

JURISDICTION

The Department of Health (the Department) acts as the single state agency to supervise the administration of the Medicaid Program in New York State. 42 USC 1396a, Public Health Law (PHL) 201(1)(v), Social Services Law (SSL) 363-a. The Office of the Medicaid Inspector General (OMIG), an independent office within the Department, has the authority to pursue administrative enforcement actions against any individual or entity that engages in fraud, abuse or unacceptable practices in the Medicaid Program, and to recover improperly expended Medicaid funds. PHL 30, 31 and 32.

The OMIG determined to seek restitution of payments made under the Medicaid Program to Byram Healthcare Centers, Inc. (the Appellant). The Appellant requested a hearing pursuant to SSL 22 and the former Department of Social Services (DSS) regulations at 18 NYCRR 519.4 to review the determination.

HEARING RECORD

OMIG witnesses: Eugene Greco, director of fee for service audits
Kevin Ryan, deputy Medicaid Inspector General
Karl W. Heiner, statistical consultant

OMIG exhibits: 1-30, 32-36

Appellant witnesses: John Ras, chief compliance officer
Uzma Naz, senior compliance auditor
Sean M. Ennis, statistical consultant

Appellant exhibits: A-G

A transcript of the hearing was made. (Transcript, pages 1-669.) The OMIG submitted one and the Appellant submitted two post hearing briefs. The record closed on December 6, 2019.

SUMMARY OF FACTS

1. Appellant Byram Healthcare Centers, Inc., in White Plains, New York, is a provider of durable medical equipment (DME) and medical/surgical supplies as defined at 18 NYCRR 505.5(a), and is enrolled as a provider in the New York State Medicaid Program.

2. In April 2014 the OMIG initiated a review of the Appellant's records to determine whether they demonstrated compliance with Medicaid Program requirements. An audit was conducted by the New York City Human Resources Administration (HRA) pursuant to a memorandum of understanding with the OMIG. (Exhibits 9, 10; Transcript, pages 39-40.)

3. During the period January 1, 2009 through December 31, 2011, the Appellant was paid \$6,500,855.27 by the Medicaid Program for 134,770 services to 12,522 Medicaid recipients. This audit reviewed a random sample of 150 of those services, paid in the total amount of \$7,919.66. (Exhibits 1, 15, 16.)

4. After reviewing the Appellant's documentation in support of its claims for Medicaid reimbursement for the 150 services in the sample, auditors identified violations of Medicaid Program requirements in the submission of 90 of the claims and disallowed payments in the total amount of \$5,283.47. (Exhibit 17.)

5. The OMIG issued a final audit report dated November 15, 2017, which listed every disallowed claim and payment, set forth reasons for each disallowance, and notified the Appellant that the OMIG had determined to seek restitution of Medicaid Program overpayments in the amount of \$4,665,532. (Exhibit 1.)

6. The restitution claim includes an extrapolation utilizing a statistical sampling method in which the value of the disallowances found among the sample of 150 claims was projected to the total of 134,770 claims paid by the Medicaid Program during the audit period. (Exhibits 22, 23.)

7. The final audit report set forth findings and disallowances for the 90 claims in six categories:

1. No written order. Seventy-seven claims, disallowances in the total amount of \$4,213.77.
2. Missing information on written order. Seven claims (samples 21, 26, 81, 98, 107, 109, 131), disallowances in the total amount of \$581.37.
3. Missing documentation confirming receipt/delivery of item. Two claims (samples 36, 49) in the total amount of \$176.37.
4. Order refilled more than 180 days after it has been initiated by the prescriber. One claim (sample 89) in the amount of \$163.20.
5. Ordering prescriber conflicts with claim prescriber. One claim (sample 57) in the amount of \$90.80.
6. Item billed does not match ordered item. Two claims (samples 22, 55) in the total amount of \$57.96.

8. Eleven claims (samples 2, 12, 59, 71, 77, 79, 85, 89, 92, 107, 117) were disallowed with findings in two disallowance categories. (Exhibit 1, page A1-21.)

9. The Appellant offered no argument or evidence in support of thirteen disallowed claims (samples 12, 21, 22, 26, 55, 69, 77, 81, 85, 89, 92, 107, 109), and does not challenge the associated overpayments. (Transcript, pages 113-14; Appellant brief, page 10.)

ISSUES

Was the OMIG's determination to recover Medicaid Program overpayments from Appellant Byram Healthcare Centers, Inc., correct? If so, what is the amount of the overpayment?

