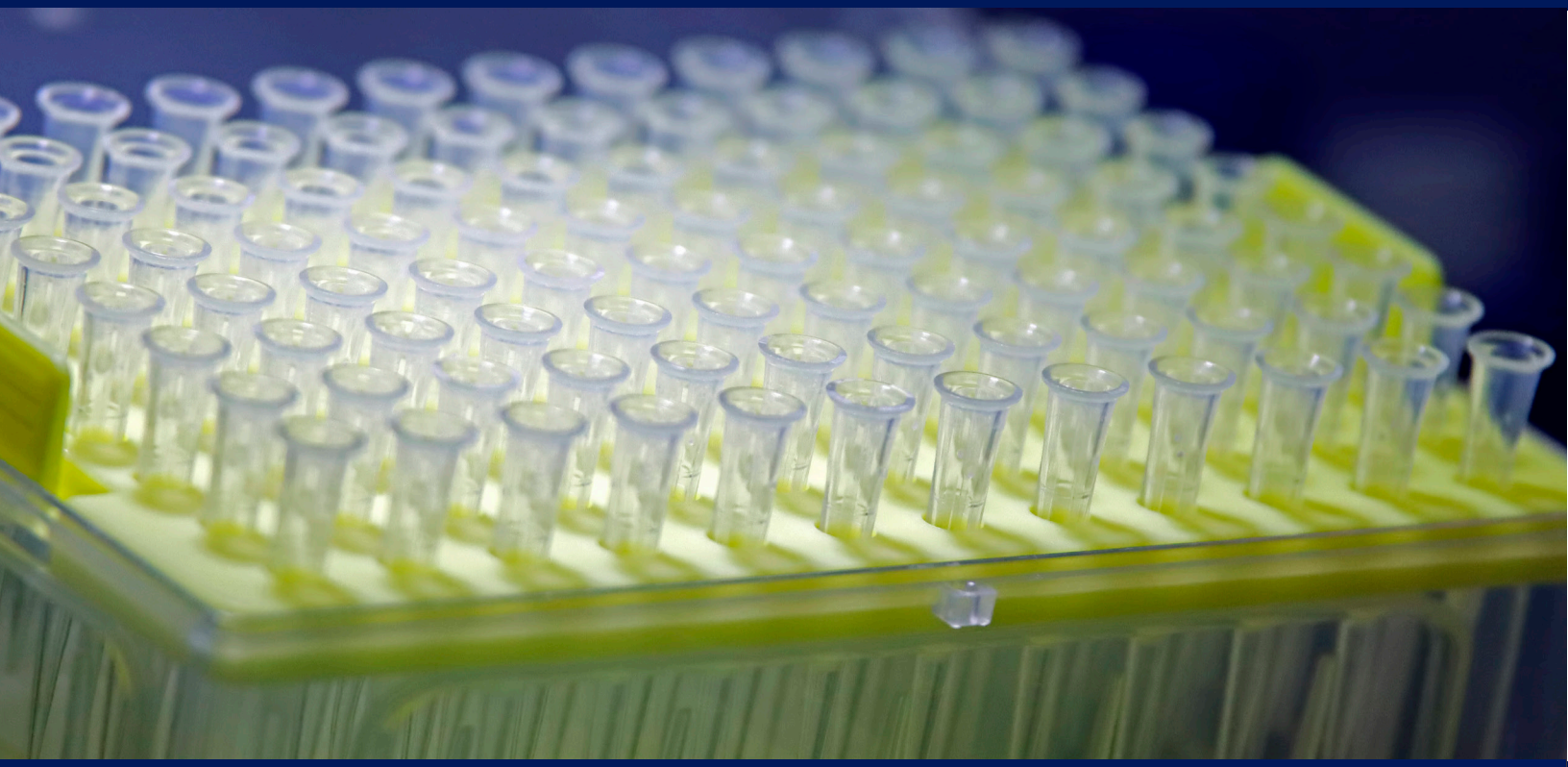
Final Audit Report of Sunrise Clinical Lab, LLC's Medicaid Billing Practices

MEDICAID FRAUD DIVISION REPORT



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Acting State Comptroller

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NEW JERSEY
OFFICE OF THE STATE
COMPTROLLER

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*Exhibits B, C, D, E, F, G, and H were omitted to maintain confidentiality.

I. Executive Summary

As part of its oversight of the Medicaid program (Medicaid), the New Jersey Office of the State Comptroller, Medicaid Fraud Division (OSC) audited Sunrise Clinical Lab, LLC (Sunrise), an independent clinical laboratory, to determine whether it billed for drug tests in accordance with applicable requirements. This audit follows several similar audits OSC conducted of independent clinical laboratories. For this audit, OSC selected a statistical sample of 183 drug testing episodes consisting of 366 claims for the period from July 1, 2017 through March 31, 2021 (Audit Period). OSC found that for 52 of 183 sample episodes (28.4 percent), Sunrise's documentation failed to comply with legal requirements.

In addition to identifying the documentation deficiencies above, OSC notes that for the vast majority of these deficiencies (44 out of 52), Sunrise completed drug tests without first obtaining the signed test requisitions from a referring physician or licensed practitioner. These 44 deficiencies were associated with four ordering physicians. OSC interviewed these four physicians and found that the physicians did not sign the requisition forms, were not involved in ordering decisions, or had their stamps affixed by unauthorized individuals such as laboratory specimen collectors or nursing staff. This means that Sunrise had no assurance that these tests were medically necessary or appropriate. Sunrise's claims and Medicaid's payments to Sunrise for these tests thus constitute a waste of Medicaid program resources. To determine the financial harm Sunrise caused to the Medicaid program, OSC reviewed a statistical sample of claims and used the results to estimate the total overpayment across Sunrise's full universe of claims. Applying a conservative approach, OSC calculated that Sunrise received an extrapolated overpayment of at least $3,434,950.[1]

Additionally, OSC found that for 44 of 183 sample episodes (24 percent), Sunrise did not perform at least one specific drug test that the physician or licensed practitioner ordered. While OSC is not seeking a monetary recovery for these deficiencies because they did not cause economic harm to the Medicaid program, OSC highlights these actions because Sunrise's failure to perform requested tests may have had an adverse impact on patient care. Such adverse impacts may include, but are not limited to, establishing a less than accurate and comprehensive medical history, which may lead to inaccurate diagnoses, missed treatment decisions, and missed opportunities for further testing.

Finally, separate from the claims in its sample universe, OSC identified nine instances during the Audit Period in which Sunrise improperly billed for definitive testing procedure codes on the same date of service for the same beneficiary. OSC also found that in six of these nine instances, the test requisitions did not include a signature from the ordering physician or licensed practitioner. For these nine deficient outlier episodes, OSC found that Sunrise received an additional non-extrapolated overpayment of $2,056 that it must repay to the Medicaid program.

[1] OSC can reasonably assert, with 90% confidence, that the total overpayment in the universe is greater than $3,434,950.26 (15.65% precision) with the error point estimate as $4,072,346.53. By using the lower limit as the recovery amount, OSC has high confidence that the actual overpayment amount is at least the lower limit, $3,434,950.26, but likely closer to the point estimate, $4,072,346.53. Program oversight bodies commonly use this approach to ensure a fair and conservative recovery amount and to factor in any uncertainty inherent in the statistical sampling/extrapolation process.

II. Background

Sunrise Clinical Lab, LLC (Sunrise), located in Irvington, New Jersey, has participated as an independent clinical laboratory in the New Jersey Medicaid program since July 21, 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, Sunrise was one of the New Jersey Medicaid program's highest-paid providers of independent clinical laboratory services.

Sunrise submitted claims to the Medicaid program primarily for presumptive and definitive drug tests. Presumptive drug tests screen for the possible use or non-use of a drug or drug class. Definitive drug tests identify specific drugs or metabolites (byproducts of a drug).

III. Audit Objective, Scope, and Methodology

The objective of this audit was to evaluate claims for services that Sunrise billed and received payment from the Medicaid program to determine whether Sunrise complied with applicable state and federal laws, regulations, and guidance.

The scope of this audit was for the period from July 1, 2017 to March 31, 2021. This audit was conducted pursuant to the authority of the Office of the State Comptroller (OSC) as set forth in N.J.S.A. 52:15C-1 to –23, and the Medicaid Program Integrity and Protection Act, N.J.S.A. 30:4D-53 to -64.

To accomplish the audit objectives, OSC reviewed a probability sample of 183 sample episodes comprised of 366 unique paid claims for one presumptive drug test and one definitive drug test, both on the same date of service, for which the Medicaid program paid Sunrise a total of $33,773. OSC selected the 183 sample episodes from a population of 86,793 episodes with 173,586 unique paid claims for presumptive and definitive drug tests for which the Medicaid program paid Sunrise a total of $15,870,880. Separate from the claims in its sample universe, OSC also separately reviewed nine outlier episodes comprised of 27 claims totaling $2,530 for presumptive and definitive testing. (See Exhibit A for code descriptions.)

OSC reviewed Sunrise's service agreements with its referring providers, test requisitions, and test results to determine whether Sunrise possessed the necessary documentation to substantiate the sample claims for these drug tests.

IV. Compliance Framework

Medicaid regulations for clinical laboratories establish safeguards to ensure program integrity, and to prevent fraud, waste, and abuse. These rules establish requirements for medical necessity, documentation, and financial arrangements. Understanding the broader compliance framework

provides essential context to understand these regulations. The following discussion outlines key provisions that regulate laboratory services and serve to protect the integrity of the program.

The relevant regulations, N.J.A.C. 10:61-1.1 et seq., impose multiple requirements on clinical laboratories as part of a comprehensive regulatory approach that was constructed to safeguard the integrity of the Medicaid program and prevent fraud, waste, and abuse. The longstanding rules, which supplement other generally applicable rules that apply to all Medicaid providers, establish guidelines to ensure the proper use of public funds. Laboratories are required to maintain detailed records of all test orders, results, and associated billing information. N.J.A.C. 10:61-1.6. The rules further mandate that standing orders must be patient-specific, medically necessary, and effective for no longer than 12 months. N.J.A.C. 10:61-1.6(c). The rules prohibit reference laboratories, service laboratories, physicians, or other providers from offering rebates, discounts, or kickbacks in any form, including money, supplies, or equipment. N.J.A.C. 10:61-2.4. Relatedly, laboratories cannot engage in arrangements in which they rent space or provide personnel to referring physicians, closing potential loopholes that could be exploited for financial gain. Ibid. These rules directly target conflicts of interest and protect taxpayer funds by ensuring ethical conduct at every step of the process.

N.J.A.C. 10:61-1.6(a) further protects Medicaid by establishing strict requirements for the authorization of clinical laboratory services to ensure that tests are medically necessary and properly documented. That regulation states:

> All 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, or be in an alternative form of order specifically authorized in (b)1 through 3 below. The written order shall contain the specific clinical laboratory test(s) requested, shall be on file with the billing laboratory and shall be available for review by Medicaid/NJ FamilyCare representatives upon request.

This provision not only guards against fraudulent billing practices, unnecessary testing, and financial arrangements that could improperly influence when and which tests are ordered but also establishes an audit trail that allows for retrospective reviews. By requiring a physician's signature, the regulation ensures that laboratory services are only provided when deemed medically necessary by a qualified professional. Requiring this explicit professional approval prevents referring providers from ordering medically unnecessary tests and drug testing laboratories from processing such unauthorized requests. Without this or a similarly effective safeguard, unscrupulous providers could generate excessive or unnecessary test orders to inflate billing, leading to wasteful Medicaid expenditures. Requiring the signed order to be maintained on file and available for review importantly provides the Medicaid program with the ability to verify the legitimacy of claims and identify potential abuses.

The signature requirement also ensures providers comply with other program integrity requirements imposed by N.J.A.C. 10:61 et seq. It functions as a direct check on financial arrangements that would violate anti-kickback laws prohibited by the rules. The regulation's requirement that all test orders be explicitly documented and retained by the billing laboratory creates a clear audit trail, reinforcing accountability at every stage of service delivery. Physicians and licensed practitioners bear direct responsibility for ordering tests, reducing the risk of abuse

by ensuring that clinical decisions remain within the purview of medical professionals rather than financially motivated entities. Without this safeguard, improper financial incentives could undermine the integrity of laboratory services.

N.J.A.C. 10:61-1.6 authorizes additional ways to authenticate the validity of testing orders that are similarly designed to ensure the physician is the one who authorizes the order. N.J.A.C. 10:61-1.6(b)(1)and (3) permit laboratories to rely on properly documented chart documentation and verbal orders followed by written or electronic confirmation within 30 days. This flexibility allows for efficient ordering while maintaining regulatory safeguards. N.J.A.C. 10:61-1.6(b)2 states:

> A test request also may be submitted to the laboratory electronically, if the system used to generate and transmit the electronic order has adequate security and system safeguards to prevent and detect fraud and abuse and to protect patient confidentiality. The system shall be designed to prevent and detect unauthorized access and modification or manipulation of records, and shall include, at a minimum, electronic encryption.

The four approaches to conveying testing orders (signature, chart documentation, electronic with safeguards to prevent and detect fraud and abuse, and verbal orders with written or electronic confirmation) permitted by N.J.A.C. 10:61-1.6 provide flexibility to providers while curbing fraud, waste, and abuse. All of the permitted approaches to authenticating testing orders ensure that physicians or other licensed practitioners make the decision to order tests and that the order is explicitly approved by them and each method ensures a direct link between the test order and responsible practitioner, reinforcing accountability.

The importance of these policies and the overarching goals of N.J.A.C. 10:61 et seq., are clear from the rulemaking proceedings that led to the adoption of these rules. The regulatory history shows that the Department of Human Services, Division of Medical Assistance and Health Services (DMAHS) was focused on preventing abuses by clinical laboratories and other providers. In response to a request to relax the physician signature requirement, DMAHS in 1996 stated:

> The requirement that all requests for laboratory services include a definitive order personally signed by the physician requesting services is a continuation of current policy (see N.J.A.C. 10:61-1.4(b)). <u>The ordering practitioner, when signing for the laboratory test, is attesting to the medical necessity of the test. This requirement is pivotal to curtailing fraud and abuse.</u> The current policy is valid and should remain unchanged.
>
> [28 N.J.R. 1054(a) (Feb. 5, 1996) (emphasis added).]

In 2010 to 2011, DMAHS amended N.J.A.C. 10:61-1.6 and again responded to concerns about physicians and licensed professionals being the only ones authorized to order laboratory tests. In response to a request to "reconsider the requirement for each paper order to be personally signed by the ordering practitioner," which was said to "'significantly detract[]' from the practitioner's time caring for patients," DMAHS responded:

> The Department does not believe that signing the order for a clinical laboratory service is so time consuming as to significantly detract from the time a practitioner is caring for a patient; however if that does become an issue for an individual practitioner, the Department maintains that the new alternatives to the submission of a signed order proposed at N.J.A.C. 10:61-1.6(b) are sufficient to ensure the efficient ordering of the services. All services reimbursed by the New Jersey Medicaid/NJ FamilyCare program must be certified as medically necessary. With regard to these specific rules, the authorization of orders for clinical laboratory services by a licensed practitioner is an integral part of ensuring that only medically necessary clinical laboratory services are provided to the beneficiaries and reimbursed by the program. For these reasons, no change will be made in response to the comment.
>
> [43 N.J.R. 423(a) (Feb. 22, 2011) (emphasis added).]

Similarly, in response to a comment that providers should be permitted to rely on an "'authorized representative' of the ordering licensed practitioner to sign the order" given that "the licensed practitioner would retain the ultimate responsibility for the authenticity of the order because they are responsible for the actions of their staff," which would "increase office efficiency," DMAHS responded that:

> the supervision of an 'authorized representative' would not necessarily be the responsibility of the individual licensed practitioner ordering the clinical laboratory services, for example, if the licensed practitioner provides services in a clinic or other setting in which multiple practitioners practice. Under the scenario suggested by the commenter, this could potentially result in the responsibility of the authenticity of the order being that of someone that has no knowledge of a beneficiary's individual medical needs. Ensuring that the licensed practitioner requesting the laboratory services is the individual responsible for attesting to its authenticity ensures that the care and treatment of the beneficiary remains the ultimate responsibility of the practitioner familiar with the medical needs of the beneficiary. For these reasons, no change will be made in response to the comment.
>
> [Id. at 423-24.]

In addition to N.J.A.C. 10:61, providers must comply with N.J.A.C. 10:49-9.8, which requires, among other things, providers to certify the accuracy of claims, maintain comprehensive records for at least five years, and ensure that all billed services were actually provided, thereby preventing fraudulent billing, enforcing accountability, and safeguarding Medicaid funds. Overall, these regulations reinforce program integrity and serve as a deterrent against improper billing practices.

Providers must also comply with N.J.A.C. 10:49-5.5(a)(13), which prohibits reimbursement for services when the corresponding medical records fail to adequately and legibly reflect the procedural requirements associated with the billed procedure code. Specifically, N.J.A.C. 10:49-5.5(a)(13)(i) states that "[f]inal payment shall be made in accordance with a review of those services actually documented in the provider's health care record." This rule ensures that Medicaid only pays for services that are properly recorded, medically justified, and compliant with professional standards. This provision serves as a safeguard against fraud, waste, and abuse by preventing providers from billing for undocumented, incomplete, or exaggerated services. By ensuring providers comply with rigorous documentation requirements, N.J.A.C. 10:49-5.5(a)(13) helps protect public funds from fraudulent claims, ensures that beneficiaries receive appropriate care, and promotes accountability among healthcare providers participating in Medicaid.

