Audit of Truetox Laboratories, LLC's Medicaid Billing Practices

Medicaid Fraud Division

For the period of January 1, 2015 through June 30, 2018

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NEW JERSEY
OFFICE OF THE STATE
COMPTROLLER

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I. Executive Summary

As part of its oversight of the Medicaid and New Jersey FamilyCare programs (Medicaid), the New Jersey Office of the State Comptroller, Medicaid Fraud Division (OSC) conducted an audit of Truetox Laboratories, LLC (Truetox), an independent clinical laboratory, to determine whether Truetox appropriately billed Medicaid for drug tests in accordance with applicable state and federal laws and regulations. OSC's audit was for the period from January 1, 2015 through June 30, 2018 (audit period).

OSC found that a high percentage of Truetox's claims failed to meet regulatory requirements. OSC's findings are divided into two groups: (1) instances in which Truetox's claims violated regulations and for which there is ascertainable monetary harm to the Medicaid program, and (2) other systemic or regulatory issues.

To initiate this audit, OSC statistically selected a sample of 82 episodes comprised of 198 unique claims of presumptive and/or definitive drug tests for which the State paid Truetox a total of $12,810. Each episode in the sample is comprised of either a single presumptive and/or definitive drug test code or multiple presumptive and definitive drug test codes with the same date of service for the same beneficiary. OSC selected the sample from a population of 140,772 episodes with 302,326 paid claims totaling $24,382,684 that the State paid to Truetox for presumptive and/or definitive drug testing. OSC identified multiple problems with the vast majority of these claims. The deficiencies that include an ascertainable monetary harm to the Medicaid program fall into three general categories, each of which is discussed below.

First, OSC found that for 70 of these 82 (85.4 percent) sample episodes, Truetox charged Medicaid an amount that exceeded its charge for identical services to other groups or individuals. Pursuant to *N.J.A.C.* 10:61-1.7, an independent clinical laboratory is prohibited from charging the Medicaid program more for a test or service than the laboratory charges another payer for an identical test or service. The difference between what the Medicaid program paid and the lowest amount that Truetox charged others for the same test is an overpayment that the laboratory must repay to the Medicaid program. OSC extrapolated the dollars in error for the 70 of 82 sample episodes, $11,161 of $12,810, across the sample universe of $24,382,684. Through this calculation, OSC determined that Truetox received an overpayment of $22,882,947.

Second, OSC found that 67 of the 82 (81.7 percent) sample episodes failed to comply with documentation and billing requirements, pursuant to *N.J.A.C.* 10:49-9.8, *N.J.A.C.* 10:61-1.6, and/or *N.J.A.C.* 10:49-5.5. These 67 sample episodes included 69 exceptions. Specifically, OSC found that Truetox: (a) failed to provide 1 test requisition for the date of service billed; (b) failed to ensure that 7 test requisitions contained the signature of the ordering physician or licensed practitioner; (c) failed to ensure that the ordering physician was engaged in patient care for the referring provider on the date the referring provider submitted the order on 7 requisitions; (d) failed to ensure that the beneficiary's gender was contained on 1 test requisition; (e) failed to maintain documentation that the referring physician actually ordered definitive drug tests on 28 test requisitions; and (f) incorrectly billed for a greater level of service than ordered or incorrectly billed a procedure code in 25 test requisitions. OSC extrapolated the dollars in error for the 67 of 82 sample episodes, $5,155 of $12,810, across the sample universe of $24,382,684. Applying this process, OSC calculated that Truetox received an overpayment of $9,124,535.

For purposes of ascertaining a total recovery amount for the findings related to the statistical sample discussed above, OSC extrapolated the consolidated dollars in error, $12,318 of $12,810, across the sample universe of $24,382,684. Through this calculation, OSC determined that Truetox received an overpayment of $23,895,319, which it must reimburse to the Medicaid program.

Third, in addition to the findings outlined above, OSC found that Truetox violated *N.J.A.C.* 10:49-9.8 and failed to adhere to the American Medical Association's (AMA) Current Procedural Terminology (CPT) guidelines, the AMA's Healthcare Common Procedure Coding System (HCPCS) guidelines, and the Centers for Medicare & Medicaid Services National Correct Coding Initiative Policy Manual for Medicaid Services (Medicaid NCCI). Specifically, OSC determined that Truetox improperly billed separately for specimen validity tests performed in conjunction with presumptive and/or definitive drug tests for the same beneficiary on the same date of service. This is considered improper unbundling of claims. Because Truetox inappropriately unbundled 39,531 specimen validity tests, OSC seeks separate reimbursement of $194,619 in improper Medicaid reimbursements that Truetox received for these validity test claims.