APPLICABLE LAW

Medicaid providers are required, as a condition of their enrollment in the program, to prepare and to maintain contemporaneous records demonstrating their right to receive payment from the Medicaid Program and fully disclosing the nature and extent of the care, services and supplies they provide; and to furnish such records, upon request, to the Department. The information provided in relation to any claim must be true, accurate and complete. All information regarding claims for payment is subject to audit for six years. 18 NYCRR 504.3(a)&(h), 517.3(b), 540.7(a)(8). Notification by the Department to the provider of the Department's intent to audit shall toll the six-year period for record retention and audit. 18 NYCRR 517.3(c).

When the Department has determined that claims for medical services have been submitted for which payment should not have been made, it may require repayment of the amount determined to have been overpaid. 18 NYCRR 518.1(b). An overpayment includes any amount not authorized to be paid under the Medicaid Program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake. 18 NYCRR 518.1(c).

A person is entitled to a hearing to have the Department's determination reviewed if the Department requires repayment of an overpayment. 18 NYCRR 519.4. At the hearing, the Appellant has the burden of showing that the determination of the

Department was incorrect and that all claims submitted and denied were due and payable under the Medicaid Program. 18 NYCRR 519.18(d).

Computer generated documents prepared by the Department or its fiscal agent to show the nature and amount of payments made under the Medicaid Program will be presumed, in the absence of direct evidence to the contrary, to constitute an accurate itemization of the payments made to a provider. 18 NYCRR 519.18(f). An extrapolation based upon an audit utilizing a statistical sampling method certified as valid will also be presumed, in the absence of expert testimony and evidence to the contrary, to be an accurate determination of the total overpayments made. The Appellant may submit expert testimony challenging the extrapolation or an actual accounting of all claims paid in rebuttal to the Department's proof. 18 NYCRR 519.18(g).

Regulations of the former DSS most pertinent to this hearing decision are at 18 NYCRR Parts 505 (medical care, in particular section 505.5 regarding DME), 517 (provider audits), 518 (recovery and withholding of payments or overpayments) and 519 (provider hearings).

The New York State Medicaid Program issues Medicaid Management Information Systems (MMIS) provider manuals, including the MMIS Provider Durable Medical Equipment Manual, which are available to all providers and include, among other things, billing policies, procedures, codes and instructions. www.emedny.org. (DME Provider Manual provisions pertinent to this audit are in Exhibits 28 & 29.) Providers are obligated to comply with these official directives. 18 NYCRR 504.3(i); Lock v. NYS Department of Social Services, 220 A.D.2d 825, 632 N.Y.S.2d 300 (3rd Dept. 1995); PSSNY v. Pataki, 58 A.D.3d 924, 870 N.Y.S.2d 633 (3rd Dept. 2009).

DISCUSSION

The audit findings

The final audit report incorporated the OMIG's conclusions after review of the Appellant's October 19, 2017 response to an August 11, 2017 draft audit report. (Exhibits 2, 3, 4.) The draft audit report had been prepared after initial audit findings and overpayment calculations were shared and reviewed with the Appellant at an April 27, 2017 exit conference (referred to in the regulations as an audit closing conference). (Exhibits 7, 8.) These exchanges took place between the parties in accordance with audit procedures set forth at 18 NYCRR 517.5 and 517.6(a).

Reasons for which the 90 claims were disallowed were set forth in six categories:

1. No written order. Seventy-seven claims, disallowances in the total amount of \$4,213.77.

DME "may be furnished only upon a written order of a practitioner." 18 NYCRR 505.5(b)(1). The audit report stated "In 77 instances pertaining to 76 patients, the written order for the items provided was missing." (Exhibit 1, page A1-5.) The Appellant did not contest the five disallowances in samples 12, 69, 77, 85 and 92 and they are affirmed. (Transcript, page 114.) The Appellant did, however, produce written orders for the remaining 72 claims disallowed in this category. The OMIG rejected these fiscal orders because the ordering practitioners had signed and dated them after the dates of service.

DME Provider Manual Policy Guidelines relevant to this disallowance are:

In the event a fiscal order for DME, medical/surgical supplies or orthotic or prosthetic appliances has been telephoned or faxed to the provider, it is the provider's responsibility to obtain the signed fiscal order from the ordering practitioner within 30 calendar days. (Exhibit 28, page J-3; Exhibit 29, page K-5.)

The *minimum* information required on a fiscal order is:...

