Truetox's Comments and OSC's Responses

Truetox submitted written comments in response to OSC's Draft Audit Report (DAR). These comments challenged OSC's conclusions regarding Truetox's charges to Medicaid exceeding charges to other groups or individuals for identical services, OSC's inclusion of Truetox's self-disclosed claims, OSC's findings regarding Truetox's deficient documentation and billing irregularities, OSC's references to Truetox's use of provider-specific blanket orders, OSC's findings regarding Truetox's violations of the rebate regulation, and OSC's sampling and extrapolation procedures. In addition, Truetox submitted comments in response to OSC's revision of the rebate section of the DAR and the corresponding change that OSC made in Recommendation #8 (Truetox's supplemental response is appended to its original response; see Appendix A). OSC organized Truetox's comments by subject matter and responded to each point. Set forth below are Truetox's point-by-point objections and OSC's responses.

Truetox's Objection No. 1

Truetox's Contractual Discounts for Uninsured Patients

Relating to Audit Finding I – Charge to Medicaid Exceeds Charge to Other Groups or Individuals for Identical Services

"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.'

"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.[1] 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

[1] 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.

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 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."

OSC's Response to Truetox's Objection No. 1

Truetox's objection fails to grasp the plain meaning of the reimbursement regulation, *N.J.A.C.* 10:61-1.7, which provides that "[i]n no event shall the charge to the Medicaid/NJ FamilyCare program exceed the provider's charge for identical services to other groups or individuals." Truetox effectively argues this regulation into non-existence with an exception that does not exist in the regulation that would allow Medicaid to pay more than others provided that the others paid the charges in accordance with a contract. Accordingly, OSC stands behind its finding that Truetox violated this regulation when it charged other groups far less than it charged the Medicaid program for identical services. Truetox bases its position on the premise that charging a "contractually-negotiated discount" instead of its "standard charge" to referring facilities for laboratory testing complies with *N.J.A.C.* 10:61-1.7. That reading of the regulation, however, ignores the plain language of the regulation, which unequivocally eliminates any such exception in stating that "in no event" will providers receive reimbursement from Medicaid at a rate higher than the provider's charge to other groups or individuals for the same services. Truetox fully acknowledges it has agreements with referring facilities and managed care organizations through which Truetox accepts a reduced fee as payment for its services. This means that NJ Medicaid, a taxpayer-funded program for the medically needy, reimbursed Truetox as much as $250 for the same service that Truetox charged other groups a mere $3.

Truetox also misconstrues the extensive fifty-year history and evolution of the regulation at issue. The gravamen of Truetox's position is that Medicaid's reimbursement is based on "usual and customary" charges. Truetox's argument that it may base its Medicaid charges on its customary or standard charges, regardless of what it charges others, is contrary to Medicaid's express rejection of reimbursement based on "customary" charges as set forth in amendments to the regulation in 1975. *See* 7 *N.J.R.* 420(a).

A review of the history of New Jersey's Medicaid reimbursement rule demonstrates the critical shortcomings of Truetox's position. While Truetox claims that the clause in *N.J.A.C.* 10:61-1.7, "[i]n no event shall the charge to the Medicaid/NJ FamilyCare program exceed the provider's charge for identical services to other groups or individuals," was added on February 5, 1996, the rule has existed since 1971 and the operative language in the rule has existed since 1975. The history of the rule changes frames the meaning and intent of the language added in 1996. *See* 3 *N.J.R.* 83(b), *see also* 7 *N.J.R.* 420(a), *see also* 28 *N.J.R.* 1054(a).

The reimbursement rule for laboratories was originally codified at *N.J.A.C.* 10:61-1.5, Basis of payment. 3 *N.J.R.* 83(b). Under the initial rule, Medicaid reimbursed laboratories based on the "customary charge." The original rule, effective April 21, 1971, stated in part:

> Reimbursement shall be on the basis of the customary charge, not to exceed an allowance determined reasonable by the Commissioner of Institutions and Agencies, and further limited by Federal policy relative to payment of practitioners and other individual providers. In no event shall the payment exceed the customary charge to practitioners for the specific service.
> [*N.J.A.C.* 10:61-1.5, Basis of payment. 3 *N.J.R.* 83(b).]

