



State of New Jersey

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

OFFICE OF THE STATE COMPTROLLER
MEDICAID FRAUD DIVISION
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KEVIN D. WALSH
Acting State Comptroller

JOSH LICHTBLAU
Director

April 05, 2024

BY ELECTRONIC, OVERNIGHT AND REGULAR MAIL

Mr. Eric Leykin, Chief Executive Officer
RDx BioScience, Inc.
629 Springfield Road
Kenilworth, NJ 07033

RE: Audit Closeout Letter – RDx BioScience, Inc.

Dear Mr. Leykin:

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 Medicaid claims submitted by and paid to RDx BioScience, Inc. (RDx), an independent clinical laboratory located in Kenilworth, NJ, for the period from September 30, 2016 through August 31, 2019 (audit period). OSC conducted this audit to determine whether RDx billed for drug tests during the audit period in accordance with applicable state and federal laws, regulations, and guidance.¹ Because of the unique nature of events surrounding this audit, as explained more fully below, OSC abbreviated its audit process and, instead of issuing a series of preliminary findings leading to a final audit report, is issuing this closeout letter, which references OSC's Settlement Agreement with RDx/Leykin (attached). The relevant facts follow.

After completion of fieldwork, OSC issued a Summary of Findings (SOF) in June 2022, which included OSC's preliminary audit findings. In July 2022, OSC held an Exit Conference with RDx to discuss OSC's preliminary findings and afford RDx an opportunity to provide facts or information to rebut these findings. RDx submitted a written rebuttal to OSC later in July 2022.

During the pendency of OSC's audit, OSC became aware of federal criminal and civil actions involving RDx/Eric Leykin. Specifically, OSC learned that in May 2023, the federal government

¹ RDx submitted claims to the Medicaid program primarily for presumptive and definitive drug tests and, to a far lesser extent, for specimen validity tests. Presumptive drug tests are used to screen for the possible use or non-use of a drug or drug class. Definitive drug tests are used to identify drugs or metabolites (byproducts of a drug). Specimen validity tests are conducted primarily to ensure that a specimen sample is unadulterated and usable for testing.

indicted RDx's President/CEO Eric Leykin for an array of wire fraud charges stemming from activity that occurred in June 2022. Based on that indictment, OSC suspended Leykin from the Medicaid program effective February 13, 2023, pending the outcome of the federal criminal proceedings against Leykin. OSC also learned that the federal government sought to resolve civil charges against RDx/Leykin stemming from allegations that RDx/Leykin paid impermissible kickbacks to third parties to induce parties to use RDx's services in violation of the federal Anti-Kickback Statute (AKS). The federal government and RDx/Leykin resolved those civil charges through a Settlement Agreement in January 2024.

In parallel to the January 2024 federal Settlement Agreement, OSC and RDx/Leykin entered into a Settlement Agreement to resolve the state's preliminary audit findings, including OSC's identified overpayments and civil penalties totaling \$2,934,877. RDx/Leykin agreed to the findings contained in the OSC Settlement Agreement and, as part of that Settlement Agreement, RDx/Leykin agreed to pay the Medicaid program the full amount identified in OSC's preliminary audit. As OSC and RDx/Leykin resolved all issues raised by OSC's preliminary audit findings through the Settlement Agreement, OSC did not complete the remaining steps in its audit reporting process, including issuing a Draft and Final Audit Report. Additionally, as detailed in OSC's Settlement Agreement, Eric Leykin remains suspended from the Medicaid program, and Leykin further agreed to be prohibited for three years from owning or operating an entity enrolled in New Jersey Medicaid and from holding a position related to the preparation, submission, or adjustment of Medicaid claims.

A summary of OSC's audit findings is detailed below.

Audit Findings Summary

To accomplish the audit objectives, OSC reviewed two probability samples with a combined total of 344 unique paid claims for presumptive and definitive drug testing, for which the Medicaid program paid RDx a total of \$52,204. Sample 1 was comprised of 120 episodes with 240 unique paid claims for one presumptive and one definitive drug test, both on the same date of service, for which the Medicaid program paid RDx a total of \$31,613. Sample 1 was selected from a population of 23,946 episodes with 47,892 unique paid claims for presumptive and definitive drug tests, for which the Medicaid program paid RDx a total of \$6,308,121. Sample 2 was comprised of 104 unique paid claims for a single definitive test without a presumptive test, for which the Medicaid program paid RDx a total of \$20,591. Sample 2 was selected from a population of 2,767 paid claims for definitive drug tests, for which the Medicaid program paid RDx a total of \$561,446.

