetox "billed for an incorrect procedure code." The DAR elaborated on this by stating that Truetox (i) billed and was paid for a greater level of definitive drug testing than ordered by the referring physician or licensed practitioner, or (2) billed for an incorrect procedure code."

As discussed in correspondence that preceded the DAR, MFD's findings as it relates to this "deficiency" are overwhelmingly wrong. For example, nine of the claims[4], are simply incorrect. The following chart is illustrative:

Px	Sample	Date	Audit	Response
[redacted]	[redacted]	[redacted]	G0480	8 confirmations (Anticonvulsants panel includes two drug classes – Gabapentin and Pregabalin, which are 2 classes), G0481 was correctly billed
[redacted]	[redacted]	[redacted]	G0480	8 confirmations (Opioid Antagonist panel contains Buprenorphine, which is 1 class and Naloxone, which is classified as an Opiate, therefore 2 classes), G0481 was correctly billed

[4] Two samples, [redacted], date of service [redacted] and Sample Number [redacted]; and [redacted], date of service [redacted] and Sample Number [redacted], were billed with 803XX codes when G-codes should have been utilized. [redacted]'s overpayment, $16.05, is conceded herein. [redacted]'s miscoding resulted in an underpayment to Truetox for $1.33. Thus, inclusion of these samples in the chart is unnecessary.

[redacted]	[redacted]	[redacted]	G0480	8 confirmations, G0481 was correctly billed
[redacted]	[redacted]	[redacted]	G0480	G0480 was the code billed
[redacted]	[redacted]	[redacted]	G0480	10 confirmations, (Gabapentin is 2 classes), G0481 was correctly billed
[redacted]	[redacted]	[redacted]	G0480	8 confirmations (Gabapentin is 2 classes), G0481 was correctly billed
[redacted]	[redacted]	[redacted]	80301	Billed 80301 instead of G0479, which pays less than G0479

For the avoidance of doubt, these requisitions were again submitted to MFD in advance of the Exit Conference at MFD000046-000050. The MFD's findings as it relates to improper coding for definitive testing is plainly erroneous as the requisitions and the corresponding test reports all support the level of service billed. Curiously, when discussing these claims during the Exit Conference, MFD stated that "we use the [AMA] drug classes to identify the different classes," yet the Medicaid program requires the use of the HCPCS codes G0480-83 in reporting multiple drug classes. *See* Exit Conference Tr. 37:19-21. Perhaps this is MFD's rebuttal; either way, MFD is wrong, and its not even a close call. The remaining claims "grouped" into this documentation category were part of Truetox's Self-Disclosure and as discussed in Section IV *infra*, it is entirely inappropriate to include them as part of MFD's audit findings here.

VI. Use of Account Consultation Protocols.

While not assessing any corresponding overpayment, MFD alleges that it "found that the tests performed by Truetox pursuant to the account set-up forms included the same tests for each referring provider's patients with little, if any, variance" and adding that "it is difficult to fathom why all tests ordered by a referring provider would be identical 'one-size-fits-all' blanket order." Even setting aside that not a single member of MFD's audit team has the appropriate clinical credentials to opine on the medical necessity of ***any*** of the 82 tests it reviewed, this is a profoundly frivolous argument.

Truetox provides UDT to patients undergoing substance use and/or addiction treatment in New York and New Jersey—two states that continue to be in the throes of an opioid epidemic. That the testing ordered by its referring facilities is similar to one another is neither surprising nor inappropriate. Moreover, Truetox's Account Consultation Protocol, whereby each facility client sets up their own individual testing panels, was developed using the guidelines established in the Consensus Statement ("Statement") developed by the American Society of Addiction Medicine ("ASAM"). A copy of the Account Consultation Protocol was included in the supplemental production of documents provided before the Exit Conference at MFD000140-000150. And while the use of custom panels in addiction treatment is generally-accepted, Truetox's ordering providers are, of course, free to order individual tests at any time.

MFD's conclusion that "Truetox's use of blanket orders is detrimental to the Medicaid program because it results in improper and unnecessary drug testing and wasteful Medicaid payments" is particularly dubious in the absence of any credible expert opinion on the necessity of even one of the tests in question. Nevertheless, MFD's disagreement with ASAM's guidance on custom panels for patients undergoing substance use disorder treatment appears to have resulted in a change in reimbursement policy applicable to NJ Medicaid effective April 1, 2021.[5] And regardless of whether that apparent change in policy followed the appropriate rulemaking procedure or not, that policy is not relevant to this audit—simply put, there was no prohibition on custom panels during the audit period. So MFD's commentary on "blanket order" is just gratuitous nonsense that has no place in an objective audit report.