V. Discussion of Auditee Comments

The release of this Final Audit Report concludes a process during which OSC afforded Sunrise multiple opportunities to provide input regarding OSC's audit findings. Specifically, OSC provided Sunrise a Summary of Findings (SOF) and offered Sunrise an opportunity to discuss the findings at an exit conference. OSC and Sunrise, represented by counsel, held an exit conference during which the parties discussed OSC's findings presented in the SOF. Before and after the exit conference, Sunrise's counsel provided OSC a written response that disputed the basis of OSC's extrapolation of the audit findings. Subsequently, OSC provided Sunrise a Draft Audit Report (DAR) with recommendations and instructed Sunrise to provide a Corrective Action Plan (CAP) as part of its formal response to the DAR. Sunrise submitted a formal response to the DAR; however, Sunrise failed to submit a CAP. (Sunrise's response to the DAR is attached as Appendix A.)

OSC addresses each argument raised by Sunrise in more detail in Appendix B to this report. After reviewing Sunrise's submission, OSC determined that there was no basis to revise any of its findings presented in this audit report.

VI. Audit Findings

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

OSC reviewed Sunrise's documentation to assess whether it properly documented the services billed to the Medicaid program. OSC found that in 52 of the 183 sample episodes (28.4 percent), Sunrise failed to properly document services it provided. OSC extrapolated the error dollars, $8,586 of $33,772, to the sample universe of 86,793 sample episodes (173,586 claims) totaling $15,870,880. Applying this process, OSC calculated that Sunrise received an overpayment of at least $3,434,950 from the sample universe.[2] Set forth below is a discussion of each type of deficiency that OSC found.

[2] See footnote 1.

1. Missing Signatures

OSC found that test requisitions for 44 of the 183 sample episodes (24 percent) failed to include the signature of the ordering physician or other licensed practitioner requesting drug testing services. Sunrise should have rejected test requisitions that lacked a physician or other licensed practitioner's signature because without a signature from a physician or licensed practitioner, Sunrise lacked assurance that there was sufficient medical necessity to perform the requested tests. Sunrise ignored the glaring omission of signed requisitions, performed the tests, then billed and received payment from the Medicaid program for these tests.

As part of this audit, OSC attempted to verify the ordering physicians' level of involvement and knowledge regarding the testing requisition forms. OSC conducted sworn interviews of four ordering physicians from sample claims that OSC reviewed. During those interviews, the physicians testified that they had not affixed their signatures on the testing requisition forms. The physicians explained that they were not directly involved in the drug test ordering and submission process but instead delegated those responsibilities to other individuals who were not authorized to sign the testing requisition forms. Their approaches undermine the integrity of the testing requisition approval process because, in the absence of a physician's signature, it is not clear whether the tests ordered were medically necessary, which is the prerequisite for ordering such tests and seeking payment by Medicaid. Allowing someone other than the physician or licensed practitioner to determine which tests are appropriate and to approve test requisitions—contrary to applicable regulations—increased the risk of harm to patients if necessary tests were not ordered and to Medicaid if unnecessary tests were ordered.

The sworn testimony revealed additional information that raises significant concerns about the integrity of the test requisition process:

- One physician testified that due to time constraints, the specimen collector employed by Sunrise affixed the physician's stamp on the ordering forms. The physician further explained that he paid this Sunrise employee to perform other administrative tasks in his office.
- Another physician revealed that the ordering physician was not involved at all in the drug test ordering and submission process. This physician explained that because he was on site just two days per week, the referring provider's specimen processing team, under the supervision of the Director of Nursing, routinely stamped his signature on the drug testing requisition forms.
- A third ordering physician revealed that the specimen collector employed by another independent clinical laboratory (not Sunrise) was responsible for collecting the specimens for both Sunrise and that laboratory and for affixing the physician's stamp to the forms.
- A fourth ordering physician stated that she had never seen a laboratory requisition form before, including from Sunrise, and that she did not know who placed her stamps on the requisitions. She explained that she had a verbal standing order with Sunrise to perform a customized urine toxicology test for all patients under her care.

The physicians' testimony collectively demonstrates that neither the referring providers nor Sunrise properly ensured the integrity of the test requisition process. By processing and billing the Medicaid program for test requisitions that did not include the approval of the ordering physician or licensed practitioner, as evidenced by their signatures, Sunrise violated its legal

oversight responsibility and facilitated drug testing that was not supported by documentation that the tests were medically necessary. Sunrise's acceptance of test requisitions that did not include actual signatures casts doubt on the medical necessity of the drug tests and likely led to waste and abuse of Medicaid program resources.

After the exit conference, Sunrise provided additional documentation that contained notes from ordering physicians, all of which still failed to address the deficiencies identified by OSC. The documentation provided by Sunrise still failed to demonstrate compliance with N.J.A.C. 10:61-1.6(a), which requires testing orders to be explicitly signed; N.J.A.C. 10:61-1.6(b), which requires the medical records to be physically present at the laboratory at the time of testing; and N.J.A.C. 10:61-1.6(d), which requires that all testing orders and medical records contain specified information, including test(s) to be performed.

OSC finds that the use of initials, stamps, and/or machine-generated signatures on non-electronic media claims violates N.J.A.C. 10:49-9.8(a), which states that providers shall "certify that the information furnished on the claim is true, accurate, and complete." In addition, this practice also violates N.J.A.C. 10:49-9.8(b)(1) and (4), which state that providers shall "keep such records as are necessary to disclose fully the extent of services provided" and that such services are "in accordance with the requirements of the . . . program." Further, Sunrise failed to ensure that the test requisitions were signed by the ordering physician in compliance with N.J.A.C. 10:61-1.6(a), which states that "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." Sunrise similarly did not comply with the alternatives to providing a signature permitted under N.J.A.C. 10:61-1.6(b), chart documentation, electronic records with safeguards to prevent and detect fraud and abuse, or verbal orders with written or electronic confirmation, and with N.J.A.C. 10:61-1.6 (d), which requires that all orders contain the necessary information.

2. Definitive Testing Not Ordered

Additionally, OSC found that in 6 of the 183 sample episodes, Sunrise performed and billed for definitive drug testing that was not requested in the corresponding test requisition or billed for a greater level of service than what was ordered.

Referring providers submitted test requisitions to Sunrise either electronically or manually. In the majority of the testing requisitions, when a referring provider submitted a manual requisition, the requisitions listed the drug tests ordered, including the type of testing (i.e., presumptive, definitive) and the specific drugs to be tested. Because these manual requisitions provided a clear description of what the referring provider ordered, OSC did not take additional steps to validate the testing ordered. However, when a referring provider submitted requisitions electronically, and in some instances when requisitions were submitted manually, the requisitions did not specify the type of testing (i.e., presumptive, definitive) or the specific drugs to be tested but instead listed a test code that corresponded to a pre-determined list of drugs to be tested. After finding that these requisitions did not contain enough information to validate the corresponding claims, OSC reviewed additional documentation to ascertain whether Sunrise properly submitted each claim. Sunrise provided drug screening agreements with its primary referring provider that listed the type of drug test ordered (i.e., presumptive, definitive) for specified drugs or drug classes. Sunrise also provided a test compendium of the unique test codes that the physician or licensed practitioner would select when ordering a drug test following the drug screening agreement. OSC found,

however, that despite this documentation, Sunrise's testing and billing in these six sample episodes was not consistent with the respective drug screening agreements or test compendium.

The American Medical Association's Healthcare Common Procedure Coding System codes recognize multiple 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.

Of these six sample episodes, in three episodes, the referring providers did not request definitive testing, but Sunrise performed and billed for such testing. In three other episodes, Sunrise billed for definitive testing involving more drug classes than the referring provider ordered.

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."

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."

3. Underbilled Definitive Testing

OSC found that in 2 of 183 sample episodes, Sunrise performed testing for the full number of definitive drug classes the referring provider ordered but billed a lower cost definitive code. As a result, OSC gave credit for these underbilled claims and factored them into its extrapolated calculation of Sunrise's overpayment.

4. Requested Testing Not Performed

In addition to downcoding claims when Sunrise billed for more drug tests than its documentation supported, OSC also found that Sunrise did not perform all drug testing that referring providers ordered. OSC found that in 44 of the 183 (24 percent) sample episodes, Sunrise did not perform at least one drug test included on the drug test order. For example, a referring provider's test requisition instructed Sunrise to perform definitive testing of cocaine following a positive presumptive test, but Sunrise failed to test for cocaine. This reveals flaws in Sunrise's processes. OSC is not seeking a monetary recovery for these omissions because they did not cause economic harm to the Medicaid program, but OSC notes this finding because Sunrise's failure to perform all ordered tests created risks to patients. Such adverse impacts may include, but are not limited to, establishing a less than accurate and comprehensive medical history, which may lead to inaccurate diagnoses, missed treatment decisions, and missed opportunities for further testing.

B. Direct Review of Outlier Claims for Presumptive and Definitive Drug Testing

During the audit period, but not within OSC's sample universe of episodes, OSC identified nine outlier episodes consisting of 27 claims totaling $2,530 where Sunrise improperly billed for some of these claims. OSC identified two separate types of deficiencies for these outlier episodes. First, six episodes lacked a physician's signature on the requisition forms and therefore OSC denied the whole episode consisting of three claims each (18 claims), totaling $1,670. Second, for all nine episodes, each consisting of one presumptive and two definitive codes, Sunrise improperly billed for two definitive codes on the same date of service for the same recipient. Further, for three of these nine episodes, OSC denied the three higher paid definitive claims totaling $386. From this analysis, OSC found that Sunrise received an additional non-extrapolated overpayment of $2,056 ($1,670 + $386) for these nine episodes consisting of 21 claims (18 + 3). OSC did not review these nine episodes as part of its sample universe and therefore separated these episodes from the sample claims in its analysis.

Pursuant to N.J.A.C. 10:61-1.6(a), "[a]ll 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." (N.J.A.C. 10:61-1.6(b)(1), (2), and (3) provide alternative approaches to the signature requirement of N.J.A.C. 10:61-1.6(a) which Sunrise did not comply.) 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."

VII. Summary of Medicaid Overpayment

OSC determined that Sunrise improperly billed and received payment for 52 of the 183 sample episodes due to deficient documentation and billing irregularities related to presumptive and definitive drug testing. OSC extrapolated the sample error dollars, $8,586 of $33,773, to the sample universe of 86,793 episodes (173,586 claims) totaling $15,870,880. Applying this process, OSC calculated that Sunrise received an extrapolated overpayment of at least $3,434,950.

OSC also found that Sunrise improperly billed for nine outlier episodes comprised of 27 claims totaling $2,530 for deficient documentation and billing irregularities for presumptive and definitive testing. OSC determined that Sunrise received an additional non-extrapolated overpayment of $2,056 for 21 of 27 claims.

In sum, OSC seeks to recover a total overpayment of $3,437,006 ($3,434,950 + $2,056).

VIII. Recommendations

Sunrise shall:

1. Reimburse the Medicaid program the overpayment amount of $3,437,006.

2. Ensure that it properly maintains all orders for clinical laboratory services and all records

and documentation supporting its claims in a manner that complies with applicable state and federal laws, regulations, and guidance.

3. Maintain the necessary documentation and ensure that it only performs and bills for those drug tests ordered by the physician or other licensed practitioner requesting such services.

4. Ensure all test orders indicate the test(s) to be performed, including the specific drugs and class of drugs as defined by the American Medical Association and that all test requisitions comply with all federal and state requirements prior to performing the requested drug tests.

5. Ensure that all drug testing ordered by a physician or licensed practitioner is performed and reported on the drug test results.

6. Ensure that all claims for drug tests comply with all applicable state and federal laws, regulations, and guidance.

7. Provide training to staff to foster compliance with Medicaid requirements under applicable state and federal laws and regulations.

8. Provide OSC with a Corrective Action Plan indicating the steps it will take to correct the deficiencies identified in this report.

Sunrise Clinical Labs, LLC
HCPCS and CPT Code Descriptions for Presumptive and Definitive Drug Testing
July 1, 2017 to March 31, 2021

AMA CPT Code Descriptions - Presumptive

Code	Code Descriptor
80307	Drug test(s), presumptive, any number of drug classes, by instrument chemistry analyzers (eg, utilizing immunoassay [eg, EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (eg, GC, HPLC), and mass spectrometry either with or without chromatography, (eg DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service.

AMA HCPCS Code Descriptions - Presumptive

Code	Code Descriptor
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analysers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service.

AMA HCPCS Code Descriptions - Definitive

Code	Code Descriptor
G0480	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed.
G0481	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed.
G0482	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed.

AMA HCPCS Code Descriptions - Definitive (*continued*)

Code	Code Descriptor
G0483	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed.

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NEW JERSEY OFFICE OF THE
STATE COMPTROLLER

Audit Examiner

vs

In the Matter of SUNRISE CLINICAL LABS, LLC.

Audit Target

Revised Memorandum Opposing Extrapolated Medicaid Overpayment Demand

Dated: 10-21-25

Introduction

Sunrise Clinical Labs, LLC ("Sunrise") submits this memorandum as its formal response to the New Jersey Office of the State Comptroller, Medicaid Fraud Division's ("OSC") Draft Audit Report dated October 8, 2025. This memorandum contests the OSC's proposed repayment demand of $3,437,006, which is predicated almost entirely on a statistically flawed, procedurally deficient, and legally impermissible extrapolated overpayment finding of $3,434,950. While Sunrise is fully prepared to vindicate its rights in a contested case at the Office of Administrative Law ("OAL"), this memorandum also presents a principled path for a reasonable resolution designed to avoid unnecessary and protracted litigation for all parties.

The Draft Audit Report reiterates findings based on a statistical sample of claims from July 1, 2017, through March 31, 2021, in which the OSC reviewed 183 episodes (366 claims), found an alleged $8,586 in overpaid claims, and then extrapolated that small sample finding to a universe of $15,870,880 in claims. Sunrise vehemently opposes this demand on both legal and technical grounds, including:

- The statistical invalidity and legal insufficiency of OSC's sampling and extrapolation methodology, under New Jersey's own audit regulations and federal Medicaid standards (e.g. lack of true randomness, improper confidence intervals/margins of error, and irreproducibility of the results).
- Relevant legal and administrative precedents in New Jersey and federal law where extrapolated Medicaid overpayment findings were overturned or sharply

limited due to similar flaws.

- Sunrise's protections under New Jersey's Health Claims Authorization, Processing and Payment Act ("HCAPPA"), N.J.S.A. 17B:30-48 et seq., which bars recovery of overpayments more than 18 months after the payment was made (absent specific exceptions). OSC's attempt to reach back 4-8 years and employ extrapolation violates this statute, as OSC has not met any exception for fraud, pattern of abuse, or coordination of benefits.

This memorandum is organized as a factual and legal analysis demonstrating why OSC's extrapolated overpayment finding cannot stand. It serves as Sunrise's formal response to the Draft Audit Report and the basis for its appeal, while also outlining a framework for a principled resolution. Sunrise respectfully requests that the extrapolated repayment demand be withdrawn or substantially reduced to reflect only actual, proven overpayments within the permissible look-back period, and that Sunrise be afforded full due process to challenge any sampling-based findings.

Background of the Audit and Findings

This matter began nearly five years ago when, on December 2, 2019, the OSC issued an audit notice to Sunrise. In connection with that audit, OSC staff conducted a site visit on January 9, 2020. During this visit, OSC staff members employed overly aggressive tactics, commandeering Sunrise's equipment, issuing peremptory demands to personnel and counsel, and disrupting business operations. Notwithstanding this unprofessional behavior, Sunrise remained cooperative. Sunrise made four document productions related to this initial audit, concluding on March 23, 2020.

Following an inexplicable two-year period of silence from the OSC, Sunrise received a *second* audit notice on April 13, 2022. The OSC conducted another site visit on July 6, 2022, and Sunrise ultimately made an additional seven document productions. This second phase culminated in the OSC issuing its initial Summary of Findings on February 11, 2025, which formed the basis for the current Draft Audit Report.

The OSC's findings stem from its post-payment audit of Sunrise's Medicaid billing for laboratory drug testing services from July 2017 through March 2021. The audit sample consisted of 183 patient episodes (366 claims), purportedly randomly selected from Sunrise's universe of claims for that period. OSC identified $8,586 in purported overpayments within the sample (for issues such as missing physician signatures on test requisitions or billing for higher-level tests than ordered). OSC then extrapolated this sample result to the entire population of claims, which totaled approximately $15.87 million in Medicaid payments. Using its statistical model, OSC calculated an alleged extrapolated overpayment of $3,434,950. The Draft Audit Report demands repayment of this amount, plus an additional $2,056 in non-extrapolated "outlier" findings, for a total of $3,437,006. Notably, OSC's

extrapolation was performed with a 90% confidence level. Sunrise timely disputes both the accuracy of the sampling findings and the validity of extrapolating those findings, especially given the small sample ($8,586) relative to the $15.87 million universe.

Throughout this lengthy and often burdensome audit process, Sunrise has cooperated fully and provided extensive records. The alleged issues largely involve documentation technicalities, not any intentional wrongdoing: e.g., test order forms missing a provider signature, or Sunrise performing a confirmatory test when only a presumptive test was explicitly ordered. Sunrise maintains that all billed tests were medically necessary and performed in good faith reliance on physician requests.[1] There have been no fraud allegations against Sunrise, and it has continued to serve Medicaid patients. Given this context, Sunrise contends that OSC's extrapolated overpayment figure is grossly disproportionate and unsupported by law or fact.