OSC found that for 29 of the 120 episodes (24.2 percent) in Sample 1 and 61 of the 104 claims (58.7 percent) in Sample 2, RDx billed for tests in violation of N.J.A.C. 10:61-1.6. Specifically, OSC found that these claims lacked required supporting documentation, lacked a physician or other licensed practitioner's signature, or were submitted under the name of a physician who had ceased treating patients at the referring facility. For these documentation deficiencies, OSC

calculated that RDx received extrapolated overpayments of \$1,225,943² and \$235,563³ for Samples 1 and 2 respectively, totaling \$1,461,506.

OSC also found that RDx “unbundled” claims, a practice that is prohibited and generally results in a higher reimbursement rate for a provider than a bundled claim. Specifically, OSC found that RDx unbundled 198 claims for specimen validity testing from presumptive and definitive drug tests. For these unbundled claims, OSC identified an overpayment of \$1,099.

In addition to the documentation related findings noted above, OSC also found that RDx charged the Medicaid program rates that exceeded the rates that it charged other payers, in violation of N.J.A.C. 10:60-1.7, the Basis of Reimbursement (BOR) regulation, as well as N.J.A.C. 10:61-2.4, a regulation that prohibits independent clinical laboratories from offering discounts or rebates. OSC found that RDx charged other payers as little as \$5.00 per test, while it charged the Medicaid program \$2,100.00, with Medicaid paying RDx the program’s fee schedule rate of \$203.10 for these same services. RDx engaged in this conduct from March 5, 2019 through the end of OSC’s audit period of August 31, 2019, charging referring providers rates for hundreds of drug tests that were so significantly discounted they were nearly free.

RDx’s consistent failure to charge Medicaid its lowest rate violated both the BOR regulation and the anti-rebate regulation. Despite the fact that it was violating these Medicaid regulations for a portion of OSC’s audit period, RDx continually submitted Medicaid claims, accepted Medicaid payments and, in each such instance, certified pursuant to N.J.A.C. 10:49-9.8(a) that “the services billed on any claim were rendered by or under [RDx’s] supervision (*as defined and permitted by program regulations*)” – and thus in conformity with all Medicaid laws and rules. RDx further certified under N.J.A.C. 10:49-9.8(a) that its Medicaid claims were “true, accurate and complete.” For this conduct, which RDx knew, or should have known, violated multiple Medicaid regulations, pursuant to N.J.S.A. 30:4D-57(d)(2), N.J.S.A. 30:4D-17(e)(3), and N.J.S.A. 2A:32C-3, OSC assessed civil penalties of \$878,020 and \$594,352 totaling \$1,472,372 for the 65 episodes in Sample 1 and 44 episodes in Sample 2 that involved this conduct.

Conclusion

With the execution of the January 2024 OSC Settlement Agreement, RDx acknowledged and agreed to OSC’s preliminary findings and agreed to repay the total identified overpayment and civil penalty totaling \$2,934,977. In addition, through this Settlement Agreement, Eric Leykin acknowledged that he remains suspended from the Medicaid program pending the outcome of the federal criminal indictment filed against him and he further agreed to be prohibited for three years from owning or operating an entity enrolled in New Jersey Medicaid and from holding a position related to the preparation, submission, or adjustment of Medicaid claims. Given those findings and acknowledgements, OSC is hereby concluding this audit and RDx is not required to take any further action regarding this matter.

² OSC can reasonably assert, with 90% confidence, that the total overpayment is greater than \$1,225,942.87 (19.69% precision) with the error point estimate as \$1,526,515.65.

³ OSC can reasonably assert, with 90% confidence that the total overpayment in the universe greater than \$235,563.12 (13.84% precision) with the error point estimate as \$273,476.75.

Sincerely,

KEVIN D. WALSH
ACTING STATE COMPTROLLER

Date: 4/5/2024

By: *Josh Lichtblau*
Josh Lichtblau
Director
Medicaid Fraud Division

Attachments:

1. RDx Settlement Agreement

c: Robert DelGiorno, Esq. (Garfunkel Wild, P.C.)
Don Catinello, Deputy Director (Medicaid Fraud Division, OSC)
Justin Berardo, Supervising Regulatory Officer (Medicaid Fraud Division, OSC)

SETTLEMENT AGREEMENT AND MUTUAL RELEASE

THIS SETTLEMENT AGREEMENT AND MUTUAL RELEASE (“Settlement Agreement”) is entered into this 8th day of January 2024 (“Effective Date”) by and between RDx Bioscience Inc. and owner Eric Leykin (hereinafter collectively “RDx”), and the State of New Jersey, Office of the State Comptroller, Medicaid Fraud Division (“MFD”). RDx and MFD are hereinafter collectively referred to as the “Parties” and each individually as a “Party.”

