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 Although originally enacted to govern private insurance carriers and HMOs, HCAPPA's public policy and explicit protections should apply equally, if not more so, to the State Medicaid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

---

[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.

---

[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,

---

[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.