- Date ordered;

- Original signature of the ordering practitioner...
(Exhibit 28, page J-15; Exhibit 29, page K-10.)

For 55 claims the Appellant produced a fiscal order signed and dated within 30 days after the date of service.¹ In these instances the Appellant had shipped DME supplies to the patient after its customer service representative (CSR) was contacted and asked to fill an order. The requests all came from the patient or (in samples 18, 53, 63, 96, 104, 110, 112, 124, 135, 139, 149) the patient's caregiver. Most of the requests were made by telephone, but a few were by web order (samples 63, 104, 110), fax (samples 96, 135) or post card (sample 137). (Exhibit A, "proof of refill request" records.)

The customer service representative generated specific informational details such as catalog numbers, procedure codes and quantities on the Appellant's "proof of refill request" record. Pertinent billing and ordering practitioner information was also obtained or was already in the Appellant's record system for an existing patient. Once Medicaid eligibility was confirmed, the order was shipped to the patient. (Transcript, pages 304-309; Exhibit F, page B-22; Appellant brief, pages 3-5.)

A fiscal order with the required information was also prepared by the Appellant and transmitted to the ordering practitioner to be signed and returned to the Appellant by mail. (Transcript, page 321; Appellant brief, page 5.) After receiving the signed fiscal order back from the practitioner, the Appellant submitted its Medicaid claim, accurately reporting the date of service as the date the DME was shipped. (Transcript, page 339.) This is why the fiscal orders are signed and dated by the ordering practitioners after the

¹ Samples 1, 4, 5, 9, 13, 16, 17, 18, 20, 23, 24, 25, 28, 32, 37, 40, 44, 50, 51, 52, 53, 56, 61, 63, 68, 73, 74, 90, 91, 95, 96, 104, 110, 112, 113, 115, 117, 118, 119, 121, 124, 125, 127, 128, 130, 134, 135, 136, 137, 138, 139, 142, 144, 149, 150. The pertinent dates are summarized in Exhibit C.

dates of service on the claims. As the Appellant pointed out, this process expedited the provision of needed supplies to the patients.

According to the OMIG's director of fee for service audit, Eugene Greco, these fiscal orders are not valid to support the claims because a fiscal order "has to exist" and "that piece of paper that existed that day" must be signed and dated on or before the date of service. (Transcript, pages 74-75, 77.) If a signed order does not "exist" in this sense at the time the service is provided, the DME provider is not authorized to dispense it. (OMIG brief, pages 6-8.) OMIG audit manager Sharon Conway wrote: "A Medicaid provider cannot furnish or bill items if the practitioner hasn't yet authorized them." (Exhibit 12, page B5-18.)

These services were not billed before the practitioners authorized them. (Transcript, page 287.) The documentation is, however, consistent with the OMIG's conclusion that they were furnished before the practitioners authorized them. A claim by the Appellant's chief compliance officer, John Ras, that DME supplies were not sent until "the right documentation" was in place (Transcript, page 276) is demonstrably untrue. Immediately after making the claim, Mr. Ras agreed that the sample 1 item was shipped on August 26 as the result of a patient telephone request although the fiscal order authorizing Medicaid payment was not signed until September 9. (Transcript, pages 277-78, 283.) All of these disallowed claims were for items shipped before the "right documentation" – the written order required by 18 NYCRR 505.5(b)(1) – was signed.

The Appellant's alternative claim is that it communicated with the ordering practitioners before the service dates in order to obtain verbal authorization. (Transcript, pages 334-35; Appellant brief, pages 17-18.) The Appellant's senior compliance officer,

Uzma Naz, said that if a patient called in a request for which there were no authorized refills “a Byram representative will call the physician’s office.” (Transcript, page 309.) The Appellant’s claim that it directly communicated with the ordering practitioners about each of these orders before they were shipped is simply not documented. As OMIG audit manager Conway pointed out, “there is no notation that these originated as telephone or fax orders from the practitioner.” (Exhibit 12, page B-5-18, *emphasis added.*)

For sample 1, for example, Ms. Naz testified that the Appellant’s records document the patient telephoned an order request on August 22, and that the order was shipped on August 26. She was unable to say when during these four days the communication with the ordering practitioner occurred, claiming only that “[i]t all happened between the order start date and the ship date.” (Transcript, pages 328-29.)

Mr. Ras was asked:

Is there any indication anywhere..., are there notes or anything showing that Byram personnel talked to Dr. Laud before shipping this order out to the patient? (Transcript, pages 280-81.)