WHEREAS, MFD initiated an audit of RDx, an independent clinical drug testing laboratory located in Kenilworth, New Jersey, with a review period covering Medicaid claims that RDx submitted for payment between September 30, 2016 and August 31, 2019; and

WHEREAS, MFD made findings during its audit and, because RDx is hereby agreeing to these findings, MFD is not completing the remaining formal steps of its audit process and instead is resolving the outstanding issues through this Settlement Agreement; and

WHEREAS, through the audit, MFD found the following facts, which RDx acknowledges and hereby agrees to (all of which is hereinafter referred to as the “Covered Conduct”):

(i) RDx charged Medicaid an amount that exceeded the amount it charged other groups and/or individuals for the same presumptive and definitive drug tests in violation of N.J.A.C. 10:61-1.7, which was also constitutes a discount in violation of N.J.A.C. 10:61-2.4;

(ii) RDx failed to properly document the services it provided, which findings included a missing test requisition, missing signatures of the physician or other licensed practitioner who ordered the services in a written requisition, and test requisitions submitted under the name of a physician no longer employed by the referring facility, in violation of N.J.A.C. 10:49-9.8, N.J.A.C. 10:61-1.6, and N.J.A.C. 10:49-5.5;

(iii) RDx 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 in violation of N.J.A.C. 10:49-9.8, 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;

(iv) based on the documentation deficiency findings noted above, MFD calculated that RDx received an extrapolated overpayment in the amount of \$1,461,506;

(v) based on the unbundling of specimen validity test findings noted above, MFD determined that RDx received an overpayment in the amount of \$1,099; and

(vi) based on RDx having charged Medicaid an amount that exceeded the amount it charged other groups and/or individuals for the same presumptive and/or definitive drug tests, in violations of N.J.A.C. 10:61-1.7 and N.J.A.C. 10:61-2.4, MFD assessed a civil penalty in the amount of \$1,472,372; and

WHEREAS, RDx has entered into, or will be entering into, a separate settlement agreement to resolve federal civil claims brought by the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (collectively, the United States); and

WHEREAS, RDx asserts that it has ceased all laboratory operations; and

WHEREAS, the parties desire to amicably resolve the Covered Conduct and have reached a mutually acceptable resolution of the controversies that exist between them; and

NOW THEREFORE, in consideration of the mutual promises contained herein, as well as for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree to settle their dispute on the following terms:

- (1) RDx agrees to pay MFD the total sum of Two Million Nine Hundred and Thirty-

Four Thousand Nine Hundred and Seventy-Seven Dollars (\$2,934,977), which is comprised of restitution in the amount of \$1,462,605 and a civil penalty in the amount of \$1,472,372 (“Total Payment Amount”) within thirty (30) days of the Effective Date of this Settlement Agreement.

(2) Payment to MFD shall be by business check, certified check, bank check, or attorney trust check made payable to “Treasurer, State of New Jersey,” and shall be mailed or delivered as follows:

Attention: Processing Bureau
Treasurer, State of New Jersey
Division of Revenue
200 Woolverton Street, Building 20
Lockbox 656
Trenton, New Jersey 08646

“RDx – [REDACTED]” must be included in the memo line so that payment is properly credited.

(3) If payment as provided for in this Settlement Agreement is more than ten (10) days late, RDx will be in default of this Settlement Agreement, and the total remaining unpaid balance plus interest accruing from the date of default will immediately become due (“the Default Amount”). Should RDx not cure the default within five (5) business days of receiving notice of default, the Default Amount immediately will be collected through any means available to MFD as provided by law.

(4) If RDx resumes laboratory services, RDx agrees to act in full compliance with all applicable state and federal rules and regulations, including but not limited to submitting only claims that accurately and completely reflect the services provided. If RDx resumes laboratory services, RDx, agrees to only submit claims for services provided for which RDx possesses sufficient documentation to support such claims and to implement policies to ensure that the underlying issues that caused or contributed to the Covered Conduct will be appropriately addressed and thereby not repeated.

(5) Eric Leykin agrees:

- That his current suspension from the New Jersey Medicaid program will continue through resolution of his criminal case in the District Court for the District of New Jersey (2:23-cr-00398), which means that while the suspension is active, Eric Leykin cannot have any involvement with or receive money from a person or entity that performs services for or on behalf of New Jersey Medicaid beneficiaries. It is expressly understood and agreed that nothing in this agreement or Eric Leykin's current suspension (or any subsequent exclusion) shall prohibit Eric Leykin from receiving payments related to the sale of RDx and/or its assets.
- Not to own or operate an entity that is enrolled in New Jersey Medicaid for three (3) years from the effective date of this Settlement Agreement, regardless of the outcome of the above-referenced suspension action.
- In the event that there is no suspension or other exclusion action that would prevent him from performing duties associated with the New Jersey Medicaid program, should he become employed (whether as a *bona fide* employee or independent contractor) by a provider who provides services to beneficiaries in the New Jersey Medicaid program, for three (3) years from the effective date of this Settlement Agreement he will not hold a position related to the preparation, submission, or adjustment of claims that will be submitted for payment to New Jersey Medicaid, nor will he hold a position related to the referral of patients (such as a position related to sales or marketing) for services reimbursable by New Jersey Medicaid.