Lastly, MFD's off-handed remark that "practitioners who no longer worked for or engaged in the care of referring provider's patients yet remained on the referring provider's order form… contributes to the submission of inaccurate claims" is more unfounded nonsense that has no place in an objective audit report. MFD has produced no credible evidence that this occurred even once. And Truetox has produced a mountain of attestations that it did not. MFD's refusal to consider those attestations does not bolster its "point."

VII. Alleged Lab Rebates and Charitable Contributions.

In a final note to the DAR and with a similarly nonsensical approach as the "charge issue," MFD references old clinical account agreements with its referring providers that state "Tox to sponsor 2 Key Employees from each site to participate at 2 conferences annually" and "Staff Testing at No Charge to clinic." Presumably, MFD is referencing the agreements previously provided in response to MFD's November 18, 2019 Subpoena. *See* TRUETOX_MFD_04895-04899; 04874-04885; 04836-04847; 04848-04853; 04854-04873. As discussed at the Exit Conference and again in follow-up, these agreements have since been superseded with new agreements and/or addendums that no longer contain such language. Indeed, during the Exit Conference, MFD specifically requested "some type of representation from your client that those things were never actualized." *See* Exit Conference Tr. 49:15-21. As such, Truetox provided those new Clinical Account Agreements at MFD000177-MFD000248. Additionally, for the avoidance of doubt, Truetox obtained certifications that reflect those outdated provisions were never actualized, except for one instance. Those certifications were enclosed at MFD000249-MFD000260. Yet, MFD fails to consider, or even make any reference to, this supplemental production despite having specifically requested it during the Exit Conference.

In terms of the one exception, Truetox sponsored a [redacted] employee to attend the International Nurses Society on Addiction Conference. The conference focused on the requisite knowledge, skills, and abilities for any nurse who cares for persons with substance abuse. As such, the conference's objective was to promote educational activities and discourse. Indeed, the main incentive for bringing attendees together was to further their knowledge on the topic being

[5] Truetox routinely works with other plans and payers—including Medicare—that prohibit custom panels and adjusts its Account Consultation Protocols accordingly.

presented. The conference was purely educational in nature, without any emphasis on other considerations returned to Truetox. This educational grant was (i) based on objective criteria that did not consider the volume or value of purchases made by, or anticipated from, the recipient; (ii) did not constitute an inducement to do business with Truetox; (iii) was appropriately documented; and (iv) not made to a private account or individual. As such, there was no risks of (i) interfering with clinical decision-making; (ii) increasing the cost to a federal healthcare program; (iii) increasing overutilization or inappropriate utilization; or (iv) raising patient safety of quality-of-care concerns. *See* 68 Fed. Reg. 23731, 23736 (May 5, 2003).

The SOF originally referenced "a referring provider that used Truetox as a drug testing laboratory disclosed in its annual report that Truetox was a 'financial contributor.'" As disclosed at the Exit Conference, MFD based this finding on the 2017-2018 Annual Financial Report of [redacted].

Since 2016, Truetox has contributed annually to [redacted]'s yearly charitable event, usually a golf tournament, but occasionally a speaking engagement. All documentation supporting those charitable donations was provided to MFD at MFD000261-MFD000270. Additionally, a breakdown of those contributions is as follows:

Date	Charitable Event	Donation Amount
March 23, 2017	Golf Tournament	$3,000.00
March 24, 2018	Golf Tournament	$3,000.00
September 26, 2018	Speaking Engagement	$5,000.00
March 13, 2019	Golf Tournament	$3,000.00
February 24, 2020	Golf Tournament	$7,500.00

The DAR, apparently tacitly acknowledging a review of this information, ends its section on lab rebates with the addition that Truetox, as a "financial contributor," contributed $6,000.00 to "this referring provider's miniature golf fundraising event." But of course, the DAR states nothing as to why this charitable donation is classified as an improper lab rebate.

Provider contributions are permissible so long as the donation fits within the *Bona Fide* Charitable Donations exception of the Federal Stark Law. An entity considering making charitable contributions must ensure that the charity is (i) a tax-exempt organization; (ii) the charitable donation is neither solicited nor offered in any way that considers the volume or value of referrals or other business generated between the physician and the entity; and (iii) the charitable contribution does not violate the Anti-Kickback Statute ("AKS") or other federal or state laws governing the submission of bills or claims.