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[1] *See, e.g., United States v. Boston Heart Diagnostics Corp.*, 296 F. Supp. 3d 155 (D.D.C. 2017) (holding that while laboratories have documentation duties, they are generally permitted to rely on the ordering physician's determination that a test is medically necessary and are not required to make an independent medical necessity determination).

I. The OSC's Demand is Barred by New Jersey Statute (HCAPPA)

Beyond any statistical issues, the OSC's demand is independently and dispositively barred by New Jersey statute. The Health Claims Authorization, Processing and Payment Act (HCAPPA),
N.J.S.A. 17B:30-48 et seq., imposes strict limits on when and how an insurer or payer can seek recoupment of paid health claims. Although originally enacted to govern private insurance carriers and HMOs, HCAPPA's public policy and explicit protections should apply equally, if not more so, to the State Medicaid program's recoupment efforts, since Medicaid providers are within the class the law seeks to protect.

Two key provisions of HCAPPA are directly relevant:

(A) The 18-Month Time Limit for Overpayment Recovery

HCAPPA provides that "**No payer shall seek reimbursement for overpayment of a claim... later than 18 months after the date the first payment on the claim was made.**" This is an unequivocal temporal limit. In Sunrise's case, the OSC is attempting to recover payments made four to eight years ago, well outside the 18-month window. Every claim in the July
2017-March 2021 audit period was paid by mid-2021 at the latest; thus, by late 2022, all of those claims became unrecoverable by statute—unless an exception applies. The only exceptions HCAPPA allows are for claims "submitted fraudulently, submitted by health care providers that have a pattern of inappropriate billing, or are subject to coordination of benefits."

If none of those exceptions is met, the law bars recovery, period. The OSC has not met any exception here:

- **No Fraud:** The OSC's audit does not allege that Sunrise engaged in fraud. There are no accusations of intentional misrepresentation or falsification of claims. Importantly, even if the OSC belatedly tried to label the conduct "fraud," HCAPPA requires "clear evidence of fraud" and that the payer must have investigated and referred the claim to the Office of the Insurance Fraud Prosecutor to invoke the fraud exception. The OSC has done no such referral. In the *Oxford* case, when Oxford Health attempted to justify extrapolated recoupments by claiming providers committed fraud, DOBI found that argument hollow because Oxford had not actually referred the cases for fraud prosecution and had treated the providers as if no fraud occurred (e.g., keeping them in-network). Similarly, the OSC cannot retroactively assert fraud now. Sunrise has not been under any fraud investigation; the OSC's own report frames the findings as regulatory non-compliance, not fraud. Thus, the fraud exception to the 18-month rule does not apply.

- **No Pattern of Inappropriate Billing:** The OSC might argue that its finding of errors in 52 of 183 sample episodes (28.4%) amounts to a "pattern of inappropriate billing." This argument fails. This exception is intended for egregious or willful misconduct—for example, a provider who consistently upcodes or bills for services not rendered, such that a clear pattern of abuse is present. Sunrise's situation is fundamentally different. The OSC's findings reflect sporadic paperwork mistakes (such as missing physician signatures) spread across a multi-year period among thousands of claims. These technical documentation issues do not equate to a "pattern of inappropriate billing" in the sense HCAPPA envisions. If the OSC's broad interpretation were accepted, any provider with a moderate rate of technical claim errors could be said to have a "pattern," which would swallow the 18-month rule entirely. The better view, and the one consistent with HCAPPA's purpose, is that a pattern means a systematic, intentional practice of incorrect billing. Sunrise's errors were not systematic and have innocuous explanations. There is no evidence Sunrise consciously adopted a practice of flouting Medicaid rules. Indeed, DOBI's enforcement action against Oxford signals skepticism of loose "pattern" allegations: Oxford had alleged a pattern of inappropriate billing by many providers to justify extrapolation, but DOBI forced Oxford to cease those recoupments because the allegations did not fall under HCAPPA's exceptions.[3] Sunrise urges the same skepticism here—the OSC cannot simply declare a pattern based on a minority of claims having documentation issues to evade the 18-month bar. It must prove a pattern of abuse, which it cannot on these facts.
- **No Coordination of Benefits Issue:** The claims at issue were billed to Medicaid as the primary payer. There is no assertion that another insurer was liable or that Sunrise failed to coordinate benefits. Thus, the coordination of benefits exception is irrelevant in this case.

Because none of the three exceptions apply, HCAPPA's 18-month limitation stands as an absolute bar to the OSC's recoupment demand for these old claims. By law, the OSC "shall not seek reimbursement" beyond 18 months. This alone is a sufficient basis to rescind the
$3.434 million demand.

(B) The Prohibition on Extrapolation Outside Formal Proceedings

HCAPPA contains another critical protection: "**No payer shall seek reimbursement... for a particular claim on an extrapolation of other claims**" except in limited circumstances.
Those circumstances include: (i) in a judicial or quasi-judicial proceeding (such as arbitration or litigation), (ii) in an administrative proceeding (e.g., during a contested case before an ALJ),
(iii) where the provider's records are insufficient or have been improperly altered, or (iv)

where there is clear evidence of fraud and a referral to the Fraud Prosecutor. None of these conditions are present.

The OSC's $3.434 million recoupment claim is based entirely on extrapolation from the sample, essentially asking Sunrise to repay thousands of other claims that the OSC never reviewed. HCAPPA forbids this except if the matter has moved into a formal proceeding or fraud/missing records are at issue. At the time of the Draft Audit Report, there was no court case or administrative law hearing pending—only an internal audit. That means the OSC was acting unilaterally, not as part of an adjudicative process. Under HCAPPA, extrapolation is not allowed to be the basis of a repayment request in these circumstances. The proper course would have been for the OSC to identify the sample overpayments (if any) and only seek those amounts, unless and until Sunrise contested the findings and the case proceeded to a hearing where extrapolation could be presented as evidence. By shortcutting straight to an extrapolated demand, the OSC violated HCAPPA's extrapolation ban.

Furthermore, the special exceptions to use extrapolation do not apply: Sunrise's records were provided and are not missing or massively reconstructed (exception (iii) not met), and as discussed, fraud with proper referral is not present (exception (iv) not met). Thus, exceptions(i) and (ii)—judicial or administrative proceedings—are the only arguable avenues. The OSC might contend that its audit process is a "quasi-judicial proceeding," but that is a stretch. The intent of HCAPPA was clearly to prevent payers from unilaterally imposing extrapolated overpayments, forcing them instead to present their case in a formal dispute resolution forum if they wished to use extrapolation. The OSC issued its demand before any such forum was convened. Therefore, the demand runs afoul of HCAPPA. Notably, when Oxford Health Plans violated this same provision by sending extrapolated refund requests to providers outside of litigation, DOBI issued a cease-and-desist order against Oxford. The state required Oxford to reimburse providers all amounts collected via unauthorized extrapolation. The message is clear: New Jersey does not tolerate extrapolation being used as a routine audit tactic outside proper channels.

Sunrise thus has a powerful statutory defense: the OSC's claim is time-barred and procedurally barred. The Office of the State Comptroller, as an arm of the State, must also abide by state laws. HCAPPA's protections should apply to Medicaid recoveries (and indeed Medicaid Managed Care Organizations are plainly subject to HCAPPA; the Medicaid Fraud Division should be held to the same standard when directly recouping on the State's behalf). Even if the OSC argued HCAPPA technically binds only "insurers" and not the State, the public policy embodied in HCAPPA should govern. That policy is to give providers finality on payments after 18 months and to prevent overzealous recoveries based on theoretical extrapolation unless a high threshold of wrongdoing is met. Here, the State's own enforcement action (*Oxford*) treats these limits as applicable to any "payer," which logically includes a Medicaid payer. Sunrise is prepared to assert HCAPPA as a complete defense to the bulk of the OSC's claim.

[3] *In the Matter of Proceedings by the Commissioner of Banking and Insurance to Fine Americhoice of New Jersey Inc., Oxford health Insurance, Inc., Oxford Health Plans (New Jersey) Inc. and UnitedHealthcare Insurance Company*, Order No. E18-12. https://www.nj.gov/dobi/division_insurance/enforcement/e18_12.pdf

In practical terms, applying HCAPPA would mean: (a) the OSC cannot recover for any claims in the audit period, all of which are older than 18 months, and (b) the OSC cannot demand any extrapolated sum unless and until an administrative law judge permits extrapolation in a contested case. At present, neither condition is satisfied. Therefore, the OSC's $3.434 million extrapolation is not legally enforceable under New Jersey law.

Flaws in OSC's Statistical Sampling and Extrapolation Methodology

Even if the OSC's claim were not statutorily barred by HCAPPA, the demand must be withdrawn because its statistical methodology is invalid and fails to meet established standards for reliability, fairness, and procedural due process. While statistical sampling can be a legitimate audit tool, it must be conducted in strict accordance with these standards. A flawed sample produces a flawed extrapolation, and any overpayment determination based on such an extrapolation is invalid.

(A) Lack of a Statistically Valid and Reproducible Random Sample

New Jersey regulations require that any extrapolation be based on a "valid random sample."[4] The OSC's own rules mandate that if sampling is used, OSC "will select a probability sample (that is, a random sample)" for the review period. This implies a rigorous scientific process. A federal court, analyzing the requirements for a valid statistical sample, provided a clear checklist, stating that sampling involves "drawing a random subset from a population where each element of the population has a known positive probability of being selected and hence included in the sample."[5] The process must involve measures of reliability and precision, known as "confidence levels" and "margins of error," which are determined by "commonly accepted mathematical formulae."[6]

Sunrise has serious concerns that the OSC's sample fails to meet these fundamental standards. The OSC has not disclosed the full sampling plan or the random seed values used to generate the sample of 183 episodes. Without this information, Sunrise (or any expert) cannot recreate the sample selection, which undermines confidence in the result and makes independent verification impossible. This is not a trivial technicality—it is a due process issue. An audit's sample must be reproducible. A federal district court in 2022 upheld an ALJ's decision to throw out a $5 million extrapolated overpayment against a hospital precisely because no witness or evidence substantiated the contractor's sampling methodology, and the sample frame could not be independently reproduced.[7] The ALJ in that case found the extrapolation did not comply with §1893 of the Social Security Act and the Medicare Program Integrity Manual, and the court agreed. Sunrise's situation is strikingly similar: the OSC's extrapolation is a black box, and it has not yet demonstrated that its methods comply with applicable guidelines.

Additionally, the universe from which the sample was drawn may be flawed. If the OSC's sample frame included claims that should have been excluded (e.g., non-Medicaid claims) or, conversely, excluded claims that should have been included (e.g., zero-paid or denied claims), that would taint the sample. The importance of a pristine sample universe was highlighted in a March 2024 federal court ruling where the court ordered CMS to produce the complete universe of claims, including zero-paid claims, because excluding certain claims "often drastically increases" the extrapolated overpayment.[8] In Sunrise's case, the OSC has not provided the full universe file for verification. Any departure from a truly random, comprehensive sample drawn from a properly defined universe undermines the OSC's extrapolation.

(B) Extrapolation is Unwarranted Absent a Sustained or High Level of Payment Error

Even if the OSC's sampling were otherwise valid, applying extrapolation in Sunrise's case is improper because the audit did not uncover a "sustained or high level of payment error." Both federal policy and basic fairness counsel against extrapolating overpayments when the measured error rate is modest.

The nation's primary authority on healthcare audits, CMS, has clearly indicated that statistical extrapolation is meant for exceptional cases of high error rates—not routine audits with moderate error findings. Federal law explicitly states that a Medicare contractor may not use extrapolation "unless the Secretary determines that… there is a sustained or high level of payment error."[9] Federal courts have consistently affirmed this as a critical pre-condition.[10]

While not binding on the OSC, the CMS Medicare Program Integrity Manual ("MPIM") provides a persuasive benchmark for what constitutes a "high" error rate, having historically defined it as a **50 percent or greater** error rate in the sample.[11] This threshold was incorporated to protect providers from punitive overpayment demands when only relatively small portions of claims are in error.

The OSC's findings in this audit fall far short of that mark. The audit found errors in 52 of 183 sample episodes (a **28.4% *episode* error rate**). The error rate in dollar terms is even lower: $8,586 in sample errors divided by a sample total of $33,773, which is a **25.4% *dollar* error rate.** This moderate error rate does not approach the level that would justify extrapolation under prevailing standards. Imposing a 400-fold liability increase on Sunrise based on a relatively moderate error finding violates best practices in healthcare auditing and Sunrise's right to fair, reasoned decision-making by the government.

The OSC may note that recent revisions to the MPIM have omitted the explicit 50% figure. But this is a distinction without a difference. The current MPIM still requires a "sustained or high" error rate; it simply doesn't tie it to a specific percentage. The policy rationale remains that extrapolation is reserved for extreme cases of provider

non-compliance. Notably, Medicare's own adjudicators have enforced this principle, with a CMS hearing officer rejecting an extrapolated overpayment because "the provider error rate [was] below the threshold of 50% required to justify extrapolation."[12] The OIG's own practices acknowledge similar thresholds for materiality: under many Corporate Integrity Agreements, providers must conduct a full extrapolated review only if an initial sample error rate exceeds 5%.[13] This reflects a common-sense understanding that minor or moderate error rates do not justify major extrapolated penalties.

The 50% threshold serves as a persuasive best practice that New Jersey should heed. The OSC's Medicaid audits do not occur in a vacuum. It would be arbitrary for the OSC to ignore the accumulated wisdom of the nation's largest payer. All relevant guidance points one way: do not extrapolate absent a high error rate. The OSC offers no reasoned justification to depart from that norm in Sunrise's case, where there is no allegation of fraud and the errors identified were mostly paperwork lapses. To wield extrapolation to pursue millions from Sunrise, when federal standards would counsel restraint, is the essence of an arbitrary enforcement action.

(C) Unacceptable Margin of Error and Failure to Offset Underpayments

Even if the sample was random, the OSC's extrapolation carries an unacceptably high margin of error and lacks the rigorous confidence level typically expected in Medicaid audits. The OSC used a 90% confidence interval, meaning there is a 10% chance that the true overpayment is outside the calculated range. A 10% risk of error is significant when millions of dollars are at stake. Moreover, the OSC's own figures indicate roughly a ±9.5% precision at 90% confidence. In practical terms, the actual overpayment could be hundreds of thousands of dollars lower than the OSC's point estimate. This lack of statistical certainty fails to meet the "fairly low risk of error" that courts require for sampling to be deemed acceptable.[14]

Furthermore, the OSC's calculation may be inflated due to a failure to properly account for underpayments. The OSC's Draft Audit Report states it found two sample episodes where Sunrise under-billed and that it "gave credit for these under billed claims and factored them into its extrapolated calculation." However, it provides no detail on how this was done. OSC's own regulations state that the "net overpayment" should include any underpayments to offset overpayments. Failing to properly include such offsets would skew the results against Sunrise. In one recent Medicare appeal, an ALJ invalidated an extrapolation because the auditor failed to consider the value of underpaid claims, which would have reduced the overpayment total.[15] The same principle should apply here.

In sum, the OSC's sampling and extrapolation are statistically and procedurally flawed. The lack of reproducibility, the moderate error rate that does not justify extrapolation, the high margin of error, and the questionable handling of underpayments all indicate

the extrapolation is not a fair or lawful measure of any overpayment. As such, it should be set aside.

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[4] N.J.A.C. 19:70-4.2. [5] *Residential Funding Co. v. HSBC Mortg. Corp. (USA) (In re Residential Capital, LLC)*, 2015 Bankr. LEXIS 1387 (Bankr. S.D.N.Y. Feb. 10, 2015). [6] *Id.* [7] *Methodist Healthcare-Memphis Hospitals v. Becerra*, No. 2:21-cv-02476, 2022 WL 4548668 (W.D. Tenn. Sep. 29, 2022). [8] *See* Phillips, Michael H., *What's Been Missing: District Court Orders the Government to Produce Complete Universe of Claims in Provider's Due Process Challenge to Extrapolated Overpayment*, K & L Gates (Mar. 8, 2024). [9] 42 U.S.C. § 1395ddd(f)(3). [10] *See, e.g., Rio Home Care, LLC v. Azar*, 2019 U.S. Dist. LEXIS 54536 (S.D. Tex. Mar. 11, 2019); *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321 (5th Cir. 2020); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 (S.D. Tex. Dec. 18, 2013). [11] *See* CMS Medicare Program Integrity Manual §8.4.1.4 (Rev. 828, issued 09-28-18). [12] https://www.nj.gov/comptroller/library/reports/Heart%20to%20Heart/Final%20Revised%20Appendix%20D%20-%20HTHs%20Comments%20and%20OSCs%20Response%20(8-26-21)%20Redacted.pdf# [13] https://oig.hhs.gov/faqs/corporate-integrity-agreement-faq/# [14] *Chaves County Home Health Service, Inc. et al. v. Louis W. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991). [15] Emanuel, Knicole C., *Medicare Auditors Fail to Follow the Jimmo Settlement*, (Dec. 27, 2024). https://medicaidlawnc.wpcomstaging.com/

(D) The OSC Demands Perfection While Exhibiting Deficiencies, Violating Due Process

The OSC's demand for absolute technical perfection from Sunrise, punishable by a multi-million dollar extrapolation, stands in stark contrast to the OSC's own demonstrable deficiencies in maintaining accurate and up-to-date regulations. This arbitrary application of standards violates fundamental principles of due process and fairness.