(6) The parties agree that this Settlement Agreement is intended to be a final resolution of all issues arising out of the Covered Conduct, referenced above, including MFD's audit, and is intended by each party to release the other party and its representatives from liability arising out of the Covered Conduct, including MFD's audit, unless MFD is mandated to act by federal or State law, or mandated by order or judgment of a court or administrative agency (other than MFD).

(7) Nothing in this Settlement Agreement waives the rights of any other state or federal agency, including, among others, the New Jersey Office of Attorney General, from continuing with a pending or beginning a future civil or criminal investigation or other action for alleged conduct concerning RDx or from taking any action for such conduct. Nothing in this Settlement Agreement waives the rights of MFD to conduct an audit or investigation for the improper submission of any claims or conduct not specifically covered by this Settlement Agreement, and to take any action for such conduct, subject to and as limited by applicable law.

(8) The terms of this Settlement Agreement may be modified only by a subsequent written agreement signed by all Parties.

(9) Subject to the express terms of this Settlement Agreement as provided for in paragraphs 1-8 above, by the signatures set forth below, the authorization of which is hereby affirmed, RDx and MFD agree to the following Release: in consideration of the provision hereof including this release, each party agrees to release the other party and its owners, principals, shareholders, employees, representatives, officers, and directors from liability, obligations, and damages arising out of the Covered Conduct and MFD's audit.

(10) Notwithstanding the release given in this Agreement, or any other term of this Agreement, the following is specifically reserved and is not released: whether any exclusion under Section 1902(a)(39) and Section 1128B(f) of the Social Security Act (42 U.S.C. 1396a(a)(39)), the

Medicaid Program Integrity and Protection Act, N.J.S.A. 30:4D-53 to -64, N.J.S.A. 30:4D-17.1(a), and N.J.A.C. 10:49-11.1 et seq., is appropriate.

(11) Nothing herein shall constitute an admission, concession, waiver or finding of wrongdoing or liability by any party.

(12) This Settlement Agreement shall be construed, enforced and governed by the laws of the State of New Jersey.

(13) This Settlement Agreement may be executed in Counterparts.

(14) This Settlement Agreement is effective upon the Effective Date reflected on the first page of the Settlement Agreement.

(15) This Settlement Agreement sets forth the entire agreement between and among the parties hereto with respect to the claims described herein and supersedes any other written or oral understanding. This Settlement Agreement does not reflect any other terms or conditions or agreements between or among the parties with respect to any other matter.

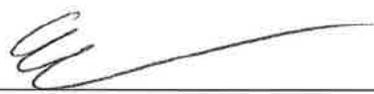
IN WITNESS WHEREOF, and intending to be legally bound, the parties hereto, on the following page, have executed the foregoing Settlement Agreement:

FORM AND CONTENT ACCEPTED AND AGREED TO BY:

RDx Bioscience Inc.

DATE:

By: _____


Eric Leykin
Individually and as authorized
signatory for RDx Bioscience Inc.

IN WITNESS WHEREOF, and intending to be legally bound, the parties hereto, on the following page, have executed the foregoing Settlement Agreement:

FORM AND CONTENT ACCEPTED AND AGREED TO BY:

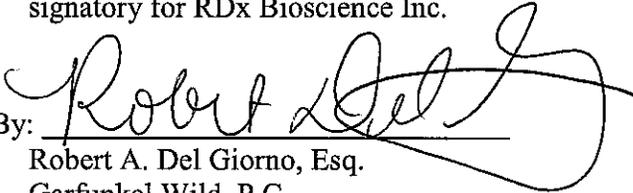
RDx Bioscience Inc.

DATE:

By: _____

Eric Leykin
Individually and as authorized
signatory for RDx Bioscience Inc.

DATE:

By:  _____

Robert A. Del Giorno, Esq.
Garfunkel Wild, P.C.
Counsel for RDx Bioscience Inc. and Eric
Leykin

**KEVIN D. WALSH
ACTING STATE COMPTROLLER**

DATE:

By: _____

Josh Lichtblau, Director
Medicaid Fraud Division

DATE:

By: _____

Justin Berardo, Supervising Regulatory Officer
Medicaid Fraud Division

DATE:

By: _____

As to form only
Robert A. Del Giorno, Esq.
Garfunkel Wild, P.C.
Counsel for RDx Bioscience Inc. and Eric
Leykin

KEVIN D. WALSH
ACTING STATE COMPTROLLER

DATE: 1/8/2024

By: Josh Lichtblau

Josh Lichtblau, Director
Medicaid Fraud Division

DATE: 1/8/2024

By: Justin Berardo

Justin Berardo, Supervising Regulatory Officer
Medicaid Fraud Division