He did not answer this question, but instead alluded to an “ERP” electronic system in which a “customer note field, conversations were all documented in there.” (Transcript, page 281.) Ms. Naz also testified that the Appellant’s ERP notes would document communication with the practitioners before the service was provided. (Transcript, page 335.) The Appellant did not produce any such records. The phone logs it did submit, in the form of computer screen shots, consistently indicate only that a fiscal order was generated and sent to a practitioner when the order was filled, and sent again if the practitioner failed to promptly sign and return it. This communication all took place after

the DME had already been shipped to the patient. (Exhibits 3, 20, 21; Exhibit A; Transcript, pages 415-16; Appellant brief, pages 6-7.)

The Appellant produced no evidence documenting that any of these fiscal orders were, as Ms. Naz claimed, “an output of the conversation, the verbal conversation that occurred on the phone between Byram CSR and healthcare practitioner’s office.” (Transcript, page 312.) The documentation is instead consistent with Ms. Nas’ testimony that it was left up to the patient to communicate with the ordering provider:

If there are no refills circled on the order, on the next one we will notify the patient there is no refills prescribed on the existing order on file. They will have to contact their physician’s office in order to get a new order. (Transcript, page 320.)

It is plausible that in many of these instances there may have been, as the Appellant claims (Appellant brief, pages 4-5), telephonic communication between the Appellant and the ordering practitioner. However, the Appellant’s suggestion that “verbal conversations” about the orders did not need to be documented because some information on the fiscal orders “must come from the practitioner directly” and so “the fiscal order itself serves as the ‘notation’ or documentation of the verbal order” (Appellant brief, pages 18-19) is unpersuasive. This circular reasoning is inconsistent with the concept of documentation by “contemporaneous records demonstrating [the provider’s] right to receive payment.” 18 NYCRR 504.3(a).

The OMIG did not explain what its position would be if the Appellant’s records did document specific telephone or other communication with practitioners authorizing these orders before the DME was shipped, such as would comply, for example, with requirements at Education Law (Ed.L) 6810(4) or 18 NYCRR 505.3(b)(5) for telephone prescriptions for drugs. In the absence of any such documentation, the issue for these

disallowances remains squarely, and only, whether under 18 NYCRR 505.5(b)(1) and the DME Manual, a fiscal order signed after the DME service is provided, but within 30 days of the service, is valid to support a Medicaid claim.

An agency's interpretation of its own regulations is entitled to deference. That the OMIG's interpretation might not be the most natural reading of a regulation, or that the regulation could be interpreted in another way, does not make the interpretation irrational. Elcor Health Services, Inc. v. Novello, 100 N.Y.2d 273, 763 N.Y.S.2d 232 (2003). Even under this test, however, the OMIG's interpretation of 18 NYCRR 505.5(b)(1) fails because it is at odds with other regulations and the plain language of the DME Manual in a way that renders significant provisions of those rules and policies irrational and meaningless.

Mr. Greco emphasized, accurately, that the claims under review required fiscal orders authorizing payment by Medicaid (Transcript, pages 64, 67-68), but he also characterized a fiscal order as "a prescription written by a doctor." (Transcript, page 69.) The OMIG's insistence that DME cannot be dispensed before a practitioner signs an order confuses a fiscal order for DME with a prescription for drugs.

Medicaid regulations define prescription drug as "any drug for which a prescription is required under Section 6810 of the Education Law." 18 NYCRR 505.3(a)(6). Since at least 2006, Medicaid Program Pharmacy Manual Policy Guidelines have defined a fiscal order as "a request... to provide non-prescription drugs or medical/surgical supplies." The DME Manual definition of fiscal order is consistent with the Pharmacy Manual:

A fiscal order refers to any original, signed, written order of a practitioner, required by Medicaid to provide supplies, durable medical equipment, prosthetic

and orthotic appliances and orthopedic footwear for which prescriptions may not be required by law or regulation. DME Provider Manual Policy Guidelines – Definitions. (Exhibit 28, page J-26; Exhibit 29, page K-6.)

Medicaid regulations specify in detail how a pharmacy must document an order for a prescription drug “prior to dispensing the drug.” 18 NYCRR 505.3(b)(5). Ed.L 6810(4) also requires pharmacies to contemporaneously record the date and time they receive oral prescriptions. Neither the regulation nor the statute mentions anything about a 30-day period for obtaining written orders. Instead, they clearly require a documented interaction between the pharmacy and ordering practitioner before a drug is dispensed.