In terms of a total monetary figure, OSC calculated that Truetox received an overpayment of $24,089,938. This overpayment is comprised of an extrapolated amount of $23,895,319 for having charged the Medicaid program more than it charged others for identical services and deficiencies with Truetox's documentation or billings. In addition, the overpayment includes a direct recovery of $194,619 for Truetox having improperly billed specimen validity claims separately from presumptive and/or definitive drug tests.

Finally, in addition to the monetary findings outlined above, OSC found that Truetox engaged in other activities that were inimical to the Medicaid program. First, Truetox and each of the drug treatment referring providers in OSC's sample entered into a "blanket" agreement in which the type of test (i.e., presumptive and/or definitive) and specific drugs to be tested for all of the referring provider's Medicaid beneficiaries were identical, definitive tests would be performed regardless of the underlying results of presumptive tests, and the parties would continue to utilize the agreement unless and until they modified the agreement. Those blanket agreements, by their nature, failed to take into account the individualized medical needs of patients because all electronic requisitions for the facility were identical, regardless of the drug testing needs of the individual patient. In other words, by routinely performing "one-size-fits-all" tests, Truetox unnecessarily performed and billed the Medicaid program for drug tests for which there was no demonstrated individualized medical necessity. As a result, the Medicaid program paid for unnecessary tests, which improperly increased the Medicaid program's costs. Second, Truetox provided benefits to referring providers that violated *N.J.A.C.* 10:61-2.4, the Medicaid regulation that prohibits independent clinical laboratories from offering rebates, or other considerations, whether or not a rebate is involved.

II. Background

Truetox, located in Garden City Park, New York, has participated as an independent clinical laboratory in the New Jersey Medicaid program since January 26, 2015. Pursuant to *N.J.A.C.* 10:61-1.2, "'[c]linical laboratory services' means 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." During the audit period, Truetox was one of the New Jersey Medicaid program's highest paid providers of independent clinical laboratory services.

Truetox submitted claims to the Medicaid program primarily for presumptive and definitive drug tests, and, to a lesser extent, for specimen validity tests. Presumptive procedures are used to screen for the possible use or non-use of a drug or drug class. Definitive procedures are used to identify drugs or metabolites (byproducts of a drug). Specimen validity tests are conducted primarily to ensure that a specimen sample is unaltered and usable for testing.

Truetox, through counsel, filed a self-disclosure with OSC dated January 31, 2019. OSC notes that Truetox self-disclosed Medicaid overpayments it received almost four months after Truetox became aware that OSC was auditing its Medicaid claims. In this self-disclosure filing, Truetox advised that it had conducted an internal review of its claims for the period from July 1, 2016 through December 1, 2018. Truetox asserted that from this review it determined that "several drug tests had been improperly classified" in its billing software. Due to these improper classifications, Truetox explained that it had billed and received Medicaid payments for higher-level drug tests than it actually had performed. Specifically, Truetox found that it had submitted improperly 64,074 out of 107,167 claims (59.8 percent error rate) to Medicaid and estimated that because of these improper submissions, it had received an overpayment of more than $2.1 million from Medicaid. As part of this audit, OSC performed more robust, comprehensive audit tests than Truetox performed in its internal review. Moreover, OSC's findings, as set forth in this Report, largely include Truetox's self-disclosed claims. Accordingly, OSC's findings herein adequately address the claims included in Truetox's self-disclosure for the period corresponding to this audit. For claims outside of this audit period (July 1, 2018 through December 1, 2018), OSC will address such claims separately from this audit.

III. Audit Objective, Scope, and Methodology

The objective of this audit was to evaluate claims for services that Truetox billed and was reimbursed by Medicaid to determine whether Truetox complied with Medicaid requirements under applicable state and federal laws and regulations.

