State of New Jersey

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

OFFICE OF THE STATE COMPTROLLER
MEDICAID FRAUD DIVISION
P.O. BOX 025
TRENTON, NJ 08625-0025
(609) 826-4700

KEVIN D. WALSH
Acting State Comptroller

JOSH LICHTBLAU
Director

January 12, 2022

BY ELECTRONIC MAIL

Mr. Imran Siddiqui, President
Breathe Rite Medical and Surgical Equipment LLC
1285 South Broad Street
Trenton, NJ 08610

Re: <u>Final Audit Report — Breathe Rite Medical and Surgical Equipment LLC</u>

Dear Mr. Siddiqui:

As part of its oversight of the Medicaid program (Medicaid), the New Jersey Office of the State Comptroller, Medicaid Fraud Division (OSC) conducted an audit of claims Breathe Rite Medical and Surgical Equipment, LLC (Breathe Rite) submitted under National Provider Identification Number [REDACTED] and Medicaid Provider Number [REDACTED] for the period from May 16, 2014 through May 15, 2019 (audit period). OSC hereby provides you with this Final Audit Report (FAR).

Executive Summary

Breathe Rite, located in Trenton, New Jersey, is a medical equipment supply store and durable medical equipment (DME) provider that specializes in orthotics, prosthetics, blood pressure machines, and power mobility devices. Breathe Rite became a New Jersey Medicaid provider in 2011.

OSC reviewed Medicaid claims paid to Breathe Rite during the audit period to determine whether Breathe Rite billed for DME and medical supplies in accordance with applicable state and federal laws and regulations.

During the audit period, Breathe Rite submitted 21,614 claims under 203 unique Healthcare Common Procedure Coding System (HCPCS) codes to the Medicaid program for which the program paid Breath Rite $2,702,551. This audit focused on the claims that Breathe Rite submitted to Horizon NJ Health (Horizon), one of the five managed care

organizations (MCO) in New Jersey's Medicaid program, which accounted for 96 percent of the claims that Breathe Rite billed to Medicaid during the audit period. The adjusted audit universe consisted of 18,457 claims Breathe Rite billed under 192 unique HCPCS codes for which Horizon paid Breathe Rite $2,600,135. From this audit universe, OSC statistically selected a sample of 39 unique beneficiaries for whom Breathe Rite submitted 303 claims for which Horizon paid Breathe Rite a total of $77,610.

OSC found that Breathe Rite failed to comply with state regulations for 144 of the 303 claims sampled (48 percent), totaling $13,048 out of the $77,610 sample paid claims (17 percent). In general, OSC found that Breathe Rite violated *N.J.A.C.* 10:49-9.8 by not maintaining documentation that fully disclosed the services provided or by improperly billing HCPCS codes. Specifically, OSC found that Breathe Rite submitted claims for which it lacked adequate supporting documentation (e.g., no prescription or Certificate of Medical Necessity (CMN)) and claims that lacked proof of delivery or other documentation showing that Breathe Rite had provided the services billed. In addition, OSC found that Breathe Rite upcoded claims (used HCPCS codes that result in a higher reimbursement than warranted); overbilled (billed for more units than provided); and underbilled (billed for a HCPCS code that resulted in a lower reimbursement than warranted).

For purposes of ascertaining a final recovery amount, OSC extrapolated the net error dollars for claims that failed to comply with state regulations to the total dollar value of claims in the universe from which the sample of claims was drawn, which in this case was 18,457 claims with a total payment of $2,600,135. By extrapolating the net dollars in error over the entire audit universe, OSC calculated that Breathe Rite improperly received an overpayment of $411,277 that it must repay to the Medicaid program.

Background

The New Jersey Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) contracts with five MCOs to administer certain provision of health care services to Medicaid beneficiaries in New Jersey. That contract requires MCOs and their network providers, including Breathe Rite, to adhere to applicable state and federal laws and regulations.

OSC reviewed Breathe Rite's claims to determine whether they complied with the state Medicaid program's recordkeeping and DME requirements. Pursuant to *N.J.A.C.* 10:49-9.8, providers must "keep such records as are necessary to disclose fully the extent of services provided." In the DME context, providers, at a minimum, must maintain a legible, dated prescription for the DME item that is signed by the prescribing practitioner and references the diagnosis and item prescribed. *See N.J.A.C.* 10:59-1.5.

DME is defined by *N.J.A.C.* 10:59-1.2 as "an item or apparatus, other than hearing aids and certain prosthetic and orthotic devices . . . which . . . is primarily and customarily prescribed to serve a medical purpose and is medically necessary . . . is not useful to a

beneficiary in the absence of a disease, illness, injury or disability and is capable of withstanding repeated use." According to *N.J.A.C.* 10:55-1.2, an orthotic appliance is a device or a brace used to provide support and increased function and to overcome physical impairment or defects. Similarly, a prosthetic appliance is a functional replacement, corrective, or supportive device. In general, prosthetics artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.

The audit universe of claims consisted of orthotic devices (an artificial support or brace) and non-orthotic devices, including the following: wheelchairs (manual and power mobility devices) and accessories; automatic blood pressure monitors; transcutaneous electrical nerve stimulation (TENS) units; nebulizers; benches, stools and commodes; walkers, canes, crutches and accessories; hospital beds and accessories; compression stockings; and other miscellaneous medical supplies (e.g., incontinence supplies, gauze, and other small medical supplies). Table I provides a breakdown of the audit universe by category, dollar amount, number of claims, and percentage of claims within the audit universe. (*See* Exhibit I for a list of HCPCS codes organized by claim category that are part of the audit sample.)

Table I
Total Claims Billed and Paid by Category
Based on the Audit Universe

Category Description	Number of Claims	Dollar Amount	Percentage of Dollars By Category
Orthotic Devices	5,802	$1,407,472	54%
Wheelchairs (Power and Manual) and Accessories	2,087	$473,556	18%
Auto Blood Pressure Machine	3,127	$306,844	12%
TENS Unit and Supplies	2,143	$153,275	6%
Nebulizer and Accessories	2,156	$67,048	3%
Benches, Stools, Chairs and Commodes	635	$54,698	2%
Walkers and Accessories, Crutches and Canes	1,245	$44,333	2%
Hospital Beds and Accessories	492	$39,181	1%

Gradient Compression Stockings	450	$32,968	1%
Miscellaneous*	320	$20,760	1%
Grand Total	**18,457**	**$2,600,135**	**100%**

*Miscellaneous refers to Incontinence Supplies, Repairs, Gauze and other small Medical Supplies.