In 1975, the rule underwent significant changes. The amended rule, effective August 1, 1975, stated in part:

> Reimbursement shall be on the basis of the lowest professional charge, not to exceed an allowance determined reasonable by the Commissioner of Institutions and Agencies, and further limited by Federal policy relative to payment of practitioners and other individual providers. In no event shall the charge to Medicaid for a laboratory functioning as a service laboratory exceed the lowest charge to other providers for the specific service.
> [*N.J.A.C.* 10:61-1.5, Basis of laboratory payment. 7 *N.J.R.* 420(a).]

The 1975 amendment most notably changed the basis of Medicaid's reimbursement to laboratories from the "customary charge" to the "lowest professional charge." *See* 7 *N.J.R.* 420(a); *see also* 3 *N.J.R.* 83(b). Furthermore, the rule was changed so that the laboratory's charge to Medicaid could not "exceed the lowest charge to other providers for the specific service." *See* 7 *N.J.R.* 420(a). The 1975 amendments, to what was then codified at *N.J.A.C.* 10:61-1.5, reflect a significant shift in the direction of the rule by the Division of Medical Assistance & Health Services (DMAHS) - NJ Medicaid would no longer reimburse laboratories based on their "customary charge." *See* 7 *N.J.R.* 420(a); *see also* 3 *N.J.R.* 83(b). Rather, laboratories were to be reimbursed based on the "lowest professional charge," never to exceed a laboratory's lowest charge to other providers for the service. *Ibid.* In other words, a laboratory was required to charge Medicaid the laboratory's <u>lowest rate</u>.

The next relevant change occurred in 1996. At that time, the rule was re-codified as *N.J.A.C.* 10:61-1.7, which contains the current version of the rule. The amended rule, effective February 5, 1996, stated in pertinent part:

> Reimbursement shall be on the basis of the lowest professional charge, not to exceed an allowance determined reasonable by the Commissioner of Human Services, and further limited by Federal policy relative to payment of clinical laboratory services. The maximum fee schedule (allowance) is set forth at *N.J.A.C.* 10:61-3. In no event shall the charge to the New Jersey Medicaid program exceed the provider's charge for identical services to other groups or individuals.
> [*N.J.A.C.* 10:61-1.7. 28 *N.J.R.* 1054(a).]

In 1996, the rule provided that Medicaid would continue to reimburse laboratories based on their "lowest professional charge." *See* 28 *N.J.R.* 1054(a). However, the 1996 amended rule also expanded on an important prohibition already included in the regulation. *See* 28 *N.J.R.* 1054(a); *see also* 7 *N.J.R.* 420(a). Specifically, the amendment revised the regulation so that a laboratory's charge to Medicaid could not exceed the laboratory's charge for identical services to other groups or individuals, not just the laboratory's lowest charge to other providers, as in the previous version of the rule. *Ibid*. The plain language of the regulation, and its evolution by way of amendments, leave no doubt as to its meaning or intent.

DMAHS' intent was also expressed during the rulemaking for the 1996 rule. When commenters requested clarification of the "changed implementation language" in *N.J.A.C.* 10:61-1.7, the agency responded:

> 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)]

The agency specified that the changes were "to make clear that the charge to Medicaid shall not exceed the provider's lowest charge for the service." *See* 28 *N.J.R.* 1054(a). DMAHS' response to the inquiry was clear and unambiguous. DMAHS notably did not make any exceptions for laboratories that maintain a multiple- or tiered-pricing structure, nor for laboratories offering "discounts" to their referring providers. The regulation does not afford any exemption at all. Plainly, laboratories must not charge Medicaid more than the lowest amount they charge for the same services to any other group or individual, without exception.

Since 1996, there has been only one additional amendment. In 2006, DMAHS amended the rule to reflect technical changes. The amended rule, effective January 17, 2006,

stated:

> Reimbursement shall be on the basis of the lowest professional charge, not to exceed an allowance determined reasonable by the Commissioner of Human Services, and further limited by Federal policy relative to payment of clinical laboratory services. The maximum fee schedule (allowance) is set forth at N.J.A.C. 10:61-3. In no event shall the charge to the Medicaid/NJ FamilyCare program exceed the provider's charge for identical services to other groups or individuals. [*N.J.A.C.* 10:61-1.7. 38 *N.J.R.* 807(a).]