The OIG has a notable favorable disposition towards *bona fide* charitable donations. As such, the OIG considers a donation made by a vendor is response to a fund-raising campaign in which community-wide contributions are solicited as a *bona fide* charitable donation. [redacted] is a foundation of the Trenton community. It not only provides emergency shelter to those in the community, but also offers a thrift store for the less fortunate. It also includes

a residential substance abuse treatment program, which refers patients to Truetox to aid in that substance abuse treatment. Rated as a Four-Star Charity by Charity Navigator, the highest possible rating, [redacted] solicits financial contributions for its once a year fundraising event – The Annual Adam Shanks Miniature Golf Tournament. Each dollar raised through the event goes directly toward funding the [redacted]'s various programs. This fundraiser is widely publicized and solicits donations throughout New Jersey and the surrounding areas.

Truetox's *bona fide* charitable contribution falls outside the scope of a "rebate" as contemplated by N.J.A.C. 10:61-2.4. A rebate includes "refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value." Because Truetox's *bona fide* charitable contribution falls outside the OIG's definition of remuneration under the AKS, it similarly must be excluded as a rebate.

VIII. Flawed Statistical Extrapolation.

Finally, the Overpayment is based on some form of statistical analysis. Indeed, the DAR claims to be based on the review of a "statistically valid sample comprised of 82 episodes with 198 unique paid claims totaling $12,810 in payments selected from a population of 140,772 episodes with 302,326 paid claims totaling $24,382,684." So, based on a review of less than one-tenth of one-percent of the claims Truetox submitted to Medicaid, MFD seeks to recover approximately 99% of the corresponding payments Medicaid made to Truetox.

A cursory review of the statistical extrapolation data provided shows it is too small of a sample to produce a reliable extrapolation. Moreover, that sample is buttressed with 16 claims that should not be included because they were part of the Self-Disclosure; thus, the "sample" MFD rests its calculations on is even smaller. We look forward to presenting a statistical expert before the Office of Administrative Law to provide corroborative testimony on this topic.

IX. Corrective Action Plan.

Truetox's Corrective Action Plan ("CAP") is limited to the findings that have merit within the DAR. As such, the CAP is limited. Of course, Truetox will continue to ensure that all orders for clinical laboratory services, as well as records and documentation supporting same are maintained by Truetox. Truetox will also ensure that only those drug tests ordered by the authorizing physician or other qualified practitioner are tested and billed. Truetox will continue to ensure requests for UDT specify what kinds of tests are ordered. Truetox will continue to comply with all applicable laws and guidelines. Finally, in line with its current referring facility agreements, Truetox will not offer rebates, including refunds, discounts, or kickbacks, to its referring providers or any other entities.

Truetox has also conceded that it improperly continued to separately bill for specimen validity testing when performed in conjunction with presumptive or drug tests for the same beneficiary on the same date of service. Truetox ceased separately billing for specimen validity testing well in advance of the initiation of this audit, but of course it will continue to do so. Truetox

will continue to provide training and support to staff to foster compliance with Medicaid requirements under state and federal law.

* * *

Thank you for your attention in this matter.

Respectfully yours,

BUTTACI LEARDI & WERNER LLC

John W. Leardi
A Member of the Firm

JWL/npa
cc: Client File (00793.04000)

BUTTACI LEARDI & WERNER
ATTORNEYS AT LAW

BUTTACI LEARDI & WERNER LLC
212 Carnegie Center, Suite 202
Princeton, NJ 08540
609-799-5150
609-799-5180 FAX
www.buttacilaw.com

JOHN W. LEARDI, ESQ.
MEMBER, NJ, NY, & MI BARS
DIRECT EXTENSION: 115
E-MAIL: JWLEARDI@BUTTACILAW.COM

June 18, 2021

VIA ELECTRONIC MAIL ONLY
Michael M. Morgese
Audit Supervisor
Office of the State Comptroller
Medicaid Fraud Division
20 West State Street, 4th Floor
P.O. Box. 025
Trenton, NJ 08625-0025
[redacted]

Re: Truetox Laboratories, LLC
MFD File No. 2016-00318

Dear Mr. Morgese:

As you know, this firm is legal counsel to Truetox Laboratories, LLC ("Truetox"). We are in receipt to the Clarifications to the Draft Audit Report ("DAR") prepared by the Medicaid Fraud Division ("MFD") dated June 4 (the "DAR Clarification").