Objective

The objective of the audit was to determine whether claims submitted by and paid to Breathe Rite complied with Medicaid requirements under applicable state and federal laws and regulations.

Audit Scope

The audit scope was May 16, 2014 through May 15, 2019. This audit was conducted pursuant to the authority of the Office of the State Comptroller as set forth in *N.J.S.A.* 52:15C-23 and the *Medicaid Program Integrity and Protection Act*, *N.J.S.A.* 30:4D-53 *et seq*.

Audit Methodology

To achieve the audit objective, OSC's methodology consisted of the following:

- Selected a statistically valid sample of 39 unique beneficiaries for whom Breathe Rite submitted 303 claims for which Horizon paid Breathe Rite a total of $77,610, out of the audit universe of 18,457 paid claims, for which the Medicaid program paid Breathe Rite a total of $2,600,135.

- Reviewed records to determine whether Breathe Rite possessed documentation that complied with the requirements of *N.J.A.C.* 10:49-1.1 *et seq., N.J.A.C.* 10:49-9.8 and *N.J.A.C.* 10:49-5.5. *See also N.J.A.C.* 10:59-1.2, -1.5.

Audit Findings

OSC reviewed 303 of Breathe Rite's Medicaid claims, which included the following items: wheelchairs (manual and power mobility devices) and accessories; automatic blood pressure monitors; TENS units; nebulizers; benches, stools and commodes; walkers, canes, crutches and accessories; hospital beds and accessories; compression stockings; and, other miscellaneous medical supplies.

OSC determined that for 144 of the 303 claims sampled (48 percent), totaling $13,048 out of $77,610 in paid claims (17 percent), Breathe Rite violated *N.J.A.C.* 10:49-9.8 by not maintaining documentation that fully documented the services provided, and/or by billing items by incorrect HCPCS code(s). *See* Table II for a breakdown of the exceptions (i.e., claims that failed to meet the audit criteria). *See* Attachment I for an individual sample claim breakdown by exception.

Table II
Audit Exceptions

Exception Type	Number of Sampled Claims in Error by Exception Type	Total Sample Dollars in Error By Exception Type
Lack of documentation or Deficient documentation	**107**	**$11,962**
No Proof of Delivery	35	4,553
Deficient Physician's Order	29	4,071
No Physician's Order	29	2,489
No Documentation	14	849
Upcoding	**26**	**1,326**
Overbilling	**4**	**60**
Underbilling	**7**	**(300)**
Total Exceptions	**144**	**$13,048**

OSC extrapolated the sample results to the audit universe to calculate a total overpayment of $411,277. OSC's findings regarding each of the exception types are set forth below.

I. Breathe Rite Claims With No or Deficient Documentation

OSC found 107 of 303 sampled claims to be deficient because Breathe Rite failed to maintain the underlying documentation, or because the documentation that Breathe Rite maintained did not demonstrate that Breathe Rite had performed services for which it had billed and been paid. Specifically, OSC failed 35 claims because they did not contain proof of delivery of the DME; 29 claims because of deficient physician orders; 29 claims because there was no physician order; and, 14 claims because they did not contain any supporting documentation. *See* Attachment I for a list of the 107 deficient claims and the reason for the deficiency.

A. No Proof of Delivery

OSC found that Breathe Rite failed to possess documentation indicating proof of delivery for 35 of the 303 sampled claims, totaling $4,553. *See* Attachment I for a list of the 35

deficient claims. Breathe Rite's failure to maintain proof of delivery violated *N.J.A.C.* 10:49-9.8. Specifically, *N.J.A.C.* 10:49-9.8 requires that claims must be true, accurate, and complete and that the records supporting such claims must disclose fully the extent of services provided. Because Breathe Rite failed to possess documentation showing that the recipient received the item, OSC cannot be assured that Breathe Rite provided the services it billed and for which it was paid.

For example, Breathe Rite billed and was paid for a claim dated September 30, 2014 for a commode (HCPCS E0163). Breathe Rite's delivery invoice, however, stated that the beneficiary "didn't take the commode bcs [sic] of no space in the house." Because the delivery invoice conflicted with Breathe Rite's claim, OSC found that claim deficient, which resulted in a disallowed payment of $47. *See* Attachment II for example details.

In another example, Breathe Rite filled a prescription dated November 20, 2014 for a power wheelchair. To support the need for this item, Breathe Rite submitted to Horizon a prescription, CMN and a letter from the prescribing physician. Horizon authorized the use of a power wheelchair (HCPCS Code K0823), protective cover (HCPCS Code E2603), gel cushion (HCPCS Code E2611), manual full reclining back (HCPCS Code E1226), and two batteries (HCPCS Code E2363). Breathe Rite submitted and was paid for a claim dated February 11, 2015, for a power wheelchair (K0823) in the amount of $1,610, protective cover (E2603) in the amount of $89, gel cushion (E2611) in the amount of $125, manual full reclining back (E1226) in the amount of $304, and two batteries (E2363) in the amount of $207. The signed delivery invoice, however, indicated that the beneficiary only received the power wheelchair, without any reference to the accessories. Because the claim and invoice were not consistent and the invoice did not demonstrate that Breathe Rite provided all of the items for which it submitted claims and was paid, OSC disallowed the claims for accessories, which amounted to an overpayment of $725. *See* Attachment III for example details.

N.J.A.C. 10:49-9.8 requires that claims must be true, accurate, and complete and the records supporting such claims must disclose fully the extent of services provided. By failing to possess adequate documentation in support of 35 claims, Breathe Rite violated this regulation, which resulted in Breathe Rite receiving an overpayment of $4,553.