OSC's interpretation of the regulation is based on the clear and unambiguous meaning of the regulation and on the rulemaking history. Truetox's position ignores the plain language of the rule and the lengthy fifty-year history and amendments to the reimbursement rule. Truetox's position relies on reimbursement based on "usual and customary" charges, but such a position is untenable after 1975. At one time Medicaid may have reimbursed laboratories based on customary charges, but the agency departed from that policy more than 45 years ago when it decided that Medicaid would not pay a laboratory more than the laboratory's lowest charge for the same service. The evolution of this rule that resulted from the various amendments, DMAHS' rule making comments, and the plain language of the rule all support OSC's interpretation of the rule.

Truetox's reliance on a federal exclusion law is also unavailing. Truetox points to the federal exclusion statute, 42 *U.S.C.* 1320a-7, in support of its position. Specifically, Truetox references 42 *U.S.C.* 1320a-7(b)(6)(A) which grants the U.S. Department of Health and Human Services, Office of Inspector General (OIG) authority to exclude a provider from participation in Medicare and State health care programs if the provider charges a Federal or State healthcare program substantially more than the provider's usual charges or substantially in excess of the provider's cost for items or services. In addition, Truetox cites guidance and advisory opinions issued by the OIG that interpret that federal statute. Truetox's reliance on the federal statute and OIG opinions is misplaced. First, the federal statute, 42 *U.S.C.* 1320a-7, sets forth various bases for the OIG to exclude individuals and entities from participation in Medicare and State healthcare programs. OSC is not seeking to exclude Truetox from Medicaid and, thus, this federal rule is not applicable here. Moreover, Medicaid's laboratory reimbursement rule has nothing to do with exclusion from healthcare programs and is clearly not the state counterpart of the federal exclusion rule, as Truetox suggests. New Jersey addresses exclusion from Medicaid in *N.J.A.C.* 10:49-11.1, which is outside the scope of this audit. Similarly, the OIG advisory opinions cited by Truetox interpret the federal government's use of its exclusion authority. OIG advisory opinions are not binding on OSC. *See* 42 *C.F.R.* 1008.59(b). Even if the federal rules and guidance were binding on OSC's audit of a New Jersey Medicaid provider, they do not support Truetox's position because OSC is not seeking to exclude Truetox from participation in the Medicaid program.

Finally, Truetox's characterization of a telephone call between OSC's Audit Supervisor and Mr. Patrick Bohan, the President and CEO of Truetox, is inaccurate and irrelevant. The purpose of the phone call was to request documentation from Truetox so OSC could accurately assess Truetox's compliance with *N.J.A.C.* 10:61-1.7. Prior to the call between OSC and Mr. Bohan, OSC obtained consent from Truetox's legal counsel to contact the provider directly for such requests. Also, OSC speaks through its formal reports, which are issued in accordance with statutory authority after appropriate review, not through the informal asides of an employee conducting audits who is surreptitiously, and without consent, being recorded. The employee's comments raised the possibility of evaluating Truetox's compliance with *N.J.A.C.* 10:61-1.7 by reference to some other higher price used by Truetox. He correctly identified the decision maker on these issues as someone other than himself and merely sought to elicit information from Truetox that was relevant to the audit. That conversation is not relevant to the substantive findings in this report, which are based on facts evidenced by documents and data provided by Truetox.

In conclusion, Truetox's comments do not provide any grounds for OSC to modify its basis for reimbursement finding, which is anchored in the plain meaning of the laboratory reimbursement rule. OSC found that Truetox violated that rule and, thus, it is requiring Truetox to correct this failing and reimburse the Medicaid program for the noted claims.

Truetox's Objection No. 2

Inclusion of Self-Disclosed Claims
Related to Truetox's Self-Disclosure

"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."

OSC's Response to Truetox's Objection No. 2

Despite having filed its self-disclosure after being notified that OSC had initiated this audit, Truetox objects to OSC including 16 claims in its audit findings, arguing that these claims should have been removed because they were part of Truetox's self-disclosure. Under Truetox's view of the self-disclosure process, a provider could avoid addressing an audit finding simply by disclosing facts involving the finding during the pendency of the audit. That position is contrary to OSC's Self-Disclosure Protocol and if followed would undermine OSC's efforts to detect waste, fraud, and abuse in the Medicaid program. OSC rejects Truetox's objection and will retain these 16 claims in its analysis.