As a threshold matter, we are confused as to what the DAR Clarification even represents. It certainly does not "clarify" any issue raised by either the DAR or our March 10 response to the DAR (the "DAR Objection"). Indeed, yet again, MFD refuses to engage with Truetox on any substantive or procedural area of dispute. Instead, the DAR Clarification appears to simply replace Paragraph V and Recommendation No. 8 of the DAR. But the re-wording of these two sections of the DAR does make any meaningful change to the substantive allegations in the DAR, or how meritless they are as explained in the DAR Objection.

First, as to MFD's allegation that Truetox's Contractual Discounts for Uninsured Patients constitutes an unlawful "rebate" under N.J.A.C. 10:61-2.4, the DAR made the same allegation. The only conceivable "clarification" is that MFD now believes that these contractual discounts, including those made by and through participating provider agreements with managed care organizations, the forms of which are approved by, among others, the New Jersey Department of Banking and Insurance, violate N.J.A.C. 10:61-2.4 as "other considerations to a physician or other practitioner, whether or not rebate is involved." We assume this is the same "layman's"

interpretation your "cracker-jack" team of auditors applied to N.J.A.C. 10:61-1.7. Perhaps the MFD should provide its auditors some rudimentary training in healthcare reimbursement; because frankly it is astounding that our client must pay us to explain to you and your audit team how contractual discounts, including managed care agreements, prompt pay discounts, and indigency discounts, are not "kickbacks" or "rebates" under New Jersey law or otherwise.

We will start, again (*see* DAR Objection a pp. 5-7), with the basics. A fee is a set amount or set price. So, for example, fee-for-service means a specific payment is made for each specific service provided. These fees are also known as a "charge." Providers have the discretion to set whatever charges they deem sufficient to cover their costs and provide a predetermined level of profit. So, for example, an optometrist, considering her overhead, frequency of patient visits, and level of time and skill required for the service, may set the cost of an average eye exam at $100. To expand her patient base and to ensure higher patient traffic, the optometrist may decide to join a commercial insurer's network of optometrists that the insurer promotes to its insureds as "in-network." To join this network, the insurer typically offers to pay the optometrist a lower rate than her typical charges in exchange for providing access to its insureds. As such, the provider accepts a *contractual discount*, which is lower than its billed charges.

As the MFD is surely aware, most payers, including the New Jersey Medicaid program, do not typically pay providers their billed charge for a service. Rather, the payer sets a "fee schedule," which is a complete listing of fees reimbursable by the payer. So, if the provider wants to get reimbursed for a specific service, it will only get reimbursed according to the fee schedule, regardless of the provider's set charge. But importantly, the provider's charge does not change in either scenario—either when the provider is reimbursed via a negotiated contract with a payer or when it is paid according to a set fee schedule. This is, of course, the MFD's inherent misunderstanding as it relates to Truetox's "charges."

To say this practice is typical is an understatement. For the last forty years, insurers demanded negotiated discounts to join their networks and the practice has pervaded ever since. *The Controversy Over Hospital Charges to the Uninsured—No Villains, No Heroes*, 51 Vill. L. Rev. 95, 110 (Cohen, Beverly) (2006) (citing Review of Hospital Billing and Collections Practices: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce, 108th Cong. 9 (2004) (statement of Rep. Charles F. Bass, Member, H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations).

Indeed, in the hospital context, it was common knowledge that hospital rates payable by health insurers, managed care plans, and governmental programs were not "full charges and often times quite a bit less than the hospitals' charge levels." *Id*. at 109. And because of this structure, there was little incentive for hospitals to decrease their charges over the last twenty years because "many of the negotiated rates continued to be structed as discounts off charges." *Id*. at 110. So, to maintain reasonable reimbursement after the discount taken by insurers, hospitals kept their high charges. And to solidify this high charge, many hospitals sent exorbitant bills to the uninsured and underinsured, all but ensuring these individuals went into massive debt or simply refused to pay. This position taken by the hospital—that they had no choice but to keep the same charge for every

patient regardless of circumstance—was flatly denied by the OIG and lead to pointed guidance related to treating the underinsured and uninsured.