The scope of this audit was for the period January 1, 2015 to June 30, 2018. This audit was conducted under the authority of the Medicaid Program Integrity and Protection Act (*N.J.S.A.* 30:4D-53 *et seq*.) and the Office of the State Comptroller *N.J.S.A*. 52:15C-1 *et seq.*

To accomplish the objective, OSC reviewed a statistically valid random sample comprised of 82 episodes with 198 unique paid claims for presumptive and/or definitive drug tests for which Truetox was paid a total of $12,810. This sample was selected from a population of 140,772 episodes with 302,326 paid claims for presumptive and/or definitive drug tests for which Truetox was paid a total of $24,382,684. (See Exhibit A for the HCPCS and CPT code descriptions.)

In addition, OSC reviewed Truetox's clinical account agreements and account set-up forms with its referring providers, test requisitions, test results, billing claim forms, and invoices, when applicable, to ensure that Truetox's charge to Medicaid did not exceed Truetox's charge for identical services to other groups or individuals. OSC reviewed Truetox's clinical account agreements and account set-up forms with its referring providers, test requisitions, and test results to determine whether proper documentation existed to substantiate the claims and ensure that Truetox properly billed and was reimbursed for such claims. Further, OSC identified and reviewed claims for specimen validity tests performed in conjunction with a presumptive and/or definitive drug test for the same beneficiary on the same date of service that Truetox billed separately and received payment under CPT codes 82570, 83986, and 84311. (See Exhibit B for these CPT code descriptions.)

IV. Discussion of Auditee Comments

The release of this Final Audit Report concludes a process during which OSC afforded Truetox multiple opportunities to provide input regarding OSC's findings. Specifically, OSC provided Truetox a Summary of Findings (SOF) and offered Truetox an opportunity to discuss the SOF at an exit conference. Truetox, through counsel, provided a written response to the SOF in advance of the exit conference. OSC and Truetox held an exit conference during which the parties discussed the SOF and Truetox's response to the SOF. Truetox then provided OSC an additional submission after the exit conference. Thereafter, OSC, after considering Truetox's submissions, provided Truetox with a Draft Audit Report (DAR) and again requested Truetox's comments. Truetox provided a response and Corrective Action Plan (CAP), which are attached as Appendix A.

Prior to the release of this final audit report, OSC recognized that the DAR did not quote a relevant portion of the rebate regulation, *N.J.A.C.* 10:61-2.4. Specifically, OSC did not quote the "other considerations" language in this regulation that forms the basis for OSC's finding that certain Truetox actions violated this regulation. In addition, the corresponding Recommendation, #8, did not reference the "other considerations" language. To remedy this omission, OSC modified its rebate finding to clarify that Truetox's actions violated the portion of the rebate regulation, *N.J.A.C.* 10:61-2.4, that prohibits laboratories from offering "other considerations" to a physician or other practitioner. Although OSC had referenced this regulation, it had not referenced the "other considerations" language in the DAR. Accordingly, OSC determined that it had not provided Truetox a sufficient opportunity to respond to that finding and the corresponding Recommendation, #8. To remedy that oversight, OSC offered Truetox the opportunity to respond to this finding and the revised language in Recommendation #8. Truetox availed itself of that opportunity, and its complete response is included in Appendix A.

In its initial response to the DAR, Truetox objected to all of OSC's conclusions as well as its sampling and extrapolation procedures. In its subsequent response, Truetox further objected to OSC's rebate findings. OSC addresses each argument raised by Truetox in both of these responses in Appendix B, entitled "Truetox's Comments and OSC's Responses." Through its responses, Truetox addressed some of OSC's recommendations. Truetox, however, failed to ensure that its charge to the Medicaid program would not exceed its charge for identical services to other groups or individuals. Additionally, Truetox failed to provide assurance that it would repay the overpayment amount. Truetox must immediately discontinue the practice of charging Medicaid more than other payers, provide OSC with the corrective actions it will take to comply with this requirement, and agree to repay the overpayment amount.

V. Audit Findings

A. Charge to Medicaid Exceeds Charge to Other Groups or Individuals for Identical Services

OSC reviewed Truetox's clinical account agreements, monthly invoices, test requisitions (i.e., a referring provider's order for testing), and test results. From this review, OSC found that Truetox charged Medicaid an amount significantly greater than the amount it charged other groups for presumptive and definitive drug tests. Independent clinical laboratories are prohibited from charging the Medicaid program more for a test or service than the laboratory charges another group or individual for an identical test or service. Pursuant to *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."