B. Deficient Order

OSC found that Breathe Rite processed claims based on deficient orders (prescriptions or CMNs) for 29 out of 303 claims reviewed, totaling $4,071. Specifically, OSC found that Breathe Rite's prescriptions or CMNs lacked one of the key elements contained in *N.J.A.C.* 10:59-1.5, such as the prescriber identification (NPI, Name, or License Number); prescriber signature; date; adequate description of the item ordered; diagnosis; or legible documents. These elements, at a minimum, are required to ensure that the physician orders or CMNs are valid and correspond to the claim billed. *See* Attachment I for a list of the 29 deficient claims and the corresponding deficiency.

For example, Breathe Rite was paid a total of $592 for three items that were supplied to a recipient on July 5, 2018. The three items included a back brace, a TENS Unit and TENS leads. All three of the items were included in a physician's prescription and CMN. OSC determined that both the prescription and CMN did not meet all of the elements set forth in *N.J.A.C* 10:59-1.5. The Breathe Rite prescription template, which prescribing providers often used, failed to contain the prescriber identification, as required by *N.J.A.C.* 10:59-1.5. Moreover, Breathe Rite's CMN template form failed to contain the prescriber's signature, as required by *N.J.A.C.* 10:59-1.5. Breathe Rite's failure to obtain a valid physician's order before supplying the items to the Medicaid recipient resulted in an overpayment of $592. *See* Attachment IV for example details.

N.J.A.C 10:59-1.5 requires DME providers to possess a legible, dated prescription signed by the prescribing practitioner that contains the beneficiary's name, a clear description of the item prescribed, a diagnosis, and the prescriber's name, address, and signature. In addition, pursuant to *N.J.A.C.* 10:49-9.8, claims must be true, accurate, and complete and the records supporting such claims must disclose fully the extent of services provided.

C. No Order

OSC found that Breathe Rite failed to maintain an order (prescription or a CMN form) for 29 of the 303 claims, totaling $2,489. OSC found that in these instances, Breathe Rite failed to possess a physician's order describing the medical necessity of the DME ordered. *See* Attachment I for a list of the 29 deficient claims.

For example, Breathe Rite submitted a claim and was paid $323 for a back brace (HCPCS Code L0631) that Breathe Rite supplied to a beneficiary on September 18, 2015. To support the service, Breathe Rite provided a dated delivery invoice showing delivery for the back brace, but Breathe Rite failed to provide a corresponding physician's order or CMN. Accordingly, OSC found this claim deficient. *See* Attachment V for example details.

N.J.A.C 10:59-1.5 requires DME providers to possess a legible, dated physician's order signed by the prescribing practitioner that contains the beneficiary's name, a clear description of the item prescribed, a diagnosis, and the prescriber's name, address, and signature. In addition, pursuant to *N.J.A.C.* 10:49-9.8, claims must be true, accurate, and complete and the records supporting such claims must disclose fully the extent of services provided.

D. No Documentation

OSC found that Breathe Rite failed to provide any documentation to support 14 of 303 claims sampled. In these instances, Breathe Rite failed to maintain a valid prescription or CMN in the recipient's file as well as any proof of delivery of these items to Medicaid beneficiaries. *N.J.A.C.* 10:49-9.8 requires that claims must be true, accurate, and complete and the records supporting such claims must disclose fully the extent of services provided. OSC found that 14 claims failed because Breathe Rite did not possess required

documentation, which resulted in an overpayment of $848. *See* Attachment I for a list of the 14 deficient claims.

II. Breathe Rite Improperly Upcoded Claims

OSC found that Breathe Rite billed and was paid for 26 out of 303 claims sampled, totaling $1,326, using incorrect HCPCS codes that reimbursed at a higher level than its documentation could support. This practice is referred to as "upcoding." *See* Attachment I for a list of the 26 deficient claims that Breathe Rite improperly upcoded.

For example, a physician's order dated April 12, 2017 requested a pair of knee-length 20-30 mmHG compression stockings. According to Breathe Rite's delivery invoice, Breathe Rite filled this order on April 21, 2017, providing 20-30 mmHG compression stockings. Breathe Rite, however, billed for HCPCS code A6531 (30-40 mmHG) instead of the appropriate code, A6530 (18-30 mmHG), resulting in an overpayment of $12.80. *See* Attachment VI for example details.

In another example, a physician's order dated September 29, 2016, a prescription and CMN all referenced a "night splint" and did not specify whether it should be custom or off-the-shelf. Breathe Rite's delivery invoice described the product as a "night splint," which usually is sold as an off-the-shelf item. Breathe Rite did not employ credentialed staff to perform customization on DME items during the audit period and, thus, only was authorized to dispense off-the-shelf orthotics. Nonetheless, Breathe Rite billed for a custom ankle brace (HCPCS Code L4396). *See* Attachment VII for example details. By billing HCPCS Code L4396 for a custom brace, as opposed to HCPCS Code L4397 for an off-the-shelf brace, Breathe Rite received an overpayment of $70.

N.J.A.C. 10:49-9.8 requires providers to "keep such records as are necessary to disclose fully the extent of services provided." Breathe Rite's records show that in these 26 instances Breathe Rite inappropriately billed HCPCS codes that resulted in higher reimbursement amounts than what Breathe Rite's documentation supported. As a result, Breathe Rite received an overpayment of $1,326.

III. Breathe Rite Overbilled by Billing More Units Than Warranted

OSC identified 4 out of 303 claims, totaling $60, in which Breathe Rite billed Medicaid for more units than ordered by the prescribing physician. This practice is referred to as "overbilling." *See* Attachment I for a list of the four deficient claims that Breathe Rite overbilled.

For example, Breathe Rite obtained a prescription for gauze bandages that failed to state a quantity. Rather than request and obtain a new prescription that stated a quantity, Breathe Rite submitted a claim dated December 10, 2015 for 100 units of Gauze bandages for which Horizon paid Breathe Rite $17.00. Further, Breathe Rite's delivery invoice shows that it delivered only 48 units. Due to the lack of a specified quantity on the

prescription, Breathe Rite only was entitled to reimbursement of one unit at $0.17, leading to an overpayment of $16.83. *See* Attachment VIII for example details.

These overbilled claims violated *N.J.A.C.* 10:49-9.8, which requires claims to be true, accurate, and complete and requires the records supporting such claims to disclose fully the extent of services provided.