Truetox was on notice of OSC's audit on or about October 4, 2018. OSC provided further notice to Truetox that it was being audited through an in-person meeting held on October 25, 2018 and during additional on-site visits on November 13 and 14, 2018. Subsequently, Truetox filed a self-disclosure dated January 31, 2019. Pursuant to OSC's Self-Disclosure Protocol, matters related to an ongoing audit of a provider generally are not eligible for resolution under the self-disclosure protocol; however, unrelated matters disclosed

during an ongoing audit may be eligible for processing under the self-disclosure protocol.[2]

The 16 claims identified in Truetox's disclosure were related to the audit. Through the aforementioned encounters, OSC placed Truetox on notice of the precise scope and objective of OSC's audit, including which types of claims were the subject of OSC's audit and the relevant dates of services. Indeed, during the in-person meeting on October 25, 2018, OSC informed Truetox that the audit would include a review of the laboratory's billing of definitive drug testing in accordance with American Medical Association (AMA) guidelines and requested and received Truetox's billing software manual. Also, during the meeting, OSC directed Truetox's attention to a similar audit that appears on OSC's website, also involving an adverse finding by OSC of the laboratory's billing of definitive drug testing in accordance with AMA guidelines. Further, OSC received documentation from Truetox for the 16 claims in question during the on-site visits in November of 2018. In its self-disclosure, Truetox in fact acknowledged that it began its internal review using the exact sample episodes that OSC had requested. Accordingly, Truetox's subsequent "self-disclosure" on January 31, 2019, which included 16 overpaid claims that were already subsumed within OSC's audit, does not require OSC to exclude the 16 claims from the audit findings, or handle the claims differently, as Truetox suggests.

OSC has broad discretion on the treatment of self-disclosed overpayments by Medicaid providers and must evaluate each case on an individual basis. The disclosed claims were related to the audit, and Truetox was previously on notice of the focus of OSC's audit. Additionally, Truetox's references to the OIG's Provider Self-Disclosure Protocol (SDP) are misplaced because the OIG's SDP applies to disclosures made to the OIG, not to State Medicaid programs. In sum, OSC's inclusion of the 16 claims in the audit findings under the circumstances is entirely consistent with OSC's Self-Disclosure Protocol.

Truetox's Objection No. 3

Miscellaneous Documentation Issues and Purported Billing Irregularities

Relating to Audit Finding II – Deficient Documentation and Billing Irregularities for Presumptive and Definitive Drug Testing

"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

[2] Medicaid Resources → When and How to Self-Disclose Medicaid Waste, Fraud, and Abuse (https://nj.gov/comptroller/resources/index.shtml)

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] [30], and [redacted], date of service [redacted], and Sample Number [redacted] [34]), 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] [23], [redacted], date of service [redacted], and Sample Number [redacted] [12]; [redacted], date of service [redacted], and Sample Number [redacted] [9]; [redacted], date of service [redacted], and Sample Number [redacted] [20]; and [redacted], date of service [redacted] and Sample Number [redacted] [17]), 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][35], 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. Presumptive v. Definitive UDT.

"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][43], 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[3], are simply incorrect. The following chart is illustrative:

Px	Sample	Date	Audit	Response
[redacted]	[redacted] [76]	[redacted]	G0480	8 confirmations (Anticonvulsants panel includes two drug classes – Gabapentin and Pregabalin, which are 2 classes), G0481 was correctly billed
[redacted]	[redacted] [64]	[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
[redacted]	[redacted] [47]	[redacted]	G0480	8 confirmations, G0481 was correctly billed
[redacted]	[redacted] [21]	[redacted]	G0480	G0480 was the code billed
[redacted]	[redacted] [75]	[redacted]	G0480	10 confirmations, (Gabapentin is 2 classes), G0481 was correctly billed
[redacted]	[redacted] [40]	[redacted]	G0480	8 confirmations (Gabapentin is 2 classes), G0481 was correctly billed
[redacted]	[redacted] [22]	[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."

[3] Two samples, [redacted], date of service [redacted] and Sample Number [redacted] [26]; and [redacted], date of service [redacted] and Sample Number [redacted] [33], 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.

OSC's Response to Truetox's Objection No. 3

OSC found 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. OSC found that 1 requisition was entirely missing a signature, 4 requisitions were signed by Certified Alcohol and Drug Counselors (CADC), 1 requisition was signed by a program aide, and 1 requisition was signed by a specimen collector.