As detailed in Table I below, from June 7, 2016 to June 30, 2018, Truetox charged a flat fee for presumptive and definitive drug tests to groups other than the Medicaid program that was significantly lower than the fee Truetox charged Medicaid for these same tests. For example, Truetox charged as low a rate as $3 to certain groups for presumptive and definitive drug tests, while it charged Medicaid $1,300 and $1,500 for identical services. Medicaid, pursuant to the Medicaid fee schedule, paid Truetox $162 and $250, respectively, for these services. OSC reached this determination after reviewing Truetox's charges to multiple referring providers, which ensured that this was not an isolated incident. Indeed, as illustrated in Table I below, OSC found repeated instances in which Truetox charged Medicaid substantially more than it charged other groups for identical services.

Table I - Comparison of Truetox's Charges for Presumptive and Definitive Tests

	Charge to Medicaid	Amount Paid by Medicaid	Lowest Charge to Other Group or Individual*	Date of Earliest Drug Test Billed to Provider
Provider A	$1,100 - 1,300	$98 - 215	$3	6/7/2016
Provider B	$1,300 - 1,500	$162 - 250	$8	9/19/2016
Provider C	$1,300	$215	$8	11/26/2016
Provider D	$1,100	$180	$8	6/20/2017
*Based on information received from Truetox and its referring providers				

For 70 of 82 sample episodes (85.4 percent), Truetox improperly charged Medicaid an amount that exceeded Truetox's charge for identical services to other groups or individuals. As a result, the Medicaid program paid Truetox significantly more than it should have paid for these services. The difference between what Truetox should have been paid and the amount Medicaid actually paid Truetox is what OSC seeks to recover on an extrapolated basis. (See Exhibit C.) OSC extrapolated the dollars in error for the 70 of 82 sample episodes, $11,161 of $12,810, across the sample universe of $24,382,684. Applying this process, OSC calculated that Truetox received an overpayment of $22,882,947.

B. Deficient Documentation and Billing Irregularities for Presumptive and Definitive Drug Testing

In addition to the finding described above, OSC reviewed Truetox's documentation to determine whether Truetox properly documented the services that it billed the Medicaid program. OSC found that 67 of the 82 sample episodes (81.7 percent) resulted in 69 exceptions, with some sample episodes containing multiple deficiencies. (See Exhibit C.) OSC extrapolated the dollars in error for the 67 of 82 sample episodes, $5,155 of $12,810, across the sample universe of $24,382,684. Applying this process, OSC calculated that Truetox received an overpayment of $9,124,535. Set forth below is a discussion of each type of deficiency that OSC found.

Deficient Documentation

OSC found that in 15 of the 82 sample episodes (18.3 percent), resulting in 16 exceptions, Truetox failed to document properly the services it provided. The breakdown of these deficiencies follows.

Truetox did not possess and, thus, could not provide OSC with a test requisition for 1 of the 82 sample episodes.

Pursuant to *N.J.A.C.* 10:49-9.8(b), providers shall keep such records as are necessary to disclose fully the extent of services provided for a minimum period of five years from the date the service was rendered. Further, in accordance with *N.J.A.C.* 10:61-1.6(a), orders shall be on file with the billing laboratory and shall be available for review by Medicaid/NJ FamilyCare representatives upon request.

In addition, 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. Of those 7 sample episodes, 1 test requisition did not include the signature of the physician or other licensed practitioner who ordered the services and 6 test requisitions were signed by specimen collectors, aides, or counselors who were not authorized to order services.

Pursuant to *N.J.A.C.* 10:61-1.6(a), "orders for clinical laboratory services shall be in the form of an explicit order personally signed by the physician or other licensed practitioner requesting the services." Pursuant to *N.J.A.C.* 10:61-1.2, "'[c]linical laboratory services' means 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." Moreover, under *N.J.A.C.* 10:49-9.8(b), providers shall "keep such records as are necessary to disclose fully the extent of services provided . . . for a minimum period

of five years from the date the service was rendered."

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. 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 order such tests.

Pursuant to *N.J.A.C.* 10:61-1.6(d)1, the laboratory must ensure that all orders contain the "name and address or other suitable identifiers of the authorized person requesting the test." 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 found that test requisitions for 1 of the 82 sample episodes did not indicate the gender of the beneficiary.