It is understandable that a practitioner should know and approve of a prescription drug before it is dispensed and ingested by the patient. To apply this rationale to fiscal orders for DME, however, is to read into 18 NYCRR 505.5, provisions of Ed.L 6810(4) and 18 NYCRR 505.3 that could have been but are not there.

The Medicaid regulation for DME fiscal orders, unlike the regulation for prescription drug orders, does not even mention oral or telephone orders or a concern that the DME provider document them before dispensing. 18 NYCRR 505.5(b). This leaves the OMIG to rely on the DME Manual, which states “[i]n the event a fiscal order for DME... has been telephoned or faxed to the provider, it is the provider’s responsibility to obtain the signed fiscal order from the ordering practitioner within 30 calendar days.”

The OMIG’s position that this means the signature on a fiscal order must be dated on or before the service date renders meaningless the 30-day period the DME Manual allows “to obtain the signed fiscal order.” There is no intelligible reason for the Medicaid Program to both require a fiscal order to be signed before the DME is dispensed, and then also specify a 30-day period to “obtain” that fiscal order. If a fiscal order must be signed

before the service is dispensed, it is not apparent why a provider must also demonstrate possession of that order other than by producing it on request for audit.

Providers obviously run a risk if they do not promptly secure necessary documentation and maintain possession and control over it for the required six years. This risk is demonstrated by other disallowances in this audit (disallowance category 3, samples 49 and 117), where the Appellant failed to obtain signed receipts from the carrier who made the deliveries. By the time this audit was conducted several years later, it was too late to obtain the receipts because the carrier's document retention policy meant they were no longer available.

It makes little sense, however, to disallow a claim on an audit conducted months or even years later if the provider is able to produce the appropriate documentation. The OMIG's interpretation would justify the disallowance, for example, of a claim with a date of service of October 1, for which a fiscal order signed September 30 is produced, if the provider does not also prove it "obtained the signed fiscal order" by October 30. This would impose a documentation requirement upon providers that is not at all apparent or reasonable, which is that they prove when timely documentation that did exist, actually came into their possession. The Medicaid requirement is not physical possession of certain documents at a certain time, it is to maintain and produce the documents upon request for audit. 18 NYCRR 504.3(a).

The 30-day period "to obtain" a signed DME fiscal order only makes sense in the context of the Education Law, 18 NYCRR Part 505 Medicaid regulations and the Medicaid Provider Manuals if it allows a DME order signed within 30 days after the service to be produced in support of the claim. Because the involvement of an ordering

practitioner in approving a DME item that the patient could purchase without a prescription is needed only for the purpose of determining whether Medicaid will pay for it, a fiscal order for DME, unlike a drug prescription, can be authorized by the ordering practitioner as long as it is done within 30 days.

This is not to suggest that the Medicaid Program could not, as a matter of official policy and directive, require as a condition of payment that a fiscal order for DME be signed and dated before the service is provided. Such a requirement would be a rational interpretation of 18 NYCRR 505.5(b)(1) and entitled to deference. Elcor Health Services, supra. But Medicaid policy and directives implementing such an interpretation, especially the extent they are more stringent than existing law and regulation, should be reasonably intelligible to providers and not be misleading. In stating “it is the provider’s responsibility to obtain the signed fiscal order from the ordering practitioner within 30 calendar days” the DME Manual does not make at all clear an additional requirement that the order must also have been signed and dated some time before those 30 days began to run, nor does other state law generally applicable to orders for medical services provide support for such a view when the service involved is DME.

The 55 claims for which the Appellant produced a fiscal order signed and dated within 30 days of the service are reversed. For a 56th claim (sample 79) the Appellant produced, with its response to the draft audit report, a fiscal order signed by the ordering practitioner on January 19, 2011 for a date of service on the claim of January 20, 2011. (Exhibit 21, page D7-519; Exhibit 3, page A3-396; Exhibit A, page 079-4; Transcript, page 409.) This disallowance is also reversed.

In 16 instances the fiscal orders were signed more than 30 days after the date of service.² It does make sense to require that the ordering practitioner sign a fiscal order authorizing a service within a reasonable time. Medicaid Policy set forth in the DME Manual has established 30 days as a reasonable time and does not allow payment on orders signed months later.

