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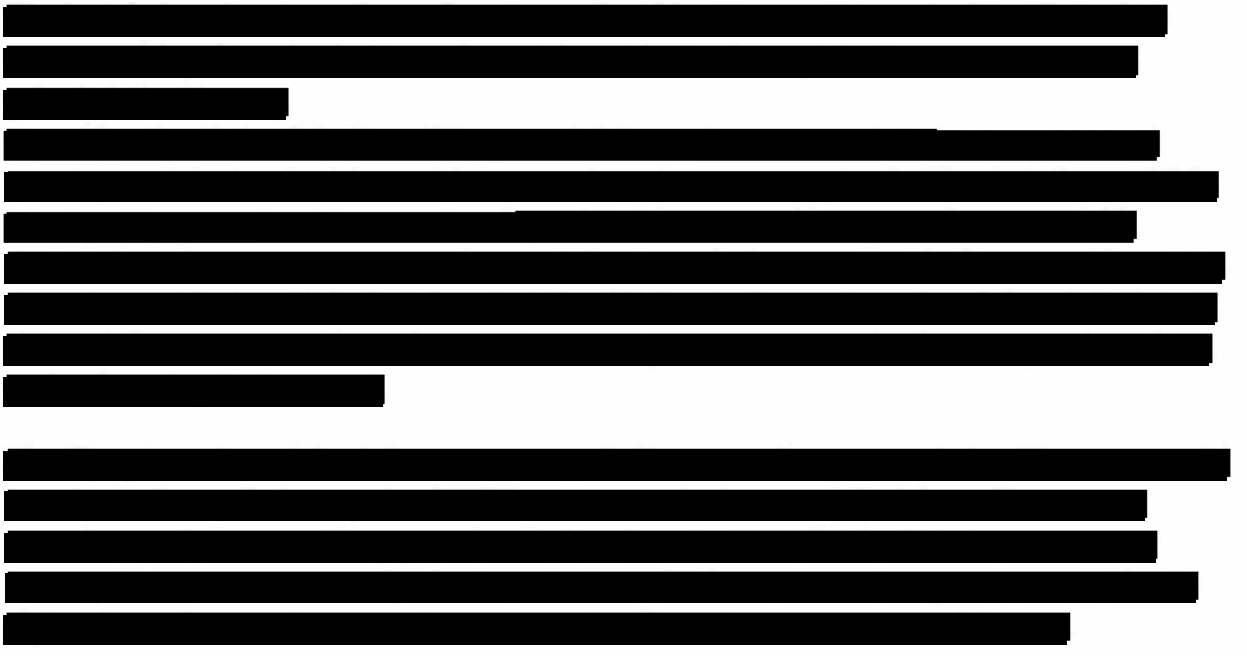
[20] N.J.A.C. 19:70-4.2(g)(4).

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