Pursuant to *N.J.A.C.* 10:61-1.6(d):

> *The laboratory must ensure that all orders…contain the following information:*
>
> *1. The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life-threatening laboratory results or panic or alert values;*
> *2. The patient's name or unique patient identifier;*
> **3. The sex and the age (or date of birth) of the patient;**
> *4. The test(s) to be performed;*
> *5. The source of the specimen, when appropriate;*
> *6. The date and, if appropriate, time of specimen collection.*
> (Emphasis added.)

Improper Billing

OSC found that in 52 of the 82 sample episodes (63.4 percent), resulting in 53 exceptions, Truetox improperly billed for its services. The breakdown of these deficiencies follows.

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, which is reimbursed at a higher rate than a presumptive test. OSC determined 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) ordered. After finding that the requisitions were insufficient, OSC reviewed additional documentation to ascertain whether Truetox properly submitted these claims as higher reimbursed definitive drug tests. OSC reviewed the corresponding account set-up forms that Truetox completed with the relevant referring providers. Based on information provided by Truetox, each referring provider that used its services completed an account set-up form that identified the type of drug test ordered (i.e., presumptive and/or definitive) for specified drugs and drug classes. The account set-up form

is to be completed and signed by the referring provider's physician or licensed practitioner. Contrary to Truetox's explanation of its own process, Truetox was unable to provide OSC with documentation demonstrating that the referring physician ordered the higher reimbursed definitive tests in 28 sample episodes. Moreover, OSC contacted the relevant referring providers to determine whether they had documentation that would show they had ordered a definitive test. None of the referring providers gave OSC additional documentation to support these 28 sample episodes.

Pursuant to *N.J.A.C.* 10:61-1.6(d)4, laboratories must ensure that all orders contain the tests to be performed. Further, pursuant to *N.J.A.C.* 10:61-1.6(h), if the laboratory enters a test requisition into a laboratory information system, the laboratory must ensure that the information entered is accurate. Moreover, in accordance with *N.J.A.C.* 10:49-9.8(b), "providers shall keep such records as are necessary to disclose fully the extent of services provided . . . for a minimum period of five years from the date the service was rendered."

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.

The American Medical Association's (AMA) Healthcare Common Procedure Coding System (HCPCS) codes are broken down into different levels of definitive drug testing. The definitive codes identify drugs or metabolites (byproducts of a drug) that will be tested, with billing categories that increase in cost based on the number of drug classes that will be tested. The lowest level of definitive testing, which has the lowest Medicaid reimbursement rate, covers 1 to 7 drug classes, with progressively higher reimbursement levels for 8 to 14 drug classes, 15 to 21 drug classes, and, finally, 22 or more drug classes, which has the highest Medicaid reimbursement rate. Additionally, each drug or drug class is separately identified by a distinct AMA Current Procedural Terminology (CPT) code that is used to bill a specific definitive drug test. OSC found that Truetox billed and was reimbursed for higher-level definitive drug tests than were actually ordered by the referring physician or licensed practitioner. OSC adjusted or downcoded these claims to conform to the level of definitive drug testing that the referring physician or licensed practitioner ordered, as supported by the documentation reviewed. OSC then used the corresponding Medicaid reimbursement rate for the downcoded level of testing to determine the amount that Truetox should have been paid by Medicaid. OSC also adjusted claims from definitive testing to presumptive testing in instances when Truetox incorrectly billed such claims as definitive testing.

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."

C. Improper Billing of Specimen Validity Testing

OSC found that Truetox improperly submitted claims for specimen validity testing separately from claims submitted for presumptive and definitive drug tests for the same beneficiary on the same date of service. A laboratory is not permitted to seek payment for specimen validity tests and presumptive and/or definitive tests performed on the same day for the same beneficiary when specimen validity tests are performed for the purposes of confirming the specimen is unadulterated. Instead, in such cases, the laboratory shall seek payment only for the presumptive and/or definitive tests. Submitting claims and receiving payment for specimen validity tests and presumptive and/or definitive tests performed on the same day constitutes improper unbundling. In total, for the period January 1, 2015 through June 30, 2018, Truetox unbundled 39,531 specimen validity claims for which it was paid $194,619. Therefore, OSC seeks reimbursement of $194,619 from Truetox for these claims. See Table II below for a breakdown by year.