While the OSC demands flawless compliance from providers, its own governing regulations under the New Jersey Administrative Code (N.J.A.C.) are replete with errors, outdated citations, and references to non-existent federal rules – deficiencies that persist despite requirements for periodic review and updating. For example:

- N.J.A.C. 10:49-1.1 and 1.3 cite 42 C.F.R. § 412.30, a federal regulation that was removed over a decade ago, in August 2011 .
- N.J.A.C. 10:49-5.5(a)(9)(i) refers to "N.J.A.C. 10:49-2.7(c)" for Retroactive Eligibility, but subsection (c) does not exist, and § 10:49-2.7 no longer deals with that topic .
- N.J.A.C. 10:49-5.5(a)(11) cites "N.J.A.C. 10:49-6," a regulation that does not exist .
- N.J.A.C. 10:49-5.5(a)(13)(ii) cites "N.J.A.C. 10:49-9.5, Provider Certification and Recordkeeping," but that regulation addresses "Observance of religious belief" and has done so since 1998
- N.J.A.C. 10:49-5.5(a)(14) refers to "N.J.A.C. 10:49-2.13(e)(2)," a subsection which does not exist .

One can only imagine the OSC's reaction if federal funding were threatened based on such errors. Indeed, we know precisely how the State reacts. When the federal government audited the New Jersey Department of Human Services (DHS) and demanded a $94 million repayment, DHS advanced arguments strikingly similar to those Sunrise presents here, including that the recoupment was based on a limited sample size, imposed unreasonable standards, and improperly relied on missing documentation from years prior. The State's own response in that context underscores the validity of Sunrise's position and highlights the double standard at play.

Furthermore, the OSC fails to provide adequate notice regarding its audit procedures, particularly the extrapolation methodology (RAT-STATS), which is not disclosed or explained in any accessible New Jersey statute, regulation, or public guidance . This lack of transparency allows the OSC to select audit periods arbitrarily, potentially maximizing recoupment demands rather than focusing on genuine compliance issues. In this case, the OSC selected an audit period ending just before Sunrise implemented corrective measures

regarding signature processes in March 2020, a fact known to the OSC, suggesting the period was chosen to penalize past, self-corrected conduct rather than address current practices. This approach contravenes the spirit of federal guidance, such as the CMS Program Integrity Manual, which favors educational intervention before resorting to punitive statistical sampling. The OSC's elevation of form over substance, demanding millions based on technical regulatory interpretations while failing to maintain accuracy in its own governing code and providing inadequate procedural notice, constitutes an arbitrary and capricious application of its authority that violates Sunrise's right to due process.

(E) The OSC's Audit Procedures Violate Due Process

The OSC's conduct throughout this audit, particularly its selection of the audit period and its lack of transparency regarding methodology, constitutes a violation of Sunrise's right to due process under both federal and state law. Medicaid investigations and audits must be conducted in a manner that affords providers due process of law, a principle codified in federal regulations applicable to state Medicaid agencies.

One glaring violation stems from the OSC's selection of the audit period (July 2017 – March 2021). There is no public notice, guidance, or disclosure regarding how the OSC selects its audit periods. The OSC does not publish any manual detailing its auditing process or how it employs statistical methods like RAT-STATS extrapolation. This opacity allows the OSC to select periods arbitrarily, potentially maximizing recoupment rather than addressing compliance in a fair manner. As discussed, the OSC chose a period largely preceding Sunrise's self-correction of the signature issue, seemingly manufacturing a larger demand despite knowing the issue was resolved. This arbitrary selection, untethered to any articulated standards, violates due process.

Procedural due process imposes constraints on governmental decisions that deprive individuals or entities of property interests. The United States Supreme Court has made clear that such protections apply in the context of administrative benefit determinations. New Jersey courts similarly emphasize that administrative rulemaking and agency actions must serve the interests of fairness and due process. Agencies must "articulate the standards and principles that govern their discretionary decision in as much detail as possible." An agency's ability to select its procedures is limited by "the strictures of due process and of the [Administrative Procedure Act]." The New Jersey Supreme Court has not hesitated to impose principles of "fundamental procedural fairness on administrative agencies... beyond constitutional demands."

The OSC's failure to publish standards governing its audit period selection and extrapolation methods, coupled with its selection of an audit period seemingly designed to capture already-corrected conduct, fails to meet these standards of

fundamental fairness and due process. This lack of transparency and potentially punitive selection process provides an independent basis for challenging the OSC's findings.

(F) The Core Regulation Underlying the OSC's Finding is Invalid

Beyond the procedural and due process violations in how the audit was conducted, the OSC's entire demand rests on an alleged violation of a regulation, N.J.A.C. 10:61-1.6, that was itself invalidly enacted and therefore lacks the force of law. An agency seeking to enforce a regulation must, at a minimum, demonstrate that the regulation was properly promulgated.
Here, the OSC cannot meet that burden.

The New Jersey Administrative Procedure Act ("NJAPA") imposes strict requirements on state agencies when they adopt regulations that are more stringent than corresponding federal standards. Specifically, N.J.S.A. § 52:14B-23 requires that an agency:

...include as part of the initial publication and all subsequent publications of such rule or regulation, a statement as to whether the rule or regulation in question contains any standards or requirements which exceed the standards or requirements imposed by federal law. Such statement shall include a discussion of the policy reasons and a cost-benefit analysis that supports the agency's decision to impose the standards or requirements...

The OSC's core finding is that Sunrise violated N.J.A.C. 10:61-1.6 because test requisitions lacked a "personally signed" order from a physician. This New Jersey requirement is demonstrably more restrictive than the federal standard. The applicable federal regulation, the Clinical Laboratory Improvement Amendments (CLIA), at 42 CFR § 493.1241, simply requires a test requisition to be "authorized" by a physician or other authorized person, with no mandate for a personal, "wet" signature for every order.

Given that the New Jersey rule imposes a more stringent standard than federal law, the NJAPA required the agency to publish a Federal Standards Statement justifying this deviation. A review of the regulatory history for N.J.A.C. 10:61-1.6 and its antecedents reveals no such statement. The agency never provided the required policy justification or cost-benefit analysis for imposing a "personally signed" requirement that exceeds the federal authorization standard.

Because the regulation was not properly promulgated in accordance with the clear mandate of the NJAPA, it is invalid and unenforceable. An administrative agency cannot demand millions of dollars from a provider for failing to comply with a rule

that the agency itself failed to properly enact. Therefore, the OSC's central finding of "missing signatures" collapses, and the extrapolated demand based upon it is invalid *ab initio*.

II. Legal and Precedential Challenges to Extrapolated Overpayments

Both New Jersey and federal law recognize that extrapolated overpayment demands are susceptible to legal challenge. Sunrise's opposition to the OSC's demand is firmly grounded in precedent. We highlight several authorities demonstrating that statistical extrapolation, if not done scrupulously, will not be upheld on appeal:

- **New Jersey OSC Regulations:** As noted, the OSC's own rules now codified at N.J.A.C. 19:70-4.2 lay out the requirements for statistical audits, implying that the OSC must play by the rules it has set. If those rules were not followed to the letter in Sunrise's audit, the extrapolation is not legally sufficient. For example, if the sample was not truly random or the extrapolation did not account for confidence intervals, the OSC would be violating its regulation. The regulation even contemplates that providers will challenge extrapolations with expert evidence—a clear acknowledgment that such findings are not infallible and can be overturned.
- **CMS Ruling 86-1 and Federal Due Process:** Since the 1980s, the use of statistical sampling in Medicare/Medicaid audits has been predicated on the idea that it is a reasonable substitute for 100% claim review only if providers still have a fair opportunity to be heard. In *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982), providers argued that extrapolation violated due process by not proving each claim overpayment. The court disagreed in principle, but only because the providers could rebut the sample extrapolation in an administrative hearing.[16] In other words, the accuracy of the extrapolation was not assumed; the state had to show its sampling was reasonable, and the provider had the chance to demonstrate errors or biases. The Seventh Circuit noted that forcing claim-by-claim proof would be impractical given the volume, so sampling was permissible as long as it wasn't "arbitrary" and the provider could challenge the calculations.[17] Sunrise is now exercising the very right contemplated in that case—to challenge whether the OSC's extrapolation is a "just and reasonable inference" of any overpayment.
- **Requirement of Representative Samples:** Courts have consistently held that an extrapolation can only stand if the underlying sample is representative of the universe. For example, the D.C. Circuit in *Chaves County Home Health v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991), upheld an extrapolation of Medicare overpayments, but explicitly because the sample was drawn properly. The court found that "in light of the fairly low risk of error so long as the extrapolation is

made from a representative sample and is statistically significant, the government interest predominates." The corollary is that if the sample is not representative or statistically significant, the risk of error is high, and the provider's interest in accuracy predominates. Sunrise's case falls in the latter category: the risk of error in the OSC's extrapolation is high (as discussed in Section II), meaning it would be a due process violation to require Sunrise to repay millions based on that sample. No court would uphold an extrapolation from a haphazard or biased sample that did not reflect the provider's claims as a whole.

- **Rulings Overturning Faulty Extrapolations:** In recent years, there is growing precedent for overturning extrapolations when auditors fail to follow proper procedures. A notable example is *Methodist Healthcare-Memphis Hospitals v. Becerra*, No. 2:21-cv-02476, 2022 WL 4548668 (W.D. Tenn. Sep. 29, 2022). In that case, a Medicare contractor extrapolated an overpayment of over $5 million against a hospital. On appeal, the ALJ scrutinized the statistical methodology and found it non-compliant with Medicare law—specifically, the sample frame included data outside the audit scope, making the results impossible to replicate.[18] The ALJ invalidated the extrapolation, and although the Medicare Appeals Council tried to reinstate it, the federal district court ultimately upheld the ALJ's decision and threw out the extrapolation. The court ruled that the provider had shown the extrapolation was not reliable and that the Appeals Council lacked authority to overrule the ALJ in that instance. This case illustrates that when an extrapolation is built on a faulty foundation, courts will reject it, leaving the provider only liable for the actual claims reviewed (if at all). Sunrise's matter is analogous—our expert analysis will show that the OSC's extrapolation deviated from established protocols and should likewise be set aside.
- **Production of Underlying Data:** Another instructive precedent is the March 2024 decision in *Advanced Care Hospitalists* (District of S.C., as reported by K&L Gates) where, for the first time, a federal court ordered CMS to produce the complete set of claims data—including zero-paid claims—in an extrapolation dispute. The provider had argued that excluding zero-paid claims from the universe skewed the error rate. The court agreed that the provider was entitled to that data and that an incomplete administrative record was a due process concern. This supports Sunrise's position that it is entitled to examine all aspects of the OSC's audit universe and sample, as formally demanded in the section that follows.
- **State Administrative Precedents:** Within New Jersey, there is recognition that extrapolation is an extraordinary measure. The logic of the HCAPPA statute (discussed in Part I) and enforcement actions under it make clear that New Jersey public policy disfavors unilateral extrapolation of overpayments outside of formal proceedings. In an enforcement action against Oxford Health Plans,

DOBI noted that payors cannot impose extrapolated overpayment demands outside of a judicial or administrative proceeding or absent clear evidence of fraud.[19] New Jersey's approach aligns with the notion that extrapolation is effectively a shortcut to allege a large debt, and therefore strict safeguards apply.

- **The OSC's Interpretation of Statutes and Regulations is Entitled to No Deference:** In issuing its Draft Audit Report, the OSC purports to act as the final arbiter of "applicable state and federal laws, regulations, and guidance." However, recent shifts in administrative law and long-standing principles in New Jersey jurisprudence establish that the OSC's interpretation of those authorities is entitled to little or no deference from a reviewing tribunal. Accordingly, its conclusions regarding Sunrise's compliance must be subjected to independent, *de novo* review. Historically, courts sometimes deferred to an agency's reasonable interpretation of an ambiguous statute under the doctrine of *Chevron* deference. However, the United States Supreme Court recently overruled *Chevron* in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024). The Court held that the Administrative Procedure Act requires courts to exercise their own independent judgment when deciding whether an agency has acted within its statutory authority. Courts may no longer defer to an agency's legal interpretation simply because a statute is ambiguous. This has profound implications for this case. If federal agencies interpreting the federal Medicaid statutes are no longer entitled to deference, a state agency like the OSC is certainly entitled to none. Indeed, New Jersey courts have long held this to be the case, even before *Loper Bright*, stating, "we will not afford to the [state agency] the deference that *Chevron* provides to federal agencies interpreting federal law." (*In re RCN of N.Y.*, 186 N.J. 83, 92-93 (2006)). Moreover, New Jersey's own parallel state doctrine of deference was based on the *Chevron* doctrine (*see Matturri v. Bd. of Trs. of the Judicial Ret. Sys.*, 173 N.J. 368, 381-82 (2002)). With its guiding federal principle now struck down, the state doctrine has been effectively gutted, particularly where state statutes are so heavily interconnected with a federal statutory regime like Medicaid. In light of the foregoing, the OSC's interpretation of N.J.A.C. 10:61-1.6 as requiring a strict, handwritten "wet signature" is baseless and entitled to no deference. There is no federal or state *statute* requiring a handwritten signature for lab orders. Rather, there is only a state regulation, which the OSC, in its discretion, is interpreting in the most restrictive way possible to justify its findings. An Administrative Law Judge or a reviewing court is now obligated to review this interpretation independently and is not bound by the OSC's self-serving reading of its own rule. This lack of deference extends to the OSC's extrapolation techniques. There are no federal or state statutes, nor any regulations, that prescribe the specific statistical methods (like RAT-STATS) or the procedural choices (like audit period selection) that the OSC must use. The OSC's decision to employ a 90% confidence interval, to select a historical audit period, and to use its preferred

> statistical software are all discretionary choices. These are not entitled to deference and must be scrutinized for their fundamental fairness, statistical validity, and compliance with due process—standards which, as argued throughout this memorandum, they fail to meet.

In light of these legal precedents, Sunrise is confident that an adjudicator reviewing this matter will closely scrutinize the OSC's sampling methodology. The consistent theme in the case law is fairness: the government may use statistical methods to estimate overpayments, but the provider must have an opportunity to challenge every aspect of that estimate. When those challenges reveal significant problems—as is true here—the extrapolation will not be allowed to stand.

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[16] Emanuel, Knicole C., *Medicare Auditors Fail to Follow the Jimmo Settlement*, (Dec. 27, 2024). https://medicaidlawnc.wpcomstaging.com/ [17] https://www.supremecourt.gov/DocketPDF/21/21-1326/255370/20230222210902882_Schutte%20States%20Amicus%20Brief.pdf [18] *Methodist Healthcare Memphis Hospitals v. Xavier Becerra*, No. 2:2021cv02476 - Document 32 (W.D. Tenn. 2022). https://law.justia.com/cases/federal/district-courts/tennessee/tnwdce/2:2021cv02476/92540/32/ [19] *In the Matter of Proceedings by the Commissioner of Banking and Insurance to Fine Americhoice of New Jersey Inc., Oxford health Insurance, Inc., Oxford Health Plans (New Jersey) Inc. and UnitedHealthcare Insurance Company*, Order No. E18-12. https://www.nj.gov/dobi/division_insurance/enforcement/e18_12.pdf

III. Demand for Procedural Compliance: Production of the RS&E File

Separate and apart from the substantive flaws in the Draft Audit Report, Sunrise must object to the OSC's failure to provide the essential documentation underlying its extrapolated findings. The OSC's demand is procedurally deficient until it complies with its own regulations, which are designed to ensure transparency and afford providers the basic elements of due process. To date, the OSC has not produced the complete Random Sampling and Extrapolation ("RS&E") file for this audit. This omission fundamentally hampers Sunrise's ability to verify, analyze, and rebut the OSC's methodology.

An extrapolation is presumed accurate only in the absence of evidence to the contrary, and the OSC's own regulations explicitly grant providers the right to rebut the extrapolation with expert testimony.[20] That right is rendered meaningless without access to the underlying data. Accordingly, we hereby formally demand, pursuant to **N.J.A.C. 19:70-4.2(g)**, that the OSC immediately produce the full and unredacted RS&E file for this matter. Per the regulation, this disclosure must include, at a minimum:

1. The full **sampling plan** used to design the audit;
2. The complete **universe of claims** from which the sample was drawn, including any claims that were considered but excluded;
3. All **formulas and calculation procedures** used in determining the point estimate, margin of error, and final extrapolated overpayment amount; and
4. The **random seed values** and any other parameters or algorithms used to select the specific sample of 183 episodes.

The production of this file is not a courtesy; it is a regulatory and constitutional prerequisite to a valid overpayment demand based on sampling. New Jersey's regulations explicitly require that any statistically extrapolated demand be accompanied by this detailed supporting information. The OSC's failure thus far to disclose the random seed or the full universe file prevents any independent replication or validation of its findings and falls short of the transparency required under law.

We formally put the OSC on notice that the continued withholding of the RS&E documentation violates N.J.A.C. 19:70-4.2(g) and deprives Sunrise of a full and fair opportunity to review and challenge the extrapolation, a right to which it is entitled before any recoupment can occur.