The Appellant made efforts to obtain timely orders but some practitioners failed to cooperate. (Transcript, pages 350, 354-58, 419-20; Appellant brief, pages 20-21.) As the Appellant itself observes, in providing these services before it had the required documentation in hand, the Appellant assumed the risk of being unable to properly document entitlement to its DME claims on audit. (Appellant brief, page 1.) These 16 disallowances, in the total amount of \$1,020.21, are affirmed.

The 56 claims reversed in this category are listed in Exhibit C. They are in the total amount of \$3,193.56. The total disallowance is accordingly reduced from \$4,213.77 to \$1,020.21.

2. Missing information on written order. Seven claims (samples 21, 26, 81, 98, 107, 109, 131), disallowances in the total amount of \$581.37.

Written orders for non-prescription DME must include “number of refills, if any.” 18 NYCRR 505.5(b)(3). The OMIG alleges that written orders produced in these instances did not comply with this requirement because “the number of refills was missing.” (Exhibit 1, page A1-5.) Only the disallowances in samples 98 and 131 are in dispute. (Transcript, pages 121-22.) The fiscal orders for these two claims did not mention refills.

² Samples 2, 3, 27, 34, 59, 64, 70, 71, 76, 78, 94, 101, 106, 108, 120, 140. The pertinent dates are summarized in Exhibit D.

For sample 98, the Appellant argued that the patient's "dual eligibility" with Medicare explained this, claiming that Medicare refills can be authorized for a "duration of need" period rather than a specific number of refills on the fiscal order. (Transcript, pages 218-20, 360-70, 426; Appellant brief, page 22 & reply brief, pages 7-8.) This argument does not excuse the Appellant from the Medicaid requirement that the number of refills, if any, be specified. As Mr. Greco said, "If they have two [payors] they have to follow both payor's requirements." (Transcript, page 220.)

Mr. Greco assumed that the disallowed service was a refill, which would not be allowable under Medicaid on this order. He offered nothing to support this speculation, which he based entirely on his observation that the claim was dated January 8 and the order was signed and dated December 8, a month earlier. While he suggested that the Medicaid database would also show a December 8 claim, the OMIG did not produce a record of any such claim and so he admitted "I don't know" if there was an earlier claim based on this fiscal order. (Transcript, pages 135-36, 139.)

The OMIG's post-hearing brief argued that even if it was not a refill this order would still not be allowable because it was filled more than 14 days after the fiscal order was signed. (OMIG brief, pages 12-13.) The OMIG relies on 18 NYCRR 505.5(b)(4) which states:

An original fiscal order for medical surgical supplies must not be filled more than 14 days after it has been written by the practitioner unless prior approval or prior authorization is required for the item.

The item disallowed (procedure code A4253) does require prior approval. DME Manual, Procedure Codes and Coverage Guidelines, Version 2019-1 (8/1/2019), pages 4&16. Mr. Greco acknowledged that a fiscal order was good for six months. (Transcript, page 221.)

There is no reason to conclude, from this evidence, that the disallowed claim was for a refill of DME previously provided on this fiscal order or was otherwise improper.

The fiscal order for sample 131 was a new order that did not include any refills. The preprinted order form stated “if no refills circled none will be assumed.” (Exhibit 21, page D7-857; Transcript, pages 140-41, 221, 372; Appellant brief, pages 22-23.)

The regulation states an order must contain “number of refills, if any.” 18 NYCRR 505.5(b)(3). There is no requirement that an order specifically document that there are no refills. The disallowances in samples 98 and 131 are reversed. The total disallowance in this category is reduced from \$581.37 to \$312.85.

3. Missing documentation confirming receipt/delivery of item. Two claims (samples 36, 49), disallowances in the total amount of \$176.37. Alternative disallowance findings in samples 71 and 117.

The DME Provider Manual specifically requires a signed receipt documenting the delivery of DME:

In addition to meeting the general record keeping requirements outlined in the General Information Section of this manual, the provider filling an order for [DME]... must keep on file the fiscal order signed by the prescriber and the delivery statement signed by the [beneficiary/recipient] for any item for which Medicaid payment is claimed. (Exhibit 28, page J-4; Exhibit 29, page K-4.)

These claims were disallowed on the grounds that “documentation confirming receipt/delivery of item was missing.” (Exhibit 1, page A1-5.)

For sample 36, the Appellant produced a signed receipt but the invoice number printed on it (#11249851) was for an order that did not include the item in question. (Exhibit 20, pages D7-255&256; Transcript, pages 149, 153-54.) With its response to the draft audit report, the Appellant produced another invoice (#11236320) that did include the item. (Exhibit 3, pages A3-747&748.