Table II - Improperly Paid Validity Claims by Year

	Number of Claims Paid	Total Dollars Paid
2015	11,758	$57,725
2016	27,728	$136,597
2017	42	$282
2018	3	$15
Total	**39,531**	**$194,619**

In accordance with *N.J.A.C.* 10:49-9.8, "all providers shall certify that the information furnished on the claim is true, accurate, and complete." In addition, pursuant to the 2016, 2017, and 2018 HCPCS and CPT guidelines, presumptive and definitive drug tests include sample validation or specimen validity testing. Lastly, the Medicaid National Correct Coding Initiative Policy Manual for Medicaid Services (Medicaid NCCI), which requires correct coding methodologies and reduces improper coding that may result in inappropriate payments of Medicaid claims, states that specimen validity testing is not separately billable from drug tests. The 2015, 2016, and 2017 Medicaid NCCI Chapter X(E) states:

> *Providers performing validity testing on urine specimens utilized for drug testing should not separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed.*

The 2018 Medicaid NCCI Chapter X(E) states:

> *Providers performing validity testing on urine specimens utilized for drug testing* **shall** *not separately bill the validity testing. For example, if a laboratory performs a urinary pH, specific*

gravity, creatinine, nitrates, oxidants, or other tests to confirm that a urine specimen is not adulterated, this testing is not separately billed. (Emphasis in original.)

D. Summary of Medicaid Overpayment

OSC determined that for the period covering 70 of the 82 sample episodes (June 7, 2016 to June 30, 2018), Truetox improperly charged Medicaid significantly more than it charged other groups for identical services. OSC also determined that during the entire audit period, Truetox improperly billed and received payment for 67 of 82 sample episodes due to deficient documentation and billing irregularities related to presumptive and definitive drug tests.

For purposes of ascertaining a total recovery amount for the findings related to the statistical sample, OSC consolidated the dollars in error for the findings discussed above. The dollars in error did not exceed the total claim payment amount for any sample claim. In instances when a sample episode failed both because Truetox improperly charged Medicaid more than it charged other groups for identical services and failed to possess adequate documentation or provided documentation that included billing irregularities, OSC assessed the dollars in error based on the charge to other groups for identical services and, when warranted because the claim was fatally flawed, reduced the remaining portion of the claim to zero. OSC then extrapolated the consolidated dollars in error, $12,318 of $12,810, across the sample universe of paid claims totaling $24,382,684. Through this calculation, OSC determined that Truetox received an overpayment of $23,895,319, which it must reimburse to the Medicaid program.

Additionally, OSC identified 39,531 Medicaid claims submitted by Truetox totaling $194,619 for specimen validity testing under CPT codes 82570, 83986, and 84311 that Truetox improperly unbundled and billed separately from presumptive and definitive drug tests that should have been bundled together. As a result, Truetox improperly submitted claims for services and was overpaid a total of $194,619, for which OSC seeks reimbursement.

In sum, OSC seeks to recover a total overpayment of $24,089,938 ($23,895,319 + $194,619 = $24,089,938).

E. Other Systemic or Regulatory Issues

Use of Provider-Specific Blanket Requests

OSC identified Truetox's use of blanket orders as an area of concern. Truetox and each of the drug treatment referring providers in OSC's sample entered into a "blanket" agreement in which the type of test (i.e., presumptive and/or definitive) and specific drugs to be tested for all of the referring provider's Medicaid beneficiaries were identical, definitive tests would be performed regardless of the underlying results of presumptive tests, and the parties would continue to utilize the agreement unless and until they modified the agreement. OSC is concerned that this "one-size-fits-all" practice contributed to unnecessary drug testing, which led to wasteful Medicaid spending. In addition, as discussed above in the context of 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, this practice contributed to the submission

of inaccurate claims.

The use of blanket orders was facilitated by Truetox's practice of establishing a pre-determined set of test orders in its account set-up form. According to Truetox, this form was completed jointly by the referring provider and a Truetox representative during the initial onboarding process. According to Truetox, it used the information in the account set-up forms to create unique provider-specific drug test panels that were stored in its web portal and available to the referring provider when ordering drug testing electronically. These unique provider-specific drug test panels are blanket orders because the account set-up forms used to order drug tests are provider-specific rather than patient-specific.