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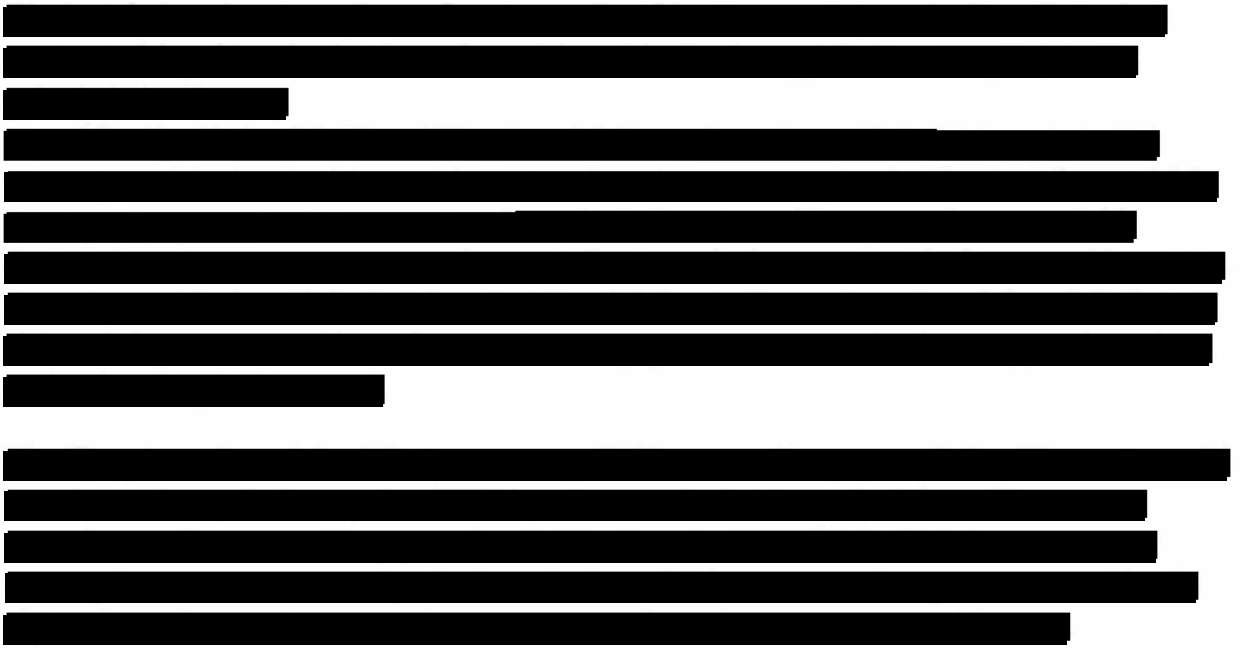
[20] N.J.A.C. 19:70-4.2(g)(4).

IV. A Principled Path to Resolution

Notwithstanding the dispositive legal and statistical defenses outlined in the preceding sections, Sunrise remains committed to full compliance with all applicable Medicaid requirements and to resolving any legitimate, substantiated overpayments. Sunrise has no interest in retaining funds to which it is not entitled and stands ready to reimburse the State for any actual overbilling errors that are proven and recoverable under law.

However, the extrapolated demand of $3,434,950 is not a valid or constructive starting point for resolution. It is wholly untenable as a basis for discussion because it is contrary to New Jersey statute and is derived from a statistically flawed and unreliable methodology. In essence, the OSC is asking Sunrise to pay millions of dollars for thousands of claims that the OSC never reviewed, based on a projection technique that carries a significant risk of error and is legally impermissible in this context. Sunrise cannot and will not accept a multi-million dollar liability that rests on what amounts to a conjectural multiplier of a small sample, especially when New Jersey's statutes were designed to prevent exactly this scenario.



V. Principles of Equity and Good Conscience Preclude the OSC's Punitive Demand

In addition to the dispositive legal, statutory, and procedural defenses detailed above, federally recognized principles of "equity and good conscience" preclude the OSC's demand for over $3.4 million.[21] Those concepts should be at the forefront in this case, where the OSC seeks to impose a devastating penalty on a provider for technical

documentation issues that stem from the actions of a non-employee third party.

The OSC seeks this massive recoupment based on statements made by a physician who was not Sunrise's employee. As Sunrise informed the OSC in its prior submissions, that physician assured Sunrise that he was reviewing every lab order and that his signature was represented by his initials on the requisition form. Sunrise reasonably relied on those assurances. The OSC, in its apparent zeal to construct a case, interviewed that physician twice until he provided testimony that contradicted his prior assurances to Sunrise. Significantly, even in that testimony, the physician did not state that Sunrise had any reason to know of his internal procedural inaccuracies. Nor did he state that the lab tests were not medically necessary. To the contrary, he informed the OSC that the tests were required by New Jersey regulations.

The OSC has never grappled with the fact that the physician was not employed by Sunrise, nor has it challenged Sunrise's assertion that the physician made these statements and that Sunrise's reliance on them was reasonable. Instead, the OSC seeks to hold Sunrise strictly liable for millions of dollars based on the internal procedural failings of a separate entity, a result that defies equity.

Furthermore, the OSC does not, and could never, live up to the standard of technical perfection it demands of small businesses that provide a critical function for the health of New Jersey residents. As detailed in Section II(D) of this memorandum, the N.J.A.C. Title and Chapters that govern the OSC itself are replete with errors and references to federal regulations that do not exist. One can only imagine the hue and cry that would issue from the OSC if the federal government threatened to withhold funding based on those errors. The OSC's demand that providers adhere perfectly to every technicality, while its own governing rules are flawed, is the very definition of an arbitrary and capricious standard.

Finally, the context of Sunrise's work cannot be ignored. Sunrise performed this drug testing for needy patients of substance use disorder facilities during what can only be described as an overwhelming opioid crisis in our State. While the OSC was working from home during the COVID-19 pandemic, Sunrise employees were on-site, performing tens of thousands of COVID tests to help stop the spread of the virus and keep New Jersey residents informed during an unprecedented and terrifying public health crisis. Sunrise should be commended for this work, not penalized with a demand that threatens its very existence based on technical paperwork errors.

For these reasons, principles of equity, fairness, and good conscience provide an independent and compelling basis for withdrawing the OSC's punitive and disproportionate demand.

[21] *See* 42 U.S.C. §§ 1395pp(a)(2) and 1395gg(c) (allowing for waiver of recovery of Medicare overpayments where the provider was without fault and where recovery would be against "equity and good conscience").

VI. Conclusion and Reservation of Rights

For the foregoing reasons, the Draft Audit Report provides no lawful, factual, or reasonable basis for the $3.437 million repayment demand asserted against Sunrise. This memorandum has demonstrated that the OSC's findings are invalid on multiple, independent grounds. The vast majority of the demand rests on an extrapolation that is:

- **Time-barred** by the Health Claims Authorization, Processing and Payment Act (HCAPPA);
- **Procedurally unauthorized** by HCAPPA outside of a formal administrative proceeding;
- Based upon an alleged violation of a core regulation, N.J.A.C. 10:61-1.6, that was **invalidly promulgated** in violation of the New Jersey Administrative Procedure Act;
- Derived from a **statistically unsound and unreliable methodology** that fails to meet state and federal standards for due process, transparency, and fairness; and
- Represents a discretionary agency interpretation that is **entitled to no deference** from a reviewing tribunal.

Furthermore, the OSC's demand is fundamentally inequitable and an arbitrary and capricious application of its authority. Sunrise has fully cooperated with this lengthy audit and remains committed to compliance, but it will not acquiesce to an improper and legally baseless demand that threatens its existence.

We urge the OSC to reconsider its position and to work with Sunrise on the cooperative and principled resolution outlined in Section V. However, should the OSC choose to finalize the audit findings in their present form—including any Final Audit Report or Notice of Claim demanding payment of the extrapolated amount—Sunrise is prepared to take immediate action to protect its rights. We will promptly file for a contested case hearing with the New Jersey Office of Administrative Law and will mount a vigorous challenge to the OSC's determination. In such a proceeding, Sunrise will assert every available defense, including the HCAPPA statutory bar, the invalidity of the sampling methodology, and the unenforceability of the underlying regulation. Sunrise will present **expert statistical evidence** to rebut the OSC's extrapolation, as expressly permitted by **N.J.A.C. 19:70-4.2(g)(4)**. Please be advised that Sunrise will also seek a stay of any recoupment and the recovery of attorneys' fees and costs as allowed by law if forced to litigate.

Sunrise sincerely hopes that litigation can be avoided and that the OSC will take this opportunity to correct the Draft Report's course. We remain available to discuss a reasonable settlement along the lines proposed. In the meantime, nothing in this response should be construed as a waiver of any of Sunrise's rights or remedies, all of which are expressively reserved.

Respectfully Submitted,

10/21/25
Date

Robert Taylor, Esq

Sunrise Clinical Labs' Comments and OSC's Responses

In response to the Draft Audit Report (DAR) issued by the Office of the State Comptroller, Medicaid Fraud Division (OSC or MFD), Sunrise Clinical Laboratories (Sunrise), through counsel, submitted a response that raises the arguments below (Sunrise's full response is attached to the Final Audit Report as Appendix A). In short, Sunrise makes numerous unsupported and, at times, internally inconsistent claims.

As part of the DAR, OSC instructed Sunrise to submit a Corrective Action Plan (CAP) to address OSC's audit findings, but Sunrise failed to do so.

After reviewing Sunrise's response, OSC determined there was no basis to revise any of its findings. The principal arguments raised by Sunrise and OSC's responses are summarized below.

Excerpt of Sunrise's Objections

I. The OSC's Demand is Barred by New Jersey Statute (HCAPPA)

Beyond any statistical issues, the OSC's demand is independently and dispositively barred by New Jersey statute. The Health Claims Authorization, Processing and Payment Act (HCAPPA), N.J.S.A. 17B:30-48 et seq., imposes strict limits on when and how an insurer or payer can seek recoupment of paid health claims. Although originally enacted to govern private insurance carriers and HMOs, HCAPPA's public policy and explicit protections should apply equally, if not more so, to the State Medicaid program's recoupment efforts, since Medicaid providers are within the class the law seeks to protect.

Two key provisions of HCAPPA are directly relevant:

(A) The 18-Month Time Limit for Overpayment Recovery

HCAPPA provides that "**No payer shall seek reimbursement for overpayment of a claim ... later than 18 months after the date the first payment on the claim was made."** This is an unequivocal temporal limit. In Sunrise's case, the OSC is attempting to recover payments made four to eight years ago, well outside the 18-month window. Every claim in the July 2017-March 2021 audit period was paid by mid-2021 at the latest; thus, by late 2022, all of those claims became unrecoverable by statute-unless an exception applies. The only exceptions HCAPPA allows are for claims "submitted fraudulently, submitted by health care providers that have a pattern of inappropriate billing, or are subject to coordination of benefits."

If none of those exceptions is met, the law bars recovery, period. The OSC has not met any exception here:

- **No Fraud:** The OSC's audit does not allege that Sunrise engaged in fraud. There are no accusations of intentional misrepresentation or falsification of claims. Importantly, even if the OSC belatedly tried to label the conduct "fraud," HCAPP A requires "clear evidence of fraud" and that the payer must have investigated and referred the claim to the Office of the Insurance Fraud Prosecutor to invoke the fraud exception. The OSC has done no

such referral. In the Oxford case, when Oxford Health attempted to justify extrapolated recoupments by claiming providers committed fraud, DOBI found that argument hollow because Oxford had not actually referred the cases for fraud prosecution and had treated the providers as if no fraud occurred (e.g., keeping them in network). Similarly, the OSC cannot retroactively assert fraud now. Sunrise has not been under any fraud investigation; the OSC's own report frames the findings as regulatory non-compliance, not fraud. Thus, the fraud exception to the 18-month rule does not apply.

- **No Pattern of Inappropriate Billing:** The OSC might argue that its finding of errors in 52 of 183 sample episodes (28.4%) amounts to a "pattern of inappropriate billing." This argument fails. This exception is intended for egregious or willful misconduct-for example, a provider who consistently upcodes or bills for services not rendered, such that a clear pattern of abuse is present. Sunrise's situation is fundamentally different. The OSC's findings reflect sporadic paperwork mistakes (such as missing physician signatures) spread across a multi-year period among thousands of claims. These technical documentation issues do not equate to a "pattern of inappropriate billing" in the sense HCAPP A envisions. If the OSC's broad interpretation were accepted, any provider with a moderate rate of technical claim errors could be said to have a "pattern," which would swallow the 18-month rule entirely. The better view, and the one consistent with HCAPP A's purpose, is that a pattern means a systematic, intentional practice of incorrect billing. Sunrise's errors were not systematic and have innocuous explanations. There is no evidence Sunrise consciously adopted a practice of flouting Medicaid rules. Indeed, DOB I's enforcement action against Oxford signals skepticism of loose "pattern" allegations: Oxford had alleged a pattern of inappropriate billing by many providers to justify extrapolation, but DOBI forced Oxford to cease those recoupments because the allegations did not fall under HCAPPA's exceptions.[3] Sunrise urges the same skepticism here-the OSC cannot simply declare a pattern based on a minority of claims having documentation issues to evade the 18-month bar. It must prove a pattern of abuse, which it cannot on these facts.

- **No Coordination of Benefits Issue:** The claims at issue were billed to Medicaid as the primary payer. There is no assertion that another insurer was liable or that Sunrise failed to coordinate benefits. Thus, the coordination of benefits exception is irrelevant in this case.

Because none of the three exceptions apply, HCAPPA's 18-month limitation stands as an absolute bar to the OSC's recoupment demand for these old claims. By law, the OSC "shall not seek reimbursement" beyond 18 months. This alone is a sufficient basis to rescind the $3.434 million demand.

[3] In the Matter of Proceedings by the Commissioner of Banking and Insurance to Fine Americhoice of New Jersey Inc., Oxford health Insurance, Inc., Oxford Health Plans (New Jersey) Inc. and UnitedHealthcare Insurance Company, Order No. E18-12. https://www.nj.gov/dobi/division insurance/enforcement/e18 12.pdf

OSC's Response

In its response, Sunrise alleges that OSC's overpayment demand is barred by the Health Claims Authorization, Processing and Payment Act (HCAPPA) and due to the absence of fraud, a pattern of inappropriate billing, or coordination of benefits issues, OSC cannot recover extrapolated overpayment for claims older than 18 months. This argument misstates the governing legal framework and is without merit.

As a Medicaid provider, Sunrise is required to comply with all applicable federal and state regulations. OSC conducts audits pursuant to N.J.S.A. 52:15C-1 to -23 and N.J.S.A. 30:4D-53 to -64. These statutes authorize the State to identify and recover Medicaid overpayments with no 18-month limitation. In addition, according to N.J.A.C. 10:49-9.8(b), Medicaid providers must retain all documentation for five years. OSC's five-year review period is therefore consistent with the regulatory retention period and is not discretionary. OSC issued the audit notice to Sunrise on April 13, 2022, with an audit period of July 1, 2017 through March 31, 2021, which is well within the five-year look back period. In addition, N.J.S.A. 2A:14-1.2 allows the State to initiate civil actions within ten years after the cause of action has accrued. Sunrise's argument that MFD is barred by HCAPPA from reviewing claims after 18 months is baseless because HCAPPA governs commercial insurers; it does not govern state Medicaid program integrity or Medicaid overpayment recovery. As Sunrise acknowledges in its own submission, HCAPPA was enacted to regulate commercial insurance and Health Maintenance Organizations (HMOs), not Medicaid program integrity enforcement. Accordingly, the fraud, pattern of inappropriate billing, and coordination of benefits exceptions under HCAPPA have no relevance in this context. Moreover, Sunrise's suggestion that HCAPPA's protections should apply to Medicaid recoupments is unfounded. HCAPPA's purpose is directed exclusively at commercial claim payment practices, and nothing in the regulatory framework supports extending its protections to Medicaid audits or Medicaid program integrity enforcement.

OSC is likewise not required to establish fraud to recover Medicaid overpayments. Medicaid overpayment recovery assessed in OSC's audit is based on regulatory non-compliance. As such, Sunrise's arguments regarding the absence of fraud or the unrelated arguments fail to address the core issues of non-compliance identified in the audit. For these reasons, Sunrise has provided no factual basis for OSC to amend its extrapolation and audit findings.

Excerpt of Sunrise's Objections

(B) The Prohibition on Extrapolation Outside Formal Proceedings

HCAPPA contains another critical protection: **"No payer shall seek reimbursement...for a particular claim on an extrapolation of other claims"** except in limited circumstances. Those circumstances include: (i) in a judicial or quasi-judicial proceeding (such as arbitration or litigation), (ii) in an administrative proceeding (e.g., during a contested case before an ALJ), (iii) where the provider's records are insufficient or have been improperly altered, or (iv) where there is clear evidence of fraud and a referral to the Fraud Prosecutor. None of these conditions are present.

The OSC's $3.434 million recoupment claim is based entirely on extrapolation from the sample, essentially asking Sunrise to repay thousands of other claims that the OSC never reviewed.

HCAPPA forbids this except if the matter has moved into a formal proceeding or fraud/missing records are at issue. At the time of the Draft Audit Report, there was no court case or administrative law hearing pending-only an internal audit. That means the OSC was acting unilaterally, not as part of an adjudicative process. Under HCAPPA, extrapolation is not allowed to be the basis of a repayment request in these circumstances. The proper course would have been for the OSC to identify the sample overpayments (if any) and only seek those amounts, unless and until Sunrise contested the findings and the case proceeded to a hearing where extrapolation could be presented as evidence. By shortcutting straight to an extrapolated demand, the OSC violated HCAPPA's extrapolation ban.