IV. Breathe Rite Underbilled Claims

OSC identified 7 out of 303 sampled claims that resulted in the underpayment of $303 to Breathe Rite. These seven cases and the corresponding underpayment were accounted for and included in the extrapolation, which reduced the net extrapolated recovery amount. *See* Attachment I for a list of these seven underbilled claims.

For example, Breathe Rite billed HCPCS code L0627 for a custom back brace for a claim dated April 5, 2017. The delivery invoice contained no evidence that the brace was customized and Breathe Rite did not provide any other evidence of customization. Therefore, Breathe Rite should have billed for an off-the-shelf brace (HCPCS code L0642). Horizon's reimbursement of $151 for HCPCS L0642 code (off-the-shelf brace) was higher than its reimbursement of $129 for the HCPCS code L0627 (customized brace) resulting in an underbilling of $22. OSC included credits for these underbilled claims in calculating the extrapolated overpayment. *See* Attachment IX for example details.

Summary of Overpayments

OSC determined that for the period of May 16, 2014 through May 15, 2019, Breathe Rite improperly billed and received payment for 144 of the 303 claims, totaling $13,048. OSC extrapolated the net error dollars to the audit universe of 18,457 claims totaling $2,600,135. By extrapolating the net error dollars over the entire audit universe, OSC calculated that Breathe Rite received an overpayment of $411,277 that it must repay to the Medicaid program.[1]

Recommendations

Breathe Rite shall:

1. Reimburse the Medicaid program $411,277.

2. Maintain documents that fully support the Medicaid services and durable medical equipment and/or medical supplies provided in a beneficiary's record in accordance with *N.J.A.C.* 10:49-9.8 and *N.J.A.C.* 10:49-5.5(a)13 before submitting a claim for payment.

---

[1] OSC can reasonably assert with 90% confidence that the total overpayment in the universe falls between $186,496 and $636,058, with the error point estimate as $411,277.

3. Ensure that all orders, particularly CMNs, include the required information in accordance with *N.J.A.C.* 10:49-9.8 and *N.J.A.C.* 10:49-5.5(a)13 before providing the DME to the beneficiary and before submitting a claim for payment to Medicaid.

4. Adhere to the CPT and HCPCS guidelines when submitting claims to Medicaid for reimbursement.

5. Provide training to its staff to foster compliance with Medicaid requirements under applicable State and federal laws and regulations.

6. Provide OSC with a Corrective Action Plan (CAP) indicating the steps it will take to implement procedures to correct the deficiencies identified and recommendations in this report.

Breathe Rite's Response to the Audit Report Findings and OSC's Comments

After receipt of OSC's Draft Audit Report, Breathe Rite, through counsel submitted a written response and Corrective Action Plan (See Appendix A). In this response, Breathe Rite did not dispute OSC's substantive findings, but challenged OSC's sampling and extrapolation methodologies. In addition, Breathe Rite proposed settlement terms, which OSC has redacted. OSC addressed each argument raised by Breathe Rite in a document entitled "Breathe Rite's Comments and OSC's Response to Draft Audit Report (DAR)" (See Appendix B).

Breathe Rite's Corrective Action Plan addresses all of OSC's recommendations, other than OSC's recommendation that Breathe Rite reimburse the Medicaid program $411,277. Accordingly, Breathe Rite must reimburse the Medicaid program $411,277.

Thank you for your attention to this matter.

Sincerely,

KEVIN D. WALSH
ACTING STATE COMPTROLLER

By: /s/ Josh Lichtblau
Josh Lichtblau
Director, Medicaid Fraud Division

Enclosures (Omitted Unless Otherwise Noted):

Exhibit I - AMA HCPCS Code Descriptions

Attachment I – Testing Results Summary
Attachment II – Example of Claim without Proof of Delivery Attachment III - Example of Claim without Proof of Delivery Attachment IV – Example of Deficient Order
Attachment V – Example of No Order
Attachment VI – Example of Claim Upcoding
Attachment VII - Example of Claim Upcoding
Attachment VIII – Example of Overbilled Claim
Attachment IX – Example of Underbilled Claim
Appendix A – Breathe Rite's Response to the Draft Audit Report (Included)
Appendix B – Breathe Rite's Comments and MFD's Response (Included)

Cc: Ms. Sheila M. Mints, Esq.
Kay Ehrenkrantz, Deputy Director (OSC – Medicaid Fraud Division)
Michael Morgese, Chief Auditor (OSC – Medicaid Fraud Division)
Don Catinello, Supervising Regulatory Officer (OSC – Medicaid Fraud Division)
Glenn Geib, Recovery Supervisor (OSC – Medicaid Fraud Division)

CAPEHART
SCATCHARD
ATTORNEYS AT LAW

Sheila M. Mints
856.840.4945
smints@capehart.com
Fax: 856.235.2786

November 30, 2021

Via Email to [redacted]
[redacted]
Auditor
Medicaid Fraud Division
Office of the State Comptroller
20 West State Street, 4th Floor
Trenton, New Jersey 08625

Re: Breathe Rite Medical & Surgical Equipment, LLC
Response to Statement of Findings
FOR SETTLEMENT PURPOSES ONLY
NOT FOR USE IN LITIGATION

Dear [redacted]:

As you are aware, we represent Breathe Rite Medical and Surgical Equipment, LLC ("Breathe Rite") in connection with the Office of the State Comptroller, Medicaid Fraud Division's ("MFD") Draft Audit Report ("DAR") dated October 27, 2021. Please accept this letter as Breathe Rite's written response to the DAR and an attempt to settle. Breathe Rite reserves all rights in any future proceedings.

While Breathe Rite disagrees with the use of extrapolation in this matter, for purposes of this response and settlement letter, we will not object. However, we request that MFD consider the issues raised in this letter with regard to the lack of precision of the sample, the incorrect use of point-estimate in reaching the amount due from Breathe Rite and the plan for corrective action when considering the offer for settlement.

Extremely Poor Degree of Precision

MFD's determinations as to percentage of error are not precise enough to draw the conclusions set forth in the DAR. Estimation methodologies using statistical sampling require analysts to weigh the estimate's uncertainty to determine whether the conclusions are useful for their desired purpose.[1] Several measures are useful when evaluating a study's uncertainty. *Precision* reflects the range of accuracy related to an estimated amount, while *confidence* is the degree of certainty that the sample correctly depicts the population. Together, confidence and precision yield the *confidence interval*, a range of values within which the true population value is estimated to fall.