Truetox responded that "the ordering provider's signature is very clearly set forth on the requisition form" on two sample episodes that OSC identified as failing to include the signature of the physician or other licensed practitioner. The two requisitions that Truetox referenced in its response only include two of the four test requisitions signed by CADCs. The error on those requisition forms was not that the signature was missing, but rather that the requisition forms were not signed by a physician or appropriately licensed practitioner. The requisitions were signed by CADCs who are not authorized to order drug tests. *N.J.A.C.* 10:61-1.2 defines clinical laboratory services as "professional and technical laboratory services provided by an independent clinical laboratory when ordered by a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by the laws of the state in which he or she practices." *N.J.A.C.* 13:34C-3.1 states that a CADC shall practice under the supervision of a licensed clinical alcohol and drug counselor (LCADC). The regulation further differentiates the scope of practice of a CADC and LCADC. The scope of practice of a CADC includes "the collection of specimen (urine, hair, or saliva) samples for drug testing," whereas the scope of practice of an LCADC includes "the ordering and collection of specimen (urine, hair, or saliva) samples for drug testing" *Ibid.* (Emphasis added.) CADCs signed the requisitions, but the scope of practice as provided by regulation does not include the ordering of specimen for drug testing. Therefore, Truetox failed to comply with *N.J.A.C.* 10:49-5.5(a)17, as claims for services ordered in violation of licensure statutes, rules, and/or regulations are excluded from payment under the New Jersey Medicaid and NJ FamilyCare-Plan A program. Additionally, the CADCs were not listed as the referring provider on the claim submitted to Medicaid. Instead, Truetox listed a different referring provider on the claim. Pursuant to *N.J.A.C.* 10:49-9.8(a), "all providers shall certify that the information furnished on the claim is true, accurate, and complete."

For the remaining sample episodes, Truetox states that the orders were received verbally by the onsite Truetox Collector at the time the sample was taken and processed. These sample episodes include the remaining 2 requisitions signed by CADCs, 1 requisition signed by a program aide, 1 requisition signed by a specimen collector, and 1 requisition that did not contain a signature. Truetox did not provide sufficient documentation to support that these claims were ordered by a physician or other licensed practitioner.

N.J.A.C. 10:61-1.6(b)3 states that "[t]elephoned or other oral laboratory orders are also permissible, but shall be followed up with a written or electronic request within 30 days of the telephone or other oral request, which shall be maintained on file with the clinical laboratory." However, the requisitions Truetox submitted to OSC in support of those verbal orders were not signed by the physician or other licensed practitioner whose name appeared on the claim submitted to Medicaid. Pursuant to *N.J.A.C.* 10:49-9.8(a), "all providers shall certify that the information furnished on the claim is true, accurate, and complete." Further, *N.J.A.C.* 10:61-1.6(b)3 states that "[i]f the laboratory is unable to obtain the written or electronic request, it must maintain documentation of its efforts to obtain them." Truetox states that two of the ordering providers, accounting for four sample episodes, are now deceased, and Truetox was therefore unable to confirm their prior verbal orders to Truetox's onsite collectors. However, Truetox did not provide any contemporaneously dated documentation to support its efforts to obtain the ordering physician or licensed practitioner's signature. Lastly, on April 6, 2020, Truetox conceded that there is no signature on the requisition for the final sample episode.

OSC also found 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. OSC reviewed the onboarding documentation that Truetox resubmitted to support that providers were onboarded prior to tests being ordered and performed. In conjunction with reviewing the onboarding documentation, OSC also corresponded and met with Truetox's referring providers to understand the providers' processes of ordering drug tests and to gain reasonable assurance that the documentation provided to OSC by Truetox was accurate. OSC also reached out to Truetox's referring providers' facilities to verify employment dates of its referring physicians or licensed practitioners. The table below summarizes the employment dates OSC received from Truetox's referring providers and information from the attestations provided by Truetox.

Table I
Employment Dates and Attestations

Sample Number	Date of Referring Provider Response to MFD	Employment Information of Ordering Physician of Licensed Practitioner from Referring Provider	Information from Attestations Provided by Truetox (April 2020)
68	6/4/2019	April 10, 2015 to September 29, 2016	No attestation received
82	10/24/2019	Left employment May 2016	No attestation received
29	10/10/2019	April 7, 2015 to June 30, 2015	Attestation indicates incorrect Medical Director listed on requisition
41	4/19/2019	Resigned end of June 2017	Attestation indicates incorrect Medical Director listed on requisition
79	10/10/2019	April 7, 2015 to June 30, 2015	Attestation indicates incorrect Medical Director listed on requisition
35	10/3/2019	1993 to December 2016	Attestation received for a different date of service
51	10/3/2019	1993 to December 2016	Attestation indicates correct Medical Director listed on requisition (see below)