Furthermore, the special exceptions to use extrapolation do not apply: Sunrise's records were provided and are not missing or massively reconstructed (exception (iii) not met), and as discussed, fraud with proper referral is not present (exception (iv) not met). Thus, exceptions (i) and (ii) — judicial or administrative proceedings—are the only arguable avenues. The OSC might contend that its audit process is a "quasi-judicial proceeding," but that is a stretch. The intent of HCAPPA was clearly to prevent payers from unilaterally imposing extrapolated overpayments, forcing them instead to present their case in a formal dispute resolution forum if they wished to use extrapolation. The OSC issued its demand before any such forum was convened. Therefore, the demand runs afoul of HCAPPA. Notably, when Oxford Health Plans violated this same provision by sending extrapolated refund requests to providers outside of litigation, DOBI issued a cease-and-desist order against Oxford. The state required Oxford to reimburse providers all amounts collected via unauthorized extrapolation. The message is clear: New Jersey does not tolerate extrapolation being used as a routine audit tactic outside proper channels.

Sunrise thus has a powerful statutory defense: the OSC's claim is time-barred and procedurally barred. The Office of the State Comptroller, as an arm of the State, must also abide by state laws. HCAPPA's protections should apply to Medicaid recoveries (and indeed Medicaid Managed Care Organizations are plainly subject to HCAPPA; the Medicaid Fraud Division should be held to the same standard when directly recouping on the State's behalf). Even if the OSC argued HCAPPA technically binds only "insurers" and not the State, the public policy embodied in HCAPPA should govern. That policy is to give providers finality on payments after 18 months and to prevent overzealous recoveries based on theoretical extrapolation unless a high threshold of wrongdoing is met. Here, the State's own enforcement action (Oxford) treats these limits as applicable to any "payer," which logically includes a Medicaid payer. Sunrise is prepared to assert HCAPPA as a complete defense to the bulk of the OSC's claim.

In practical terms, applying HCAPPA would mean: (a) the OSC cannot recover for any claims in the audit period, all of which are older than 18 months, and (b) the OSC cannot demand any extrapolated sum unless and until an administrative law judge permits extrapolation in a contested case. At present, neither condition is satisfied. Therefore, the OSC's $3.434 million extrapolation is not legally enforceable under New Jersey law.

OSC's Response

Sunrise's argument that HCAPPA prohibits extrapolation outside a judicial or administrative proceeding is unfounded for the reasons previously stated. HCAPPA does not govern state

Medicaid overpayments. The Oxford matter cited by Sunrise involved recoupment actions governed by HCAPPA and therefore has no applicability to Medicaid program integrity audits such as this one. As Sunrise stated, certain Medicaid Managed Care Organizations may be subject to HCAPPA in certain circumstances; however, this does not extend HCAPPA to Medicaid program integrity audits, which are governed by separate statutory and regulatory frameworks. Medicaid extrapolation is governed by N.J.A.C. 19:70-4.2, which explicitly authorizes OSC to use statistical sampling and extrapolation during audits and does not require a pending judicial or administrative proceeding. Extrapolation is a standard technique, and by design, does not require OSC to conduct an individual review of every claim in the universe to determine the payment.

The exceptions cited by Sunrise, such as missing records, fraud referrals, or ongoing adjudicatory proceedings are drawn exclusively from HCAPPA and have no applicability to OSC's Medicaid authority. In Medicaid audits, extrapolation is permissible for the audits itself and does not require referral to an Administrative Law Judge (ALJ), nor does it depend on the presence of fraud or missing records.

Excerpt of Sunrise's Objections

Flaws in OSC's Statistical Sampling and Extrapolation Methodology

(A) Lack of a Statistically Valid and Reproducible Random Sample

New Jersey regulations require that any extrapolation be based on a "valid random sample."[4] The OSC's own rules mandate that if sampling is used, OSC "will select a probability sample (that is, a random sample)" for the review period. This implies a rigorous scientific process. A federal court, analyzing the requirements for a valid statistical sample, provided a clear checklist, stating that sampling involves "drawing a random subset from a population where each element of the population has a known positive probability of being selected and hence included in the sample."[5] The process must involve measures of reliability and precision, known as "confidence levels" and "margins of error," which are determined by "commonly accepted mathematical formulae."[6]

Sunrise has serious concerns that the OSC's sample fails to meet these fundamental standards. The OSC has not disclosed the full sampling plan or the random seed values used to generate the sample of 183 episodes. Without this information, Sunrise (or any expert) cannot recreate the sample selection, which undermines confidence in the result and makes independent verification impossible. This is not a trivial technicality-it is a due process issue. An audit's sample must be reproducible. A federal district court in 2022 upheld an ALJ's decision to throw out a $5 million extrapolated overpayment against a hospital precisely because no witness or evidence substantiated the contractor's sampling methodology, and the sample frame could not be independently reproduced.[7] The ALJ in that case found the extrapolation did not comply

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[4] N.J.A.C. 19:70-4.2.
[5] *Residential Funding Co. v. HSBC Mortg. Corp. (USA) (In re Residential Capital, LLC)*, 2015 Bankr. LEXIS 1387 (Bankr. S.D.N.Y. Feb. 10, 2015).
[6] *Id.*
[7] *Methodist Healthcare-Memphis Hospitals v. Becerra,* No. 2:21-cv-02476, 2022 WL 4548668 (W.D. Tenn. Sep. 29, 2022).

with § 1893 of the Social Security Act and the Medicare Program Integrity Manual, and the court agreed. Sunrise's situation is strikingly similar: the OSC's extrapolation is a black box, and it has not yet demonstrated that its methods comply with applicable guidelines.

Additionally, the universe from which the sample was drawn may be flawed. If the OSC's sample frame included claims that should have been excluded (e.g., non Medicaid claims) or, conversely, excluded claims that should have been included (e.g., zero-paid or denied claims), that would taint the sample. The importance of a pristine sample universe was highlighted in a March 2024 federal court ruling where the court ordered CMS to produce the complete universe of claims, including zero-paid claims, because excluding certain claims "often drastically increases" the extrapolated overpayment.[8] In Sunrise's case, the OSC has not provided the full universe file for verification. Any departure from a truly random, comprehensive sample drawn from a properly defined universe undermines the OSC's extrapolation.

OSC's Response

Sunrise claims that "OSC has not disclosed the full sampling plan or random seed values used to generate the sample of 183 episodes," but this is incorrect. OSC provided to Sunrise the Random Sample and Extrapolation Provider Copy with the Summary of Findings OSC issued on February 11, 2025, and provided it again with the Draft Audit Report on October 8, 2025. The Random Sample and Extrapolation Provider Copy includes the Sampling Plan, the Universe data (in both detailed and cluster formats), the Full Sample with audit results (i.e., whether a claim was passed or failed, the reason it was failed, and the dollars in error, if any), and the Recovery Summary outlining how the overpayment was calculated (i.e., extrapolation methodology). Accordingly, contrary to Sunrise's assertion, OSC did provide Sunrise with all of the information it needed to fully understand OSC's sample and extrapolation.

Further, OSC does not have access to non-Medicaid claims, and zero-paid or denied claims are not included because they involve no Medicaid payment (i.e., a third party covered the entire payment). As OSC's responsibility is to protect the Medicaid program, and there is no Medicaid liability, there is no reason to audit or investigate those particular claims. Additionally, neither statistical standards nor New Jersey Medicaid requires denied or zero-paid claims to be included in the universe of claims.

Excerpt of Sunrise's Objections

(B) Extrapolation is Unwarranted Absent a Sustained or High Level of Payment Error

Even if the OSC's sampling were otherwise valid, applying extrapolation in Sunrise's case is improper because the audit did not uncover a "sustained or high level of payment error." Both federal policy and basic fairness counsel against extrapolating overpayments when the measured error rate is modest.

The nation's primary authority on healthcare audits, CMS, has clearly indicated that statistical

[8] *See* Phillips, Michael H., *What's Been Missing: District Court Orders the Government to Produce Complete Universe of Claims in Provider's Due Process Challenge to Extrapolated Overpayment*, K & L Gates (Mar. 8, 2024).

extrapolation is meant for exceptional cases of high error rates-not routine audits with moderate error findings. Federal law explicitly states that a Medicare contractor may not use extrapolation "unless the Secretary determines that ... there is a sustained or high level of payment error."[9] Federal courts have consistently affirmed this as a critical pre-condition.[10] While not binding on the OSC, the CMS Medicare Program Integrity Manual ("MPIM") provides a persuasive benchmark for what constitutes a "high" error rate, having historically defined it as a **50 percent or greater** error rate in the sample.[11] This threshold was incorporated to protect providers from punitive overpayment demands when only relatively small portions of claims are in error.

The OSC's findings in this audit fall far short of that mark. The audit found errors in 52 of 183 sample episodes (a **28.4% *episode* error rate).** The error rate in dollar terms is even lower: $8,586 in sample errors divided by a sample total of $33,773, which is a **25.4% *dollar* error rate.** This moderate error rate does not approach the level that would justify extrapolation under prevailing standards. Imposing a 400-fold liability increase on Sunrise based on a relatively moderate error finding violates best practices in healthcare auditing and Sunrise's right to fair, reasoned decision-making by the government.

The OSC may note that recent revisions to the MPIM have omitted the explicit 50% figure. But this is a distinction without a difference. The current MPIM still requires a "sustained or high" error rate; it simply doesn't tie it to a specific percentage. The policy rationale remains that extrapolation is reserved for extreme cases of provider non-compliance. Notably, Medicare's own adjudicators have enforced this principle, with a CMS hearing officer rejecting an extrapolated overpayment because "the provider error rate [was] below the threshold of 50% required to justify extrapolation.[12] The OIG's own practices acknowledge similar thresholds for materiality: under many Corporate Integrity Agreements, providers must conduct a full extrapolated review only if an initial sample error rate exceeds 5%.[13] This reflects a common-sense understanding that minor or moderate error rates do not justify major extrapolated penalties.

The 50% threshold serves as a persuasive best practice that New Jersey should heed. The OSC's Medicaid audits do not occur in a vacuum. It would be arbitrary for the OSC to ignore the accumulated wisdom of the nation's largest payer. All relevant guidance points one way: do not extrapolate absent a high error rate. The OSC offers no reasoned justification to depart from that norm in Sunrise's case, where there is no allegation of fraud and the errors identified were mostly paperwork lapses. To wield extrapolation to pursue millions from Sunrise, when federal standards would counsel restraint, is the essence of an arbitrary enforcement action.

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[9] 42 U.S.C. §1395ddd(f)(3).

[10] *See, e.g.*, *Rio Home Care, LLC v. Azar*, 2019 U.S. Dist. LEXIS 54536 (S.D. Tex. Mar. 11, 2019); *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321 (5th Cir. 2020); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 (S.D. Tex. Dec. 18, 2013).

[11] *See* CMS Medicare Program Integrity Manual §8.4.1.4 (Rev. 828, issued 09-28-18).

[12] https://www.nj.gov/comptrol1er/library/reports/Heart%20to%20Heart/Final%20Revised%20Appendix%20D%20-%20HTHs%20Comments%20and%20OSCs%20Response%20(8-26-21)%20Redacted.pdf#

[13] https://oig.hhs.gov/faqs/corporate-integrity-agreement-faq/#

OSC's Response

Sunrise's challenge that OSC must have a "sustained or high level of payment error" is invalid for numerous reasons. Most importantly, the Centers for Medicare and Medicaid Services (CMS) Medicare Program Integrity Manual (MPIM) is not applicable to OSC. It was created and designed for Medicare contractors, which is clearly stated in the opening statement of Section 8.4, not for a Medicaid audit such as this one. Instead, OSC relies on its own governing regulation, N.J.A.C. 19:70-4.2 (d), which states, "[t]he MFD may use statistical sampling and extrapolation to determine overpayments regardless of the error rate determined during the review of the sample."

Secondly, there is no statistical reason for requiring a "sustained or high level of payment error" for extrapolation. The primary purpose of statistical sampling is to project findings to the universe. An appropriate metric to evaluate the performance of an extrapolation is to calculate the precision, which can be high (or tight) regardless of the level of payment error because precision is based on other factors as well. In this case, OSC achieved a reasonable precision of 15.65 percent. Moreover, even if the precision was not as high, this would only benefit the provider since OSC determines its overpayment amount using the lower limit of a one-sided 90 percent confidence interval. When the precision is high, the lower limit is close to the point estimate. When the precision is low, the lower limit is further from the point estimate. Therefore, a lower precision would result in a lower recovery amount.

Third, CMS never had an official rule that required contractors to achieve a 50 percent error rate in order to extrapolate. As Sunrise acknowledges, a 50 percent error rate threshold is no longer mentioned anywhere in the CMS MPIM. This is due to repeated incorrect assumptions by providers that a 50 percent error rate was required for extrapolation for all cases. Additionally, Sunrise fails to recognize that the MPIM states that "sustained or high level" can be determined by "a variety of means, including, but not limited to," and then lists six different options to consider. As if this wasn't enough, CMS also states, "If the contractor believes that statistical sampling and/or extrapolation should be used for purposes of estimation, and it does not meet any of the criteria listed above, it shall consult with its BFL [business function lead]." Essentially, a CMS Contractor can select a statistical sample and extrapolate for any reason as long as it consults with its BFL prior to starting.

Fourth, Sunrise argues that a 25.42 percent dollar error rate and 28.42 percent episode error rate is not "sustained or high level". The definition of sustained is "to continue for an extended period of time." OSC reviewed a little less than a four-year period, ranging from 2017 to 2021, and Sunrise had errors in the sample from 2017 through 2020. Errors occurring across four years clearly meet the definition of sustained.

Excerpt of Sunrise's Objections

(C) Unacceptable Margin of Error and Failure to Offset Underpayments

Even if the sample was random, the OSC's extrapolation carries an unacceptably high margin of error and lacks the rigorous confidence level typically expected in Medicaid audits. The OSC used

a 90% confidence interval, meaning there is a 10% chance that the true overpayment is outside the calculated range. A 10% risk of error is significant when millions of dollars are at stake. Moreover, the OSC's own figures indicate roughly a ±9.5% precision at 90% confidence. In practical terms, the actual overpayment could be hundreds of thousands of dollars lower than the OSC's point estimate. This lack of statistical certainty fails to meet the "fairly low risk of error" that courts require for sampling to be deemed acceptable.[14]

Furthermore, the OSC's calculation may be inflated due to a failure to properly account for underpayments. The OSC's Draft Audit Report states it found two sample episodes where Sunrise under-billed and that it "gave credit for these under billed claims and factored them into its extrapolated calculation." However, it provides no detail on how this was done. OSC's own regulations state that the "net overpayment" should include any underpayments to offset overpayments. Failing to properly include such offsets would skew the results against Sunrise. In one recent Medicare appeal, an ALJ invalidated an extrapolation because the auditor failed to consider the value of underpaid claims, which would have reduced the overpayment total.[15] The same principle should apply here.

In sum, the OSC's sampling and extrapolation are statistically and procedurally flawed. The lack of reproducibility, the moderate error rate that does not justify extrapolation, the high margin of error, and the questionable handling of underpayments all indicate the extrapolation is not a fair or lawful measure of any overpayment. As such, it should be set aside.

OSC's Response

Sunrise claims that "OSC's extrapolation carries an unacceptably high margin of error and lacks the rigorous confidence level typically expected in Medicaid audits". Sunrise fails to provide any support to either claim. Sunrise follows this statement by speculating about the precision OSC achieved, despite OSC having already provided the exact precision the extrapolation achieved (i.e., 15.65 percent).

Additionally, Sunrise characterizes CMS as the "nation's primary authority on healthcare audits." The CMS MPIM states that "the lower limit of a one-sided 90 percent confidence interval should be used as the amount of overpayment to be demanded for recovery from the provider/supplier." Notwithstanding that CMS endorsed the exact approach that OSC used, the lower limit of a one-sided 90 percent confidence interval, Sunrise still claims that more rigorous confidence levels are typically expected elsewhere.

In both state and federal healthcare audits, the use of the lower limit of a one-sided 90 percent confidence interval is universally accepted as a very conservative overpayment demand in the provider's favor. The provider argues that "there is a 10% chance that the true overpayment is outside the calculated range," but using the same logic, there is also a 90 percent chance that the true overpayment is greater than the lower limit (i.e., OSC's overpayment demand). In fact, the actual overpayment is expected to be close to the point estimate, but OSC calculates confidence intervals and utilizes the lower limit in order to have a degree of statistical certainty. As a result,

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[14] *Chaves County Home Health Service, Inc. et al. v. Louis W. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991).
[15] Emanuel, Knicole C., *Medicare Auditors Fail to Follow the Jimmo Settlement*, (Dec. 27, 2024). https://medicaidlawnc.wpcomstaging.com/

OSC is willing to accept an overpayment amount that has a 90 percent chance of being less than the true amount.

Sunrise also argues that OSC failed to account for underpayments. As per N.J.A.C. 19:70-4.2 (b), "The MFD will calculate the net overpayment amount, which is comprised of any underpayments and overpayments in the statistical sample." OSC followed this requirement and explicitly confirmed in the Audit Report that underpayments were included in the net calculation. Also, had Sunrise reviewed the Random Sample and Extrapolation Provider Copy that was provided, it easily could have confirmed how the underpayments were applied.

Excerpt of Sunrise's Objections

(D) The OSC Demands Perfection While Exhibiting Deficiencies, Violating Due Process

The OSC's demand for absolute technical perfection from Sunrise, punishable by a multi-million dollar extrapolation, stands in stark contrast to the OSC's own demonstrable deficiencies in maintaining accurate and up-to-date regulations. This arbitrary application of standards violates fundamental principles of due process and fairness.