[1] United States, Internal Revenue Service, Bulletin 2007-23, Sampling Plan Standards, 2007.

In healthcare overpayment matters, precision levels from 5 to 10 percent are generally sought. However, the precision of MFD's analysis in this matter is significantly worse: 55 percent.[2] In addition to its overall precision, MFD also achieved extremely poor precision in each and every stratum. The actual precision of MFD's analysis in this case was dramatically higher than 10 percent, yielding distinctly imprecise conclusions. This imprecision is highlighted by MFD's extremely large confidence interval (i.e., estimated range of overpayments) ranging from $186,496 to $636,058 as set forth in the DAR;

> *MFD can reasonably assert, with 90% confidence that the total overpayment in the universe falls between $186,496 and $636,058 (54.65% precision) with the error point estimate as $411,276.90.*[3]

In contrast to MFD's precision in this matter, most healthcare post-payment audits seek significantly lower (i.e., better) precision levels ranging from 5 to 10 percent, and RAT-STATS software (which MFD purportedly used) prepopulates with desired precision levels from 1 to 15 percent. Even guidance for OIG Corporate Integrity Agreements prescribes a maximum precision level of 25 percent.[4] The poor degree of precision in this case indicates a lack of technical rigor applied by MFD and a high degree of variability in MFD's analysis. It also indicates the inadequacy of the sample size chosen by MFD in this matter, since increasing sample size is generally the most effective technique for improving precision.

<u>Improper Use of Point-Estimate</u>

As a result of the lack of precision in MFD's analysis and small sample size, MFD is precluded from using the point-estimate as the amount owed by Breathe Rite. In reaching its conclusions regarding Breath Rite's extrapolated overpayment amount, MFD based its overpayment demand on the *point-estimate*, stating that "*OSC calculated that Breathe Rite improperly received an overpayment of $411,277 that it must repay to the Medicaid program.*"[5] Here, MFD incorrectly contends that the point estimate accurately reflects the overpayments received by Breath Rite. In fact, MFD fails to even acknowledge that its demanded overpayment is an *estimate*. MFD's characterization is misleading, and it suggests a limited understanding of probability theory. In fact, the true overpayment is no more likely to be $411,277 than $186,496, and it could be even lower 10 percent of the time.

Selecting the point-estimate (or any value in a confidence interval) is not a probabilistic statement, and no value that lies within the confidence interval is more likely than another to be the *true* overpayment value. The point-estimate is simply the convenient midpoint of the confidence interval and is therefore anticipated to over-assess the disallowance almost half of the time. This distinction becomes more significant as the level of imprecision in a particular analysis grows, since the confidence interval grows wider with increased imprecision and over-assessments may be even greater.

---

[2] MFD Spreadsheet, *Extrapolation Methodology - Breathe Rite Medical and Surgical.xlsx,* Recovery Summary tab.
[3] MFD Spreadsheet, *Extrapolation Methodology - Breathe Rite Medical and Surgical.xlsx,* Recovery Summary tab.
[4] U.S. Department of Health and Human Services, Office of the Inspector General, Corporate Integrity Agreement FAQs, CIA Claim Reviews. Available at https://bit.ly/2MertiD
[5] Breathe Rite Medical and Surgical Equipment LLC - Draft Audit Report.pdf

In cases of extremely poor precision, such as this, the point-estimate is not the preferred estimate. Instead, the lower-bound of the 90 percent confidence interval is preferred in cases where adequate precision is not achieved. For example, CMS prefers the use of the lower-limit "in most cases" in post-payment audits since it "allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point-estimate."[6] Similarly, the OIG's Statistical Sampling Toolkit for MFCUs states "When the precision is poor, the uncertainty in the sample can often be managed through the use of alternate estimates such as the lower limit of a confidence interval."[7] In this matter, the lower-limit of the 90% confidence interval is $186,496 using MFD's own calculations and without considering any of Breath Rite's other arguments.[8]

Corrective Action Plan

Breathe Rite is a small family-owned business providing much needed services primarily to Medicaid recipients in the Trenton area. Breathe Rite is not part of a national or regional DME provider. It has suffered significant financial setbacks due to the COVID pandemic, as have many medical providers.

Any billing errors made by Breathe Rite found by the MFD audit were the result of human error rather than an intent to defraud. Over a five (5) year period, MFD determined that Breathe Rite received $13,048 in overpayments, without extrapolation. There was clearly no systematic or sustained practice of intentionally fraudulent billing. Breathe Rite is absolutely committed to correcting its billing and documentation to ensure that the errors identified by MFD do not reoccur in the future. I am attaching a proposed Corrective Action Plan which Breathe Right will implement immediately with training starting in December 2021.

The Corrective Action Plan will require that Breathe Rite retain a certified coder to provide training on the areas of deficiency in billing identified in MFD's audit. The coder will also conduct random audits of files to ensure that billed services are properly supported by the required documentation.

Settlement Proposal

---

[6] Medicare Program Integrity Manual, 8.4.5.1.
[7] U.S. Department of Health and Human Services, Office of the Inspector General, Statistical Sampling: A Toolkit for MFCUs, September 2018.
[8] MFD Spreadsheet, *Extrapolation Methodology - Breathe Rite Medical and Surgical.xlsx,* Recovery Summary tab.

In accordance with the Medicare Program Integrity Manual, the circumstances in which estimated overpayments may be extrapolated is limited. The MPIM states, "before using extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there *must be a determination of sustained or high level of payment error,* or documentation that educational intervention has failed to correct the payment error."[9] The MPIM also provides guidance on what constitutes a high error rate where extrapolation is permissible, stating that, "[f]or extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to: high error rate determinations by the contractor or by other medical reviews (i.e., *greater than or equal to 50 percent* from a previous pre- or post-payment review)."[10]

In this matter, New Jersey MFD analyzed a sample of claims for 39 recipients and found a net financial error rate of less than 17 percent, which is materially below the 50 percent threshold. In similar matters, such findings have led to exclusion of extrapolated conclusions since "the Provider error rate is below the threshold of 50%" required to justify extrapolation.[11] New Jersey MFD has also presented no evidence that Breath Rite's error rate was sustained over any period of time. Consequently, there is a credible case for the argument that extrapolation is impermissible for the purpose of estimating overpayments in this matter given the limited error rate.