Indeed, the OIG has expressly embraced discounts to the underinsured and uninsured, and confirmed that contractual arrangements related to same do not violate the fraud and abuse laws, including prohibitions on so-called rebates: "frankly, we do not know why lawyers advising hospitals would tell them that the fraud and abuse laws are an impediment to discounts to the uninsured. Such discounts do not violate the fraud and abuse laws. We have never taken any enforcement action in this area." *Id*. at 116. Indeed, in 2004, Lewis Morris, the Chief Counsel to the Inspector General, testified before Congress that there is absolutely no impediment to providers to offer discounts to patients who cannot afford to pay for their care. https://oig.hhs.gov/documents/testimony/80/20040624_-_Morris.pdf. This is directly in line with the OIG Advisory Opinions and other federal guidance we provided to MFD in the DAR Rebuttal (pp.6-7).

The OIG is authorized to exclude providers from participation in federal health care programs if the provider or supplier "*charges* Medicare or Medicaid substantially more than it usually charges other customers." *Id*. at 3 (emphasis added). Of course, this provision is analogous to the "charge" regulation cited by the MFD. In discussing the excessive charges exclusion authority, Mr. Morris testified that:

> Some providers have expressed concern that discounting to uninsured patients might skew their "usual charges" to other customers and possibly subject them to exclusion under this provision. Let me assure you this is not the case. OIG has never excluded or even contemplated excluding any provider or supplier for offering discounts to uninsured patients or other patients who cannot afford their care.

Presumably now recognizing that its "charge" argument under N.J.A.C. 10:61-1.7 is complete and total idiocy (and again refusing to provide any corresponding legal analysis, despite multiple requests from Truetox to do so), MFD now pivots to "clarifying" that that same conduct is violative of N.J.AC. 10:61-2.4. So again, let us start with the basics. A rebate in the healthcare reimbursement context is typically a payment made after a sale in exchange for meeting certain conditions set forth in the original sale agreement. New Jersey's prohibition on laboratory rebates explains that "rebates shall include refunds, discounts, or kickbacks, whether in the form of money, supplies, equipment, or other things of value." N.J.A.C. 10:61-2.4. The regulation then concludes that "laboratories shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved."

The MFD's "clarification" is that the DAR did not contain the "other considerations" language from the "Rebate regulation." So, apparently, the MFD reasons that the "other considerations" language prohibits Truetox's contractual discounts for its uninsured patients. The MFD's argument is facially illogical because if the MFD found issue with Truetox's contractual discounts under this regulation, it would not need the encompassing language of "other considerations." Indeed, the regulation prohibits discounts. But of course, the *discount* this regulation prohibits is not the sort Truetox provides. Rather, it is well-established that a discount

in the form of a rebate under the regulation contemplates a refund after the full-price sale of the healthcare service or product is made. This is plainly inapplicable.

More importantly, the authorizing statute that restricts "rebates" in the clinical laboratory setting, N.J.S.A. 45:9-42.42d, states that: "no person shall either personally, or through an agent, solicit referral of specimens to his or any other clinical laboratory or contract to perform clinical laboratory examinations of specimens in a manner which offers or implies an offer of rebates to a person or persons submitting specimens, other fee-splitting inducements, participation in any fee-splitting arrangements, or other unearned remuneration." *Id*. Simply put, MFD cannot plausibly allege that managed care agreements, prompt pay discounts, and indigency discounts are "unearned remuneration" to any facility Truetox services. *See* DAR Objection pp. 5-7. So no corrective action plan is necessary with respect to Truetox's contractual agreements to expand access to reliable drug testing for HMO members and the indigent.

Second, color us shocked that MFD is doubling-down on its prior finding that Truetox "engaged in other activities that violated the rebate prohibition regulation." We disposed of this nonsense previously. *See* DAR Objection pp. 18-20. We have nothing further to add other than to note that we are not entirely sure how you can refer to this process as an "audit" if you simply ignore every shred of paper or clarifying information you and your team are provided. Either way, the educational grant and sponsorships of [redacted]'s annual golf outing identified in the DAR are not violative of any law, let alone N.J.A.C. 10:61-2.4. And there is no corrective action plan necessary with respect to Truetox's charitable giving.

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Thank you for your attention in this matter. As always, we are happy to discuss any of these issues at any time. But based on the consistent refusal of MFD's audit team to engage in any meaningful dialogue with us, we are resigned to having to wait until after the conclusion of the audit to do so—which, frankly, is absurd.

Respectfully yours,

BUTTACI LEARDI & WERNER LLC

John W. Leardi
A Member of the Firm

JWL/npa
cc: Client File (00793.04000)