While the OSC demands flawless compliance from providers, its own governing regulations under the New Jersey Administrative Code (N.J.A.C.) are replete with errors, outdated citations, and references to non-existent federal rules – deficiencies that persist despite requirements for periodic review and updating. For example:

- N.J.A.C. 10:49-1.1 and 1.3 cite 42 C.F.R. § 412.30, a federal regulation that was removed over a decade ago, in August 2011.
- N.J.A.C. 10:49-5.5(a)(9)(i) refers to "N.J.A.C. 10:49-2.7(c)" for Retroactive Eligibility, but subsection (c) does not exist, and§ 10:49-2.7 no longer deals with that topic.
- N.J.A.C. 10:49-5.S(a)(l 1) cites "N.J.A.C. 10:49-6," a regulation that does not exist.
- N.J.A.C. 10:49-5.5(a)(13)(ii) cites "N.J.A.C. 10:49-9.5, Provider Certification and Recordkeeping," but that regulation addresses "Observance of religious belief" and has done so since 1998[.]
- N.J.A.C. 10:49-5.5(a)(14) refers to "N.J.A.C. 10:49-2.13(e)(2)," a subsection which does not exist.

One can only imagine the OSC's reaction if federal funding were threatened based on such errors. Indeed, we know precisely how the State reacts. When the federal government audited the New Jersey Department of Human Services (DHS) and demanded a $94 million repayment, DHS advanced arguments strikingly similar to those Sunrise presents here, including that the recoupment was based on a limited sample size, imposed unreasonable standards, and improperly relied on missing documentation from years prior. The State's own response in that context underscores the validity of Sunrise's position and highlights the double standard at play. Furthermore, the OSC fails to provide adequate notice regarding its audit procedures, particularly the extrapolation methodology (RAT-STATS), which is not disclosed or explained in any accessible New Jersey statute, regulation, or public guidance. This lack of transparency allows the OSC to select audit periods arbitrarily, potentially maximizing recoupment demands rather than focusing on genuine compliance issues. In this case, the OSC selected an audit

period ending just before Sunrise implemented corrective measures regarding signature processes in March 2020, a fact known to the OSC, suggesting the period was chosen to penalize past, self-corrected conduct rather than address current practices. This approach contravenes the spirit of federal guidance, such as the CMS Program Integrity Manual, which favors educational intervention before resorting to punitive statistical sampling. The OSC's elevation of form over substance, demanding millions based on technical regulatory interpretations while failing to maintain accuracy in its own governing code and providing inadequate procedural notice, constitutes an arbitrary and capricious application of its authority that violates Sunrise's right to due process.

OSC's Response

In its response, Sunrise alleges that OSC violated its due process rights by arbitrarily selecting the audit period and by failing to provide a public notice, guidance, or transparency particularly regarding its use of RAT-STATS. Sunrise also claims that OSC's enforcement is arbitrary because certain Medicaid regulations contain outdated citations or cross-references. In support of its position, Sunrise references New Jersey Department of Human Services (DHS) response to an unrelated federal audit.

OSC's selection of the audit period was neither arbitrary nor capricious. OSC selected a standard look-back period to ensure a comprehensive review of claims consistent with Medicaid's five-year documentation retention requirement. As a Medicaid provider, Sunrise is mandated by N.J.A.C 10:49-9.8(b) to maintain documentation supporting the services billed to the Medicaid program for at least five years from the date the service was rendered. OSC issued the audit notice to Sunrise on April 13, 2022, and selected an audit period of July 1, 2017 through March 31, 2021, which is well within the applicable five-year look back period. Further, with regard to the audit period, sample selection, and audit methodology, OSC also met with Sunrise at an entrance conference to outline each of these processes, and again provided Sunrise an opportunity to discuss the audit findings at the Exit Conference following the issuance of the Summary of Findings.

With respect to the use of RAT-STATS, OSC is not required by New Jersey law to publish detailed manuals or pre-announce its use of RAT-STATS. The governing regulation, N.J.A.C. 19:70-4.2, expressly authorizes statistical sampling and extrapolation, and RAT-STATS is a widely accepted tool used in federal and state program integrity audits. Throughout the audit process, OSC afforded Sunrise all processes required by law, including audit notice, opportunities to submit records and written responses, and the ability to challenge the statistical OSC's methodology.

Sunrise's additional assertions regarding outdated citations and references to the federal audit of DHS or other unrelated matters have no relevance to the scope or findings of this audit. These unrelated arguments fail to address the core issues of non-compliance identified during the audit.

In sum, Sunrise's due-process arguments are specious. OSC applied documentation requirements that were established through rule-making and that have been consistently applied. Moreover, throughout the audit process, OSC repeatedly communicated these requirements to Sunrise. Accordingly, notwithstanding Sunrise's claims, it had more than ample notice of the requirements it was being held to and still did not provide documentation or information that would lead OSC to change the adverse findings contained in its Final Audit Report.

Excerpt of Sunrise's Objections

(E) The OSC's Audit Procedures Violate Due Process

The OSC's conduct throughout this audit, particularly its selection of the audit period and its lack of transparency regarding methodology, constitutes a violation of Sunrise's right to due process under both federal and state law. Medicaid investigations and audits must be conducted in a manner that affords providers due process of law, a principle codified in federal regulations applicable to state Medicaid agencies.

One glaring violation stems from the OSC's selection of the audit period (July 2017 March 2021). There is no public notice, guidance, or disclosure regarding how the OSC selects its audit periods. The OSC does not publish any manual detailing its auditing process or how it employs statistical methods like RAT-STATS extrapolation. This opacity allows the OSC to select periods arbitrarily, potentially maximizing recoupment rather than addressing compliance in a fair manner. As discussed, the OSC chose a period largely preceding Sunrise's self-correction of the signature issue, seemingly manufacturing a larger demand despite knowing the issue was resolved. This arbitrary selection, untethered to any articulated standards, violates due process. Procedural due process imposes constraints on governmental decisions that deprive individuals or entities of property interests. The United States Supreme Court has made clear that such protections apply in the context of administrative benefit determinations. New Jersey courts similarly emphasize that administrative rulemaking and agency actions must serve the interests of fairness and due process. Agencies must "articulate the standards and principles that govern their discretionary decision in as much detail as possible." An agency's ability to select its procedures is limited by "the strictures of due process and of the [Administrative Procedure Act]." The New Jersey Supreme Court has not hesitated to impose principles of "fundamental procedural fairness on administrative agencies...beyond constitutional demands."

The OSC's failure to publish standards governing its audit period selection and extrapolation methods, coupled with its selection of an audit period seemingly designed to capture already-corrected conduct, fails to meet these standards of fundamental fairness and due process. This lack of transparency and potentially punitive selection process provides an independent basis for challenging the OSC's findings.

OSC's Response

Sunrise primarily asserts that OSC's selection of the audit period and its sampling methodology violate due process. As previously discussed in the section above, OSC afforded Sunrise full due process consistent with clearly established regulations and through the standard administrative process that OSC has conducted to evaluate whether Sunrise complied with the applicable law. Sunrise was on notice of the applicable regulations, agreed to comply with them as a Medicaid provider, and was given multiple opportunities to demonstrate compliance and contest OSC's audit findings. Sunrise has provided no evidence of compliance with N.J.A.C. 10:61-1.6 for the claims at issue for which OSC seeks reimbursement.

Further, OSC's authority permits discretion in selecting audit periods, as explained more fully in OSC's response to Section D above. From the outset and throughout the audit, Sunrise was afforded ample due process. It received a notice of audit identifying the audit's scope and objective, was given multiple opportunities to submit records, received a written Summary of Findings, participated in an exit conference, received a written Draft Audit Report, and was invited to submit a written response and a corrective action plan, which it declined to provide. As such, Sunrise has provided no basis for OSC to amend its audit findings.

Excerpt of Sunrise's Objections

(F) The Core Regulation Underlying the OSC's Finding is Invalid

Beyond the procedural and due process violations in how the audit was conducted, the OSC's entire demand rests on an alleged violation of a regulation, N.J.A.C. 10:61-1.6, that was itself invalidly enacted and therefore lacks the force of law. An agency seeking to enforce a regulation must, at a minimum, demonstrate that the regulation was properly promulgated. Here, the OSC cannot meet that burden.

The New Jersey Administrative Procedure Act ("NJAPA") imposes strict requirements on state agencies when they adopt regulations that are more stringent than corresponding federal standards. Specifically, N.J.S.A. § 52: 14B-23 requires that an agency:
…include as part of the initial publication and all subsequent publications of such rule or regulation, a statement as to whether the rule or regulation in question contains any standards or requirements which exceed the standards or requirements imposed by federal law. Such statement shall include a discussion of the policy reasons and a cost-benefit analysis that supports the agency's decision to impose the standards or requirements...

The OSC's core finding is that Sunrise violated N.J.A.C. 10:61-1.6 because test requisitions lacked a "personally signed" order from a physician. This New Jersey requirement is demonstrably more restrictive than the federal standard. The applicable federal regulation, the Clinical Laboratory Improvement Amendments (CLIA), at 42 CFR § 493.1241, simply requires a test requisition to be "authorized" by a physician or other authorized person, with no mandate for a personal, "wet" signature for every order.

Given that the New Jersey rule imposes a more stringent standard than federal law, the NJAPA required the agency to publish a Federal Standards Statement justifying this deviation. A review of the regulatory history for N.J.A.C. 10:61-1.6 and its antecedents reveals no such statement. The agency never provided the required policy justification or cost-benefit analysis for imposing a "personally signed" requirement that exceeds the federal authorization standard.

Because the regulation was not properly promulgated in accordance with the clear mandate of the NJAPA, it is invalid and unenforceable. An administrative agency cannot demand millions of dollars from a provider for failing to comply with a rule that the agency itself failed to properly enact. Therefore, the OSC's central finding of "missing signatures" collapses, and the extrapolated demand based upon it is invalid *ab initio*.

OSC's Response

Sunrise alleges that OSC cannot use N.J.A.C. 10:61-1.6 because this regulation was improperly promulgated and therefore lacks the force of law. Sunrise further claims that the physician-signature requirement in N.J.A.C. 10:61-1.6 is invalid because it allegedly exceeds the federal Clinical Laboratory Improvement Amendments (CLIA) standards and that the agency failed to issue a federal-standards statement at the time of adoption. These assertions are incorrect. This regulation was properly adopted and remains in full force and effect. CLIA establishes minimum federal requirements and expressly permits states to impose stricter standards. New Jersey's requirement that testing requisitions be personally signed orders for Medicaid payment does not conflict with CLIA and is entirely within the State's authority. As Medicaid providers, laboratories must comply with state Medicaid regulations regardless of whether those rules impose obligations beyond CLIA's baseline requirements. Sunrise has not identified any defect in the rulemaking process and regulation's adoption that would render N.J.A.C. 10:61-1.6 invalid or unenforceable.

Sunrise's arguments also fail because they do not account for the text and purpose of N.J.A.C. 10:61-1.6. That regulation is part of a comprehensive program integrity and regulatory framework that was designed to safeguard the integrity of Medicaid program and prevent fraud, waste, and abuse in an industry with a history of corruption in New Jersey. N.J.A.C. 10:61-1.6(a) protects Medicaid by establishing clear requirements for authorizing clinical laboratory services to ensure that tests are medically necessary and properly documented. The signature requirement serves as a critical safeguard against fraudulent billing practices, unnecessary testing, and improper financial arrangements that could improperly influence when and which tests are ordered. By requiring a physician's explicit approval, the rule ensures that clinical decisions remain the responsibility of a qualified practitioner rather than entities with financial incentives.

The regulation also promotes accountability by requiring laboratories to maintain the signed order on file and available for review. This requirement provides the Medicaid program with a verifiable audit trail that allows reviewers to assess the legitimacy of claims and detect potential abuses. The four permissible methods for conveying testing orders (signature, chart documentation, secure electronic system with safeguards, and verbal orders with written or electronic confirmation) permitted by N.J.A.C. 10:61-1.6 provide flexibility while preserving essential program integrity functions. Each method ensures that only a licensed practitioner authorized testing and that the testing order is authenticated in a manner that protects against fraud, waste, and abuse.

The rulemaking history for N.J.A.C. 10:61 further confirms these goals. During adoption of the rules, the Department of Human Services, Division of Medical Assistance and Health Services (DMAHS), emphasized the importance of preventing unauthorized and medically unnecessary laboratory testing. For example, in 1996, DMAHS explained that the requirement for "a definitive order personally signed by the physician requesting services" was "pivotal to curtailing fraud and abuse." 28 N.J.R. 1054(a) (Feb. 5, 1996). In 2011, when stakeholders again requested relaxation of the signature requirement, DMAHS reaffirmed that all Medicaid services must be certified as medically necessary and that requiring practitioner authorization is integral to ensuring only appropriate services are reimbursed. 43 N.J.R. 423(a) (Feb. 22, 2011). These comments underscore the State's longstanding and well-supported policy rationale for the signature requirement. Additionally, background on this rulemaking history and program integrity concerns

addressed by N.J.A.C. 10:61 is summarized in the Final Audit Report. The history of this rulemaking was also included and provided to Sunrise in both the Summary of Findings and the Draft Audit Report. Despite having this information, Sunrise's response fails to understand the regulatory framework.

Further, Sunrise's reliance on stamp-generated or otherwise non-compliant orders contravened these program integrity standards. By becoming a Medicaid provider, Sunrise agreed to comply with N.J.A.C. 10:61 and the accompanying requirements. Its failure to do so resulted in unsupported claims and overpayments that OSC is obligated to address.

Finally, instead of responding to the audit findings, Sunrise attempts to invalidate the state regulations promulgated to govern laboratory services. The arguments raised by Sunrise are unrelated to the deficiencies OSC identified during the audit and do not affect the enforceability of N.J.A.C. 10:61-1.6 or the validity of OSC's findings. Accordingly, Sunrise has provided no basis for OSC to amend its audit findings.

Excerpt of Sunrise's Objections

II. Legal and Precedential Challenges to Extrapolated Overpayments

Both New Jersey and federal law recognize that extrapolated overpayment demands are susceptible to legal challenge. Sunrise's opposition to the OSC's demand is firmly grounded in precedent. We highlight several authorities demonstrating that statistical extrapolation, if not done scrupulously, will not be upheld on appeal:

- **New Jersey OSC Regulations:** As noted, the OSC's own rules now codified at N.J.A.C. 19:70-4.2 lay out the requirements for statistical audits, implying that the OSC must play by the rules it has set. If those rules were not followed to the letter in Sunrise's audit, the extrapolation is not legally sufficient. For example, if the sample was not truly random or the extrapolation did not account for confidence intervals, the OSC would be violating its regulation. The regulation even contemplates that providers will challenge extrapolations with expert evidence-a clear acknowledgment that such findings are not infallible and can be overturned.

- **CMS Ruling 86-1 and Federal Due Process:** Since the 1980s, the use of statistical sampling in Medicare/Medicaid audits has been predicated on the idea that it is a reasonable substitute for 100% claim review only if providers still have a fair opportunity to be heard. In Illinois Physicians Union v. Miller, 675 F .2d 151 (7th Cir. 1982), providers argued that extrapolation violated due process by not proving each claim overpayment. The court disagreed in principle, but only because the providers could rebut the sample extrapolation in an administrative hearing.[16] In other words, the accuracy of the extrapolation was not assumed; the state had to show its sampling was reasonable, and the provider had the chance to demonstrate errors or biases. The Seventh Circuit noted that forcing claim-by-claim proof would be impractical given the volume, so sampling was permissible as long as it wasn't "arbitrary" and the provider could challenge the

[16] Emanuel, Knicole C., *Medicare Auditors Fail to Follow the Jimmo Settlement*, (Dec. 27, 2024). https://medicaidlawnc.wpcomstaging.com/

calculations.[17] Sunrise is now exercising the very right contemplated in that case-to challenge whether the OSC's extrapolation is a "just and reasonable inference" of any overpayment.

- **Requirement of Representative Samples:** Courts have consistently held that an extrapolation can only stand if the underlying sample is representative of the universe. For example, the D.C. Circuit in Chaves County Home Health v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991), upheld an extrapolation of Medicare overpayments, but explicitly because the sample was drawn properly. The court found that "in light of the fairly low risk of error so long as the extrapolation is made from a representative sample and is statistically significant, the government interest predominates." The corollary is that if the sample is not representative or statistically significant, the risk of error is high, and the provider's interest in accuracy predominates. Sunrise's case falls in the latter category: the risk of error in the OSC's extrapolation is high (as discussed in Section II), meaning it would be a due process violation to require Sunrise to repay millions based on that sample. No court would uphold an extrapolation from a haphazard or biased sample that did not reflect the provider's claims as a whole.

- **Rulings Overturning Faulty Extrapolations:** In recent years, there is growing precedent for overturning extrapolations when auditors fail to follow proper procedures. A notable example is Methodist Healthcare-Memphis Hospitals v. Becerra, No. 2:21-cv-02476, 2022 WL 4548668 (W.D. Tenn. Sep. 29, 2022). In that case, a Medicare contractor extrapolated an overpayment of over $5 million against a hospital. On appeal, the ALJ scrutinized the statistical methodology and found it non-compliant with Medicare law-specifically, the sample frame included data outside the audit scope, making the results impossible to replicate.[18] The ALJ invalidated the extrapolation, and although the Medicare Appeals Council tried to reinstate it, the federal district court ultimately upheld the ALJ's decision and threw out the extrapolation. The court ruled that the provider had shown the extrapolation was not reliable and that the Appeals Council lacked authority to overrule the ALJ in that instance. This case illustrates that when an extrapolation is built on a faulty foundation, courts will reject it, leaving the provider only liable for the actual claims reviewed (if at all). Sunrise's matter is analogous-our expert analysis will show that the OSC's extrapolation deviated from established protocols and should likewise be set aside.