As of the issuance of this FAR, OSC has not received documentation to support two of the sample episodes in question (Sample Numbers 68 and 82). For three of the remaining five sample episodes (Sample Numbers 29, 41, and 79), the attestations submitted by Truetox confirmed that the ordering physician or licensed practitioner listed on the requisitions were incorrect. The incorrect referring provider was also reflected on the claim submitted to Medicaid. Pursuant to *N.J.A.C.* 10:49-9.8(a), "all providers shall certify that the information furnished on the claim is true, accurate, and complete." OSC further reviewed the two sample episodes (Sample Numbers 35 and 51) for which the attestations, albeit one for an incorrect date of service, indicated that the ordering physician or licensed practitioner was employed on the corresponding dates of services. Due to conflicting information provided by the same Clinical Services Director in the October 2019 email to OSC and the April 2020 attestations from Truetox, OSC took additional measures to verify the referring physician's employment dates. OSC reviewed the referring provider's employee time cards, human resource records, and scheduling systems, wage information in the Claim and Wage Record System, and requested and received an email from the physician in question with his employment dates. In doing so,

OSC gained reasonable assurance that the ordering physician was no longer engaged in patient care on the dates of services for the two sample episodes.

OSC found that for 28 of the 82 sample episodes, Truetox failed to provide documentation to support that a referring physician or licensed practitioner had ordered a definitive drug test. Truetox claims that it is "ludicrous" to assert that "panel" is not descriptive enough to describe definitive testing and states, "A 'panel' has always referred to a definitive test performed on a LCMS instrument, which is better known as a confirmation." However, AMA's CPT code 80307, billed by Truetox and reimbursed by Medicaid for presumptive drug tests, lists LC-MS as an instrument that may be used to test presumptive drug tests, which shows that the LC-MS instrument is not specific only to definitive drug tests. (See Exhibit A for code description.) Moreover, *N.J.A.C.* 10:61-1.2 defines a panel as "laboratory tests that are associated with organ or disease oriented areas, such as organ 'panels' (for example, hepatic function panel). The tests listed with each panel identify the defined components of that panel." The definition of panel in the regulation does not indicate that "panel" refers to a definitive test.

Truetox also states 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 . . . Truetox updated its LIMS to add 'confirmation' to the requisition where indicated that a specific drug class 'panel' needed to be tested." As a result, the electronic requisitions that were resubmitted to OSC were different from the original requisitions submitted to OSC and now include the word "confirmation" on all panel testing. A laboratory is not permitted to alter or change prior requisitions after a system update takes place. Pursuant to *N.J.A.C.* 10:61-1.6(b)2, "[a] test request also may be submitted to the laboratory electronically, if the system used to generate and transmit the electronic order has adequate security and system safeguards to prevent and detect fraud and abuse and to protect patient confidentiality. The system shall be designed to prevent and detect unauthorized access and modification or manipulation of records, and shall include, at a minimum, electronic encryption." (Emphasis added.) A requisition is an order from a physician or licensed practitioner on a specific date in time and, therefore, Truetox's system update should not have generated requisitions that differed from the requisitions on the original date of service. OSC's review of Truetox's original documentation in conjunction with correspondence with its referring providers found that none of the sample episodes in question contemporaneously documented that a referring physician or licensed practitioner had ordered a definitive drug test.

OSC also found that in 25 of the 82 sample episodes Truetox (1) 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. Truetox concedes it miscoded

two sample episodes (Sample Numbers 26 and 33). The table below summarizes the seven sample episodes that Truetox refuted. As of the issuance of this FAR, Truetox has not provided any supporting documentation for the remaining 16 sample episodes.