These arguments along with (i) the demonstrated lack of precision, (ii) improper application of the point-estimate, (iii) the willingness of Breathe Rite to enter into a Corrective Action and (iv) the financial pummeling that Breathe Rite, a small family-owned business, has incurred during the COVID pandemic, will inure to my client's benefit in any litigation on this matter.

Very truly yours,

CAPEHART & SCATCHARD, P.A.

Sheila M. Mints

Sheila M. Mints

SMM/mmf

Enclosures
cc: Breathe Rite breatherite@hotmail.com

---

[9] Medicare Program Integrity Manual, Ch. 8, § 8.4.1.2 (emphasis added).
[10] Medicare Program Integrity Manual, Ch. 8, § 8.4.1.4 (emphasis added).
[11] QIC redetermination decision, dated June 1, 2017.

JT@medco.co

Christoper.haney@forensus.com

Corrective Action Plan
Breathe Rite Medical and Surgical Equipment
November 27, 2021

Identified Issues	Corrective Actions	Corrective Actions Effective Date	Audit Process	Audit Start Date	Percent of Compliance
Documentation in the medical record must support the billed service, including, but not limited sufficient documentation to support the DME Vendor's HCPCS code(s) billed, claims with valid orders or CMN, proof of delivery, and the appropriate number of units where applicable.	The DME Vendor will include full documentation in the medical records for the billed service, including, but not limited to the issues identified in Column 1. The DME Vendor will undergo training with a certified coder to assist the DME Vendor in implementing the CAP.	Training to be scheduled in December 2021.	The DME Vendor will retain a certified coder to conduct a random sampling audit of 25 claims to determine if the DME Vendor is in compliance with the issues identified in Column 1. If the DME Vendor has a 5 percent or greater error rate, education will be provided by a Certified coder and a second audit will be provided 1 month following the education. This process will continue until the DME Vendor reaches a 5 percent or less error rate Once the DME Vendor has an error rate of 5% or less, going forward, the DME Vendor will self-audit 15 of the DME records quarterly for Year 1, and then yearly thereafter as part of routine compliance. .	30 days after education has been provided	
Valid orders will include at minimum, the following information from the prescriber, prescriber identification number, NPI#, name and or license number, legible prescriber name and signature, date, and adequate description of the item.	The DME Vendor will undergo training with a certified coder to assist the DME Vendor in properly documenting valid orders.	Training to be scheduled in December 2021.	The DME Vendor will retain a certified coder to conduct a random sampling audit of 25 claims to determine if the DME Vendor is in compliance with the issues identified in Column 1. If the DME Vendor has a 5 percent or greater error rate, education will be provided by a Certified coder and a second audit will be provided 1 month following the education. This process will continue until the DME Vendor reaches a 5 percent or less error rate Once the DME Vendor has an error rate of 5% or less, going forward, the DME Vendor will self-audit 15 of the DME records quarterly for Year 1, and then yearly thereafter as part of routine compliance. .	30 days after education has been provided	
The DME Vendor will only bill items which were picked up as documented on the proof of delivery regardless of what was ordered.	The DME Vendor will undergo training with a certified coder to assist the DME Vendor in implementing a protocol with checks and balances to ensure only items picked up are billed.	Training to be scheduled in December 2021.	The DME Vendor will retain a certified coder to conduct a random sampling audit of 25 claims to determine if the DME Vendor is in compliance with the issues identified in Column 1. If the DME Vendor has a 5 percent or greater error rate, education will be provided by a Certified coder and a second audit will be provided 1 month following the education. This process will continue until the DME Vendor reaches a 5 percent or less error rate Once the DME Vendor has an error rate of 5% or less, going forward, the DME Vendor will self-audit 15 of the DME records quarterly	30 days after education has been provided	

			for Year 1, and then yearly thereafter as part of routine compliance. .		

KEY:

Column 1 – To be completed by the Certified Coder as per Deficiencies indicated in the State of New Jersey Medicaid letter dated 10/27/21

Column 2 – To be completed by the Certified Coder to enter the corrective actions to be taken

Column 3 – To be completed by the Certified Coder to include the effective date of the implemented corrective action

Column 4 – To be completed by the Certified Coder outlining the plan for monitoring their compliance with the CAP

Column 5 – To be completed by the Certified Coder to enter the date the auditing will begin

Column 6 –To be completed by the Certified Coder during the audit process

"

Breathe Rite's Comments and OSC's Response to Draft Audit Report (DAR)

Breathe Rite submitted a response to the DAR that did not take exception to OSC's substantive findings, but objected to OSC's sampling and extrapolation methodology. As part of its response, Breathe Rite also proposed a Corrective Action Plan (CAP) and referenced a payment amount to settle this matter. OSC redacted the portions of Breathe Rite's comments that referenced a settlement offer. Set forth below are Breathe Rite's objections to the DAR and OSC's response to each objection.

Breathe Rite's Comments: Extremely Poor Degree of Precision

"MFD's determinations as to percentage of error are not precise enough to draw the conclusions set forth in the DAR. Estimation methodologies using statistical sampling require analysts to weigh the estimate's uncertainty to determine whether the conclusions are useful for their desired purpose.[1] Several measures are useful when evaluating a study's uncertainty. *Precision* reflects the range of accuracy related to an estimated amount, while *confidence* is the degree of certainty that the sample correctly depicts the population. Together, confidence and precision yield the *confidence interval*, a range of values within which the true population value is estimated to fall.