- **Production of Underlying Data:** Another instructive precedent is the March 2024 decision in Advanced Care Hospitalists (District of S.C., as reported by K&L Gates) where, for the first time, a federal court ordered CMS to produce the complete set of claims data-including zero-paid claims-in an extrapolation dispute. The provider had argued that excluding zero-paid claims from the universe skewed the error rate. The court agreed that the provider was entitled to that data and that an incomplete administrative record was a due process concern. This supports Sunrise's position that

[17] https://www.supremecourt.gov/DocketPDF/21/21-1326/255370/20230222210902882_Schutte%20States%20Amicus%20Brief.pdf

[18] *Methodist Healthcare Memphis Hospitals v. Xavier Becerra*, No. 2:2021cv02476 -Document 32 (W.D. Tenn. 2022). https://law.justia.com/cases/federal/districtcourts/tennessee/tnwdce/2:2021cv02476/92540/32/

it is entitled to examine **State Administrative Precedents:** Within New Jersey, there is recognition that extrapolation is an extraordinary measure. The logic of the HCAPP A statute (discussed in Part I) and enforcement actions under it make clear that New Jersey public policy disfavors unilateral extrapolation of overpayments outside of formal proceedings. In an enforcement action against Oxford Health Plans, all aspects of the OSC's audit universe and sample, as formally demanded in the section that follows. DOBI noted that payors cannot impose extrapolated overpayment demands outside of a judicial or administrative proceeding or absent clear evidence of fraud.[19] New Jersey's approach aligns with the notion that extrapolation is effectively a shortcut to allege a large debt, and therefore strict safeguards apply.

- **The OSC's Interpretation of Statutes and Regulations is Entitled to No Deference:** In issuing its Draft Audit Report, the OSC purports to act as the final arbiter of" applicable state and federal laws, regulations, and guidance." However, recent shifts in administrative law and long-standing principles in New Jersey jurisprudence establish that the OSC's interpretation of those authorities is entitled to little or no deference from a reviewing tribunal. Accordingly, its conclusions regarding Sunrise's compliance must be subjected to independent, de novo review. Historically, courts sometimes deferred to an agency's reasonable interpretation of an ambiguous statute under the doctrine of Chevron deference. However, the United States Supreme Court recently overruled Chevron in Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244 (2024). The Court held that the Administrative Procedure Act requires courts to exercise their own independent judgment when deciding whether an agency has acted within its statutory authority. Courts may no longer defer to an agency's legal interpretation simply because a statute is ambiguous. This has profound implications for this case. If federal agencies interpreting the federal Medicaid statutes are no longer entitled to deference, a state agency like the OSC is certainly entitled to none. Indeed, New Jersey courts have long held this to be the case, even before Loper Bright, stating, "we will not afford to the [state agency] the deference that Chevron provides to federal agencies interpreting federal law." (In re RCN of NY, 186 N.J. 83, 92-93 (2006)). Moreover, New Jersey's own parallel state doctrine of deference was based on the Chevron doctrine (see Matturri v. Ed. Of Trs. of the Judicial Ret. Sys., 173 N.J. 368, 38182 (2002)). With its guiding federal principle now struck down, the state doctrine has been effectively gutted, particularly where state statutes are so heavily interconnected with a federal statutory regime like Medicaid. In light of the foregoing, the OSC's interpretation of N.J.A.C. 10:61-1.6 as requiring a strict, handwritten "wet signature" is baseless and entitled to no deference. There is no federal or state statute requiring a handwritten signature for lab orders. Rather, there is only a state regulation, which the OSC, in its discretion, is interpreting in the most restrictive way possible to justify its findings. An Administrative Law Judge or a reviewing court is now obligated to review this interpretation independently and is not bound by the OSC's self-serving reading of its own rule. This lack of deference extends to the OSC's extrapolation techniques. There are no federal or state statutes, nor any regulations, that prescribe the specific statistical methods (like RAT-STATS) or the

[19] *In the Matter of Proceedings by the Commissioner of Banking and Insurance to Fine Americhoice of New Jersey Inc., Oxford health Insurance, Inc., Oxford Health Plans (New Jersey) Inc. and UnitedHealthcare Insurance Company*, Order No. E18-12. https://www.nj.gov/dobi/division insurance/enforcement/e18 12.pdf

> procedural choices (like audit period selection) that the OSC must use. The OSC's decision to employ a 90% confidence interval, to select a historical audit period, and to use its preferred statistical software are all discretionary choices. These are not entitled to deference and must be scrutinized for their fundamental fairness, statistical validity, and compliance with due process-standards which, as argued throughout this memorandum, they fail to meet. In light of these legal precedents, Sunrise is confident that an adjudicator reviewing this matter will closely scrutinize the OSC's sampling methodology. The consistent theme in the case law is fairness: the government may use statistical methods to estimate overpayments, but the provider must have an opportunity to challenge every aspect of that estimate. When those challenges reveal significant problems-as is true here-the extrapolation will not be allowed to stand.

OSC's Response

Sunrise alleges that the "New Jersey and federal law recognize that extrapolated overpayment demands are susceptible to legal challenge," and "Sunrise's opposition to the OSC's demand is firmly grounded in precedent" citing several cases and general due-process authorities. These cases and cited authorities do not alter the legal framework governing OSC's authority or the standards that apply to Medicaid program oversight.

Sunrise's reliance on federal Medicare precedent and generalized due-process concepts does not change the legal framework for OSC's Medicaid audits in New Jersey. Medicaid overpayment recovery in New Jersey is governed by New Jersey statutes and regulations, not by Medicare manuals, federal contractor decisions, or federal cases applying Medicare-specific requirements.

New Jersey's regulation governing statistical sampling, N.J.A.C. 19:70-4.2, expressly authorizes OSC to review Medicaid claims using random sampling and extrapolation. The regulation sets forth the applicable standards, including requirements for random sample selection, confidence intervals, and disclosure of methodology. OSC applied these regulatory standards here. The sample was selected using a statistically valid, random sample methodology, and the extrapolation was calculated in accordance with the requirements set forth in N.J.A.C. 19:70-4.2. Sunrise has not identified any deviation from N.J.A.C. 19:70-4.2. Instead, Sunrise relies on speculative assertions about theoretical "risks of error" that are insufficient to invalidate a methodology that complies with the regulation. Further, Sunrise's assertion that OSC's application of Medicaid regulations is entitled to "no deterrence" mischaracterizes the nature of this audit. OSC is not interpreting ambiguous statutory language – it is applying clear, longstanding Medicaid requirements that remain fully enforceable. In addition, Sunrise's reliance on decisions regarding the production of Medicare data is misplaced and is also inapposite. Under N.J.A.C. 19:70-4.2(g), OSC provided Sunrise with the underlying sampling and extrapolation documentation, including the universe, sample, results, and recovery calculations, as more fully explained in the relevant sections above.

In sum, the authorities cited by Sunrise do not undermine OSC's statutory and regulatory authority to use sampling and extrapolation, nor do they identify any defect in OSC's methodology. Sunrise has not shown that the sample was unrepresentative or that any claim in the universe was improperly included or excluded. Sunrise has not identified any missing data that would affect the extrapolation. OSC's extrapolated overpayment determination complies with New Jersey law and remains valid and recoverable.

Excerpt of Sunrise's Objections

III. Demand for Procedural Compliance: Production of the RS&E File

Separate and apart from the substantive flaws in the Draft Audit Report, Sunrise must object to the OSC's failure to provide the essential documentation underlying its extrapolated findings. The OSC's demand is procedurally deficient until it complies with its own regulations, which are designed to ensure transparency and afford providers the basic elements of due process. To date, the OSC has not produced the complete Random Sampling and Extrapolation ("RS&E") file for this audit. This omission fundamentally hampers Sunrise's ability to verify, analyze, and rebut the OSC's methodology.

An extrapolation is presumed accurate only in the absence of evidence to the contrary, and the OSC's own regulations explicitly grant providers the right to rebut the extrapolation with expert testimony.[20] That right is rendered meaningless without access to the underlying data. Accordingly, we hereby formally demand, pursuant to **N.J.A.C. 19:70-4.2(g),** that the OSC immediately produce the full and unredacted RS&E file for this matter. Per the regulation, this disclosure must include, at a minimum:

1. The full **sampling plan** used to design the audit;
2. The complete **universe of claims** from which the sample was drawn, including any claims that were considered but excluded;
3. All **formulas and calculation procedures** used in determining the point estimate, margin of error, and final extrapolated overpayment amount; and
4. The **random seed values** and any other parameters or algorithms used to select the specific sample of 183 episodes.

The production of this file is not a courtesy; it is a regulatory and constitutional prerequisite to a valid overpayment demand based on sampling. New Jersey's regulations explicitly require that any statistically extrapolated demand be accompanied by this detailed supporting information. The OSC's failure thus far to disclose the random seed or the full universe file prevents any independent replication or validation of its findings and falls short of the transparency required under law.

We formally put the OSC on notice that the continued withholding of the RS&E documentation violates N.J.A.C. 19:70-4.2(g) and deprives Sunrise of a full and fair opportunity to review and challenge the extrapolation, a right to which it is entitled before any recoupment can occur.

OSC's Response

Sunrise again claims that OSC failed to provide Random Sample and Extrapolation documentation and therefore violated N.J.A.C. 19:70-4.2(g), depriving Sunrise of a full and fair opportunity to review and challenge the sampling and extrapolation methodology. This assertion is incorrect.

[20] N.J.A.C. 19:70-4.2(g)(4).

As explained in OSC's responses to Sections A, B, and C above, Sunrise's claim that "OSC has not disclosed the full sampling plan or random seed values used to generate the sample of 183 episodes" is factually incorrect. OSC provided a Random Sample and Extrapolation Provider Copy on several occasions. First, OSC provided Sunrise the Random Sample and Extrapolation along with the first report, Summary of Findings, and then again along with the DAR. The Random Sample and Extrapolation Provider Copy includes the Sampling Plan, the Universe data (both in detail and cluster formats), the Full Sample with the results of the audit (i.e., whether a claim was passed or failed, the reason it was failed, and the dollars in error, if any), and a Recovery Summary that outlined how the overpayment was calculated (i.e., extrapolation methodology). Sunrise may not have reviewed the Random Sample and Extrapolation Provider Copy, but that does not change the fact that OSC provided this information to Sunrise on multiple occasions. Accordingly, Sunrise's objections, which rely on the mistaken premise that OSC failed to provide the Random Sample and Extrapolation file, are factually inaccurate and, thus, fatally flawed.

Excerpt of Sunrise's Objections

IV. A Principled Path to Resolution

Notwithstanding the dispositive legal and statistical defenses outlined in the preceding sections, Sunrise remains committed to full compliance with all applicable Medicaid requirements and to resolving any legitimate, substantiated overpayments. Sunrise has no interest in retaining funds to which it is not entitled and stands ready to reimburse the State for any actual overbilling errors that are proven and recoverable under law.

However, the extrapolated demand of $3,434,950 is not a valid or constructive starting point for resolution. It is wholly untenable as a basis for discussion because it is contrary to New Jersey statute and is derived from a statistically flawed and unreliable methodology. In essence, the OSC is asking Sunrise to pay millions of dollars for thousands of claims that the OSC never reviewed, based on a projection technique that carries a significant risk of error and is legally impermissible in this context. Sunrise cannot and will not accept a multi-million dollar liability that rests on what amounts to a conjectural multiplier of a small sample, especially when New Jersey's statutes were designed to prevent exactly this scenario.

[**OSC Note** – The remainder of Sunrise's response contains settlement language that could compromise Sunrise's position should this matter be disputed in a court proceeding. To protect Sunrise's position in that event, OSC has omitted this language from Sunrise's response.]

OSC's Response

Sunrise's proposal to limit this matter to only the individually reviewed claims misunderstands both OSC's statutory obligations and the regulatory framework governing Medicaid overpayment recovery. New Jersey law expressly authorizes the use of statistical sampling and extrapolation in Medicaid audits, and OSC is required by statute to recover all identified overpayments—not only those discovered through 100 percent claim reviews. The extrapolated overpayment is therefore the legally appropriate measure of the improper payments identified in this audit.

Sunrise's request that OSC withdraw the extrapolated finding is incompatible with OSC's duties under N.J.S.A. 30:4D-53 to – 64 and N.J.A.C. 19:70-4.2. Likewise, Sunrise's attempt to condition any resolution on OSC stipulating that its conduct does not constitute a "pattern of inappropriate billing" under HCAPPA is misplaced, as HCAPPA does not govern Medicaid overpayment recovery and has no bearing on this audit.

While Sunrise may dispute the results through the established administrative process, OSC must issue findings consistent with applicable law. Accordingly, the extrapolated overpayment of $3,434,950 remains valid, enforceable, and recoverable.

Excerpt of Sunrise's Objections

V. Principles of Equity and Good Conscience Preclude the OSC's Punitive Demand

In addition to the dispositive legal, statutory, and procedural defenses detailed above, federally recognized principles of "equity and good conscience" preclude the OSC's demand for over $3.4 million.[21] Those concepts should be at the forefront in this case, where the OSC seeks to impose a devastating penalty on a provider for technical documentation issues that stem from the actions of a non-employee third party.

The OSC seeks this massive recoupment based on statements made by a physician who was not Sunrise's employee. As Sunrise informed the OSC in its prior submissions, that physician assured Sunrise that he was reviewing every lab order and that his signature was represented by his initials on the requisition form. Sunrise reasonably relied on those assurances. The OSC, in its apparent zeal to construct a case, interviewed that physician twice until he provided testimony that contradicted his prior assurances to Sunrise. Significantly, even in that testimony, the physician did not state that Sunrise had any reason to know of his internal procedural inaccuracies. Nor did he state that the lab tests were not medically necessary. To the contrary, he informed the OSC that the tests were required by New Jersey regulations. The OSC has never grappled with the fact that the physician was not employed by Sunrise, nor has it challenged Sunrise's assertion that the physician made these statements and that Sunrise's reliance on them was reasonable. Instead, the OSC seeks to hold Sunrise strictly liable for millions of dollars based on the internal procedural failings of a separate entity, a result that defies equity.

Furthermore, the OSC does not, and could never, live up to the standard of technical perfection it demands of small businesses that provide a critical function for the health of New Jersey residents. As detailed in Section II (D) of this memorandum, the N.J.A.C. Title and Chapters that govern the OSC itself are replete with errors and references to federal regulations that do not exist. One can only imagine the hue and cry that would issue from the OSC if the federal government threatened to withhold funding based on those errors. The OSC's demand that providers adhere perfectly to every technicality, while its own governing rules are flawed, is the very definition of an arbitrary and capricious standard.

Finally, the context of Sunrise's work cannot be ignored. Sunrise performed this drug testing for needy patients of substance use disorder facilities during what can only be described as an

[21] *See* 42 U.S.C. §§ 1395pp(a)(2) and 1395gg(c) (allowing for waiver of recovery of Medicare overpayments where the provider was without fault and where recovery would be against "equity and good conscience").

overwhelming opioid crisis in our State. While the OSC was working from home during the COVID-19 pandemic, Sunrise employees were on-site, performing tens of thousands of COVID tests to help stop the spread of the virus and keep New Jersey residents informed during an unprecedented and terrifying public health crisis. Sunrise should be commended for this work, not penalized with a demand that threatens its very existence based on technical paperwork errors.

For these reasons, principles of equity, fairness, and good conscience provide an independent and compelling basis for withdrawing the OSC's punitive and disproportionate demand.

OSC's Response

Medicaid overpayment recovery is governed by New Jersey law, which requires the state to find an overpayment for paid claims that lack required documentation. The federal waiver provisions Sunrise cites apply only to Medicare and do not extend to state Medicaid program integrity.

Sunrise's argument that the documentation deficiencies stem from the conduct of a non-employee physician does not alter this requirement. Sunrise has failed to acknowledge its responsibility to maintain requisitions that are personally signed by the ordering physician or licensed practitioner as required under N.J.A.C. 10:61-1.6(a). OSC's sworn interviews with the ordering physicians confirmed that that they had not reviewed the orders and did not affix the stamps on the test requisitions. Moreover, those stamps do not constitute a signature or other acceptable form of approval and they are deemed unacceptable by N.J.A.C. 10:49-9.8(a)(1)(i)(2). It was obvious that the documentation did not include a physician's signature.

Further, providers billing Medicaid are responsible for ensuring that documentation supporting their claims, including required physician orders, is true, accurate, complete, and compliant before billing the Medicaid program, regardless of who performs the underlying service or supplies the documentation. The physician's employment relationship, internal procedures, or representations to Sunrise do not shift that responsibility or excuse noncompliance.

Further, Sunrise's broader argument that its public health work should absolve it of its responsibility is also unavailing. Such considerations raised by Sunrise do not negate the regulatory requirements to be compliant and maintain proper documentation for Medicaid services. When providers enroll into the Medicaid program they accept the responsibility to ensure compliance with program rules. As a result, in this case, the absence of required physician authorization renders the claims unsupported and requires recovery.

Accordingly, Sunrise has provided no factual basis for OSC to modify its audit findings. The overpayment remains valid and recoverable under New Jersey law.