Table II
Definitive Drug Tests Ordered and Tested

Sample Number	Codes Billed and Paid	Correct Codes Per Audit	# of Definitive Drug Classes Ordered	# of Drug Classes Tested
76	80307, G0481	80307, G0480	6	9
64	80307, G0481	80307, G0480	2	8
47	G0479, G0481	G0479, G0480	1	9
21	G0480	80307, G0480	3	8
75	80307, G0481	80307, G0480	4	11
40	G0479, G0481	G0479, G0480	4	8
22	80301, 80361, 80354, 80365, 80372, 80346	G0479	0	5

The table above for the seven refuted sample episodes shows that the number of drug classes tested exceeds the number of drug classes ordered. OSC adjusted or downcoded these claims to conform to the level of definitive drug testing that was ordered by the referring physician or licensed practitioner, as supported by the documentation reviewed. For example, Truetox states that it properly billed AMA's definitive HCPCS code G0481 (used for billing 8 to 14 drug classes) for Sample Number 76. OSC agrees that gabapentin and pregabalin are two drug classes based on the AMA's drug classifications. However, MFD found that only six of the nine drug classes tested were ordered by the referring provider's physician based on the signed account set-up form between Truetox and its referring provider. Therefore, OSC downcoded the claim to AMA's definitive HCPCS code G0480 (used for billing 1 to 7 drug classes). In another example, Sample Number 21, Truetox billed AMA's definitive HCPCS code, G0480. However, OSC found that the ordering physician also ordered presumptive drug tests in conjunction with definitive drug tests. Since Truetox performed presumptive drug tests but had not billed for a presumptive code, OSC correctly coded the claim to include a presumptive drug test. Truetox was underpaid in this circumstance and OSC gave credit to Truetox for the underpayment. OSC reviewed Truetox's documentation and correctly adjusted and downcoded the claims in question. Pursuant to *N.J.A.C.* 10:49-5.5(a)13, Medicaid will not cover services billed for which the corresponding records do not adequately and legibly reflect the requirements of the procedure code utilized by the billing provider. In accordance with *N.J.A.C.* 10:49-5.5(a)13(i), "[f]inal payment shall be made in accordance with a review of those services actually documented in the provider's health care record."

Truetox's Objection No. 4

Use of Account Consultation Protocols

Relating to Audit Finding IV - Use of Provider-Specific Blanket Requests

"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.[4] 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

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

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.'"

OSC's Response to Truetox's Objection No. 4

OSC's audit revealed that Truetox routinely entered into blanket orders with its referring providers for which it conducted laboratory testing. These blanket orders stemmed from a practice in which Truetox and its referring providers established a predetermined set of drug test orders in their account set-up forms. The blanket orders provided for nearly identical drug testing of all Medicaid beneficiaries, by default, regardless of the beneficiaries' particular substance problems and history. OSC identified Truetox's use of blanket orders as an area of significant concern because it results in improper and unnecessary drug testing and wasteful Medicaid payments. Contrary to Truetox's assertion that OSC's concern is "profoundly frivolous," the federal government and New Jersey's Medicaid program have prohibited blanket orders. Pursuant to Local Coverage Determination, "Controlled Substance Monitoring and Drugs of Abuse Testing," the federal government prohibited blanket orders in the Medicare program in New Jersey. *See* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35006. Furthermore, the state recently addressed this through a DMAHS issued Newsletter that also prohibited blanket orders. *See* https://www.njmmis.com/downloadDocuments/31-11.pdf. In short, the issue of waste caused by the use of blanket orders falls squarely within OSC's Medicaid program integrity oversight mandate.

Truetox further claims it was acting in conformance with guidelines established in a Consensus Statement, "Appropriate Use of Drug Testing in Clinical Addiction Medicine," published by the American Society of Addiction Medicine (ASAM) in 2017.[5] However, Truetox could not have relied on the Consensus Statement to justify its practices because the guidance was adopted by ASAM on April 5, 2017, nearly two and a half years after the audit period had commenced.

Moreover, the Consensus Statement recommended addiction treatment programs establish routine panels but made clear that test selections should be "adjusted based on the patient's drug of choice, prescribed medications, and drugs commonly used in the patient's geographic location and peer group." *Ibid*. The Statement underscored the need for test selection to be "individualized based on a patient's clinical needs and their self-reported substance use." *Ibid*. Furthermore, the recommendations do not supersede any federal or state regulations. *Ibid.* OSC is not seeking a monetary recovery of the claims

[5] https://www.asam.org/docs/default-source/quality-science/the-asam-appropriate-use-of-drug-testing-in-clinical-addiction-medicine-full-document.pdf?Status=Temp&sfvrsn=700a7bc2_2

based on blanket orders, but notes these concerns because laboratories, such as Truetox, must ensure that the tests ordered are medically necessary in order to prevent wasteful spending of taxpayer funds. *See N.J.A.C.* 10:49-5.5(a)(13)(i).