"In healthcare overpayment matters, precision levels from 5 to 10 percent are generally sought. However, the precision of MFD's analysis in this matter is significantly worse: 55 percent.[2] In addition to its overall precision, MFD also achieved extremely poor precision in each and every stratum. The actual precision of MFD's analysis in this case was dramatically higher than 10 percent, yielding distinctly imprecise conclusions. This imprecision is highlighted by MFD's extremely large confidence interval (i.e., estimated range of overpayments) ranging from $186,496 to $636,058 as set forth in the DAR;

> *MFD can reasonably assert, with 90% confidence that the total overpayment in the universe falls between $186,496 and $636,058 (54.65% precision) with the error point estimate as $411,276.90.*[3]

"In contrast to MFD's precision in this matter, most healthcare post-payment audits seek significantly lower (i.e., better) precision levels ranging from 5 to 10 percent, and RAT-STATS software (which MFD purportedly used) prepopulates with desired precision levels from 1 to 15 percent. Even guidance for OIG Corporate Integrity Agreements prescribes a maximum precision level of 25 percent.[4] The poor degree of precision in this case indicates a lack of technical rigor applied by MFD and a high degree of variability in

[1] United States, Internal Revenue Service, Bulletin 2007-23, Sampling Plan Standards, 2007.
[2] MFD Spreadsheet, Extrapolation Methodology - Breathe Rite Medical and Surgical.xlsx, Recovery Summary tab.
[3] MFD Spreadsheet, Extrapolation Methodology - Breathe Rite Medical and Surgical.xlsx, Recovery Summary tab.
[4] U.S. Department of Health and Human Services, Office of the Inspector General, Corporate Integrity Agreement FAQs, CIA Claim Reviews. Available at https://bit.ly/2MertiD.

MFD's analysis. It also indicates the inadequacy of the sample size chosen by MFD in this matter, since increasing sample size is generally the most effective technique for improving precision."

OSC Response

Breathe Rite claims that precision levels between 5-10% "are generally sought" in healthcare overpayment matters, but does not provide any context or cite any source for this assertion. Moreover, Breathe Rite confuses the aim of seeking a precision level with the outcome of obtaining a precision level, which are two different elements. Finally, Breathe Rite does not address the central issue involving precision, which is what precision level is required to support an overpayment demand.

First, contrary to Breathe Rite's claim, there is no "industry standard" or statistical rule that establishes a 5-10% precision rate. In fact, there is no statistically valid reason to establish an arbitrary precision level that must be satisfied prior to seeking a recovery.

Although Breathe Rite discusses pre-populated precision levels in RAT-STATS, it fails to note that RAT-STATS offers the option to enter any desired precision level in conjunction with the standard 1-15% levels. Moreover, the Office of Inspector General (OIG), Corporate Integrity Agreements Frequently Asked Questions (FAQ) that Breathe Rite relies on is outdated. The current FAQ does not include any precision level requirements for extrapolation.

Second, Breathe Rite alleges that OSC's process lacks "technical rigor" and that OSC chose an "inadequate sample size." OSC followed its own well-established and independently validated sampling and extrapolation process. OSC is confident that its approach is robust, reliable, and reproducible.

With respect to Breathe Rite's claim that a larger sample size would increase precision, this position fails to consider the inherent burdens this would place on OSC and the provider. Increasing sample sizes as Breathe Rite suggests would require OSC and the provider to devote significantly more time and resources to producing and reviewing additional documents, which would significantly burden both parties. OSC appropriately and fairly balanced these factors in developing its sampling approach.

Breathe Rite's Comments: Improper Use of Point-Estimate

"As a result of the lack of precision in MFD's analysis and small sample size, MFD is precluded from using the point-estimate as the amount owed by Breathe Rite. In reaching its conclusions regarding Breath Rite's extrapolated overpayment amount, MFD based its overpayment demand on the *point-estimate,* stating that '*OSC calculated that Breathe Rite improperly received an overpayment of $411,277 that it must repay to the Medicaid*

program.'[5] Here, MFD incorrectly contends that the point estimate accurately reflects the overpayments received by Breath Rite. In fact, MFD fails to even acknowledge that its demanded overpayment is an *estimate*. MFD's characterization is misleading, and it suggests a limited understanding of probability theory. In fact, the true overpayment is no more likely to be $411,277 than $186,496, and it could be even lower 10 percent of the time.

"Selecting the point-estimate (or any value in a confidence interval) is not a probabilistic statement, and no value that lies within the confidence interval is more likely than another to be the *true* overpayment value. The point-estimate is simply the convenient midpoint of the confidence interval and is therefore anticipated to over-assess the disallowance almost half of the time. This distinction becomes more significant as the level of imprecision in a particular analysis grows, since the confidence interval grows wider with increased imprecision and over-assessments may be even greater.

"In cases of extremely poor precision, such as this, the point-estimate is not the preferred estimate. Instead, the lower-bound of the 90 percent confidence interval is preferred in cases where adequate precision is not achieved. For example, CMS prefers the use of the lower-limit 'in most cases' in post-payment audits since it 'allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point-estimate.'[6] Similarly, the OIG's Statistical Sampling Toolkit for MFCUs states 'When the precision is poor, the uncertainty in the sample can often be managed through the use of alternate estimates such as the lower limit of a confidence interval.'[7] In this matter, the lower-limit of the 90% confidence interval is $186,496 using MFD's own calculations and without considering any of Breath Rite's other arguments.[8]"

OSC Response

While there is no confidence in the point estimate itself, the calculation of this figure is derived from the average (i.e. mean) of the overpayment amounts. The mean is perhaps the most common and widely used measure of central tendency. The measure of central tendency gives a single number that is most representative of all of the data points. Therefore, when discussing an initial overpayment amount, the point estimate is a reasonable figure to use.

Breathe Rite suggests that by seeking to recover the point estimate, OSC has a "limited understanding of probability theory." Breathe Rite then states that "[i]n fact, the true overpayment is no more likely to be $411,277 than $186,496, and it could be even lower

[5] Breathe Rite Medical and Surgical Equipment LLC - Draft Audit Report.pdf.
[6] Medicare Program Integrity Manual, 8.4.5.1.
[7] U.S. Department of Health and Human Services, Office of the Inspector General, Statistical Sampling: A Toolkit for MFCUs, September 2018.
[8] MFD Spreadsheet, Extrapolation Methodology - Breathe Rite Medical and Surgical.xlsx, Recovery Summary tab.

10 percent of the time." That statement is not accurate. For a two-sided 90% confidence interval, which is the case here, there is only a 5 percent chance that the total overpayment falls below the lower bound. There is also a 5 percent chance that the total overpayment exceeds the upper bound.