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. Given the individualized needs of each patient, it is difficult to fathom why all tests ordered by a referring provider, including definitive tests that were not based on the underlying results of presumptive tests, would be identical "one-size-fits-all" blanket orders. By relying on blanket orders, Truetox and its referring providers failed to consider the individual medical needs of the Medicaid beneficiaries. Moreover, in many cases there were multiple account set-up forms between Truetox and its referring providers that were not signed or dated, or contained the names of practitioners who no longer were engaged in the care of the referring provider's patients. As the provider that submitted claims for payment to the Medicaid program, Truetox plays an integral role, and thus bears some responsibility, for ensuring the medical necessity of the services for which it is seeking payment. Pursuant to *N.J.A.C.* 10:49-5.5(a)(13)(i), for a claim to qualify for payment, "the medical necessity for the services must be apparent and the quality of care must be acceptable as determined upon review by an appropriate and qualified health professional consultant."

The use of these blanket orders raises serious concerns regarding the medical necessity of the tests requested, administered, billed, and paid. Truetox's use of blanket orders was detrimental to the Medicaid program because it resulted in improper and unnecessary drug testing and wasteful Medicaid payments.

Laboratory Rebates

OSC found that Truetox violated *N.J.A.C.* 10:61-2.4, a regulation that prohibits rebates, including money discounts, and other considerations, whether or not a rebate is involved.

As discussed above, Truetox charged its referring providers an amount much lower than it charged Medicaid for identical services. Compared to the rate charged to Medicaid, the lower rates that Truetox charged its referring providers constitutes a "discount" in violation of *N.J.A.C.* 10:61-2.4. The same overall course of conduct that constituted a violation of *N.J.A.C*. 10:61-1.7, which is discussed above and for which OSC seeks to recover funds, also constitutes a violation of *N.J.A.C.* 10:61-2.4.

In addition, OSC found that Truetox entered into clinical account agreements with its referring providers that included a provision in which Truetox agreed to give "Staff Testing at No Charge to clinic." Some clinical account agreements also stated that "Tox to sponsor 2 Key Employees from each site to participate at 2 conferences annually." OSC found also that Truetox sponsored one referring provider's employee to attend the four-day 2016 International Nurses Society on Addiction Conference in Las Vegas, Nevada. OSC also found that a Truetox referring provider disclosed in its annual report that Truetox was a "financial contributor." Specifically, OSC found that Truetox contributed $6,000 to this referring

provider's miniature golf fundraising event. These actions constitute forms of "other considerations" that are prohibited by *N.J.A.C.* 10:61-2.4.

Pursuant to *N.J.A.C.* 10:61-2.4, "[r]ebates by reference laboratories, service laboratories, physicians or other utilizers or providers of laboratory service are prohibited under the Medicaid/NJ FamilyCare program. Rebates shall include refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value. Laboratories shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved."

VI. Recommendations

1. Truetox shall reimburse the Medicaid program $24,089,938.

2. Truetox must ensure that the charge to the Medicaid program does not exceed Truetox's charge for identical services to other groups or individuals.

3. Truetox must ensure that all orders for clinical laboratory services and all records and documentation are maintained by Truetox and comply with applicable statutes and regulations, including the regulations cited above.

4. Truetox must maintain the necessary documentation and ensure that only those drug tests ordered by the physician or other licensed practitioner requesting the services are tested and billed. Truetox must contemporaneously document all changes to the tests ordered.

5. Truetox must ensure all test orders for drug tests clearly indicate the test(s) to be performed, including the specific drugs or class of drugs as defined by the AMA.

6. Truetox must ensure all claims for drug tests comply with all applicable laws and guidelines.

7. Truetox must not separately submit claims for specimen validity testing to confirm that a urine specimen is unadulterated from claims submitted for presumptive and definitive drug tests.

8. Truetox shall not offer rebates, including refunds, discounts, or kickbacks, to its referring providers or to any other entities. Truetox shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved.

9. Truetox must provide training to its staff to foster compliance with Medicaid requirements under applicable state and federal laws and regulations.

10. Truetox must provide OSC with a Corrective Action Plan indicating the steps it will take to implement procedures to correct the deficiencies identified in this report.