Lastly, Truetox argues that OSC's finding 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 "unfounded nonsense." This finding is addressed more fully above in "Truetox's Objection No. 3," but it must be noted that the evidence gathered throughout the entirety of the audit provided OSC with a reasonable basis for the findings contained in this Final Audit Report.

Truetox's Objection No. 5

Alleged Lab Rebates and Charitable Contributions

Relating to Audit Finding V – Laboratory Rebates
Initial Response

"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 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."

Alleged Lab Rebates and Charitable Contributions

Relating to Audit Finding V – Laboratory Rebates
Supplemental Response

"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."

OSC's Response to Truetox's Objection No. 5

Pursuant to *N.J.A.C.* 10:61-2.4, rebates are prohibited under the Medicaid program. "Rebates shall include refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value." *Ibid*. OSC found that Truetox violated the rebate prohibition based on evidence that Truetox gave discounts to its referring providers. In addition to finding that Truetox offered a rebate by charging its referring providers less than Medicaid for identical services, OSC also found Truetox violated *N.J.A.C.* 10:61-2.4 when it sponsored an employee from one of its referring providers to attend the four-day 2016 International Nurses Society on Addiction Conference in Las Vegas, Nevada. *N.J.A.C.* 10:61-2.4 states, in part, that "laboratories shall not . . . provide personnel or other considerations to a physician or other practitioner." The conference was a form of consideration provided to one of Truetox's referring providers. The OIG guidance cited by Truetox in defense of this violation is inapplicable, as the federal guidance sets forth the OIG's views on compliance programs for the pharmaceutical industry. *Ibid*. This inapplicable federal guidance does not relieve Truetox of its obligations to comply with Medicaid's state regulation prohibiting rebates.

Lastly, OSC found Truetox violated *N.J.A.C.* 10:61-2.4 because Truetox contributed $6,000 to another referring provider's miniature golf fundraising event. Truetox admits it made these contributions, and an additional $15,500 in contributions to this referring provider during a time period outside the scope of OSC's audit. Truetox defends these financial contributions, claiming that "provider contributions are permissible so long as the donation fits within the *Bona Fide* Charitable Donations exception of the Federal Stark Law." Truetox also claims that its financial contributions to referring providers are not rebates because they would not be considered such under the Federal Anti-Kickback Statute (AKS). Once again, Truetox's reliance on federal laws to evade its responsibilities under a state Medicaid regulation is misplaced. OSC's audit did not find or allege that Truetox violated the Federal Stark Law or the AKS. Rather, OSC found that Truetox failed to comply with *N.J.A.C.* 10:61-2.4, a state Medicaid regulation that prohibits rebates and other considerations, which notably does not contain any exceptions. Truetox was required to comply with New Jersey's rules and may not rely upon inapplicable federal laws to justify its noncompliance with a state regulation.

It is important to note that the audit performed by OSC did not exhaustively review Truetox's contracts with referring providers, did not obtain a list of all things of value provided by Truetox to referring providers, and did not review all of Truetox's corporate donations. The limited relevant information available to OSC alone, however, is reflective of corporate practices that violate *N.J.A.C.* 10:61-2.4. As a participant in the Medicaid program, and as an entity that is entrusted to bill Medicaid and to receive public funds, Truetox is not permitted to give rebates or other considerations to its referring providers. Prohibitions of such practices commonly are imposed on public employees and government contractors to ensure the integrity of government programs, to prevent fraud, waste, and abuse.

OSC's concerns regarding rebates and other considerations provided by Truetox to its referring providers should be viewed in the broader context of this audit. They are especially problematic in the context of Truetox's practices of charging Medicaid substantially more than others and in the context of Truetox's use of blanket orders that lead to unnecessary testing. Each of these practices alone is troubling and contrary to Medicaid rules, but the collective impact of these practices substantially increases the risk of fraud, waste, and abuse in the Medicaid program.

Truetox's Objection No. 6

Flawed Statistical Extrapolation

Relating to the Audit's Statistical Sample and Extrapolation Method

"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."

OSC's Response to Truetox's Objection No. 6

OSC provided Truetox with all of the data and tools necessary to analyze every aspect of OSC's random sampling and extrapolation (RS&E) process and to recreate it entirely, step-by-step. Truetox acknowledges that it only performed a "cursory review" of the extrapolation data. Truetox failed to offer any basis for OSC to revise its RS&E approach or results.