Breathe Rite next asserts that the probability of the point estimate over-assessing the total overpayment amount increases as the level of imprecision grows. This is incorrect because the probability underlying the point estimate never changes. The point estimate is always the mid-point, and therefore, is always just as likely to understate the overpayment amount as it is to overstate it.

Finally, contrary to Breathe Rite's assertion, the use of the lower bound is by no means an industry standard or a statistical requirement. Additionally, OSC is not bound by the CMS Medicare Program Integrity Manual (MPIM) or the OIG Sampling Toolkit. Both of these policies referenced by Breathe Rite simply state those agencies' preferences regarding the use of the lower bound. Moreover, the OIG Sampling Toolkit recognizes, that "there is no bright-line statistical rule for how precise a sample needs to be to reasonably rely on the point estimate." *See* Footnote OIG Sampling Toolkit, Footnote #6.

Breathe Rite's Comments: Corrective Action Plan

"Breathe Rite is a small family-owned business providing much needed services primarily to Medicaid recipients in the Trenton area. Breathe Rite is not part of a national or regional DME provider. It has suffered significant financial setbacks due to the COVID pandemic, as have many medical providers.

"Any billing errors made by Breathe Rite found by the MFD audit were the result of human error rather than an intent to defraud. Over a five (5) year period, MFD determined that Breathe Rite received $13,048 in overpayments, without extrapolation. There was clearly no systematic or sustained practice of intentionally fraudulent billing. Breathe Rite is absolutely committed to correcting its billing and documentation to ensure that the errors identified by MFD do not reoccur in the future. I am attaching a proposed Corrective Action Plan which Breathe Right will implement immediately with training starting in December 2021.

"The Corrective Action Plan will require that Breathe Rite retain a certified coder to provide training on the areas of deficiency in billing identified in MFD's audit. The coder will also conduct random audits of files to ensure that billed services are properly supported by the required documentation."

OSC Response

OSC accepts Breathe Rite's CAP and refers Breathe Rite to the Recommendations Section in the final audit report for additional efforts that OSC believes Breathe Rite should take.

Breathe Rite's Comments: Settlement Proposal

OSC Response

OSC redacted Breathe Rite's comments above and in the last portion of the comments below because they reference a proposed settlement, which is not appropriate for disclosure in the body of an audit.

Breathe Rite's Comments: Error Rate Does Not Justify Extrapolation

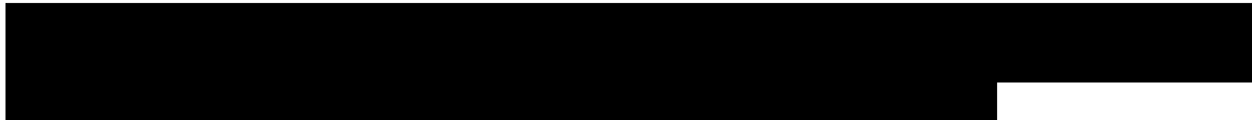
"In accordance with the Medicare Program Integrity Manual, the circumstances in which estimated overpayments may be extrapolated is limited. The MPIM states, 'before using extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, there *must be a determination of sustained or high level of payment error*, or documentation that educational intervention has failed to correct the payment error.'[9] The MPIM also provides guidance on what constitutes a high error rate where extrapolation is permissible, stating that, '[f]or extrapolation, a sustained or high level of payment error shall be determined to exist through a variety of means, including, but not limited to: high error rate determinations by the contractor or by other medical reviews (i.e., *greater than or equal to 50 percent* from a previous pre- or post-payment review).'[10]

"In this matter, New Jersey MFD analyzed a sample of claims for 39 recipients and found a net financial error rate of less than 17 percent, which is materially below the 50 percent threshold. In similar matters, such findings have led to exclusion of extrapolated conclusions since 'the Provider error rate is below the threshold of 50%' required to justify extrapolation.[11] New Jersey MFD has also presented no evidence that Breath Rite's error rate was sustained over any period of time. Consequently, there is a credible case for the

[9] Medicare Program Integrity Manual, Ch. 8, § 8.4.1.2 (emphasis added).
[10] Medicare Program Integrity Manual, Ch. 8, § 8.4.1.4 (emphasis added).
[11] QIC redetermination decision, dated June 1, 2017.

argument that extrapolation is impermissible for the purpose of estimating overpayments in this matter given the limited error rate.

"These arguments along with (i) the demonstrated lack of precision, (ii) improper application of the point estimate, (iii) the willingness of Breathe Rite to enter into a Corrective Action and (iv) the financial pummeling that Breathe Rite, a small family-owned business, has incurred during the COVID pandemic, will inure to my client's benefit in any litigation on this matter.



OSC Response

Breathe Rite argues that extrapolation is not permissible because the error rate is below 50%, which Breathe Rite cites as the CMS "threshold" for extrapolation. OSC is not bound by the guidelines set forth in the CMS MPIM. Additionally, CMS's decision to apply a 50% error rate threshold is not an industry standard and, in fact, only applies to Medicare audits, not to Medicaid audits such as this one. There is no basis, in statistics or in the audit industry, to require a 50% error rate in order to extrapolate and, thus, the 50% threshold is not applicable here.

OSC also notes that claims relating to more than 69% (27 out of 39) of the recipients reviewed contained at least one error. In total, MFD found 144 claims in error out of the 303 reviewed (~48%). Table 1 below shows the number of claims found in error in each year reviewed. The percentage of claims in error and the consistency of these errors in each year of the audit period demonstrate an unmistakable pattern that justifies the extrapolation employed in the final audit report.

Table 1

2014	**2015**	**2016**	**2017**	**2018**	**2019**	**Total**
30	35	24	21	23	11	144

In summary, Breathe Rite has not put forth any viable arguments that invalidate, or require OSC to modify its audit findings or sample/extrapolation methodology. With respect to Breath Rite's settlement offer, to maintain appropriate internal controls and separation of responsibilities, OSC does not consider settlement offers made during the course of an audit. Instead, OSC will address Breathe Rite's settlement offer after it issues the final audit report when OSC seeks to recover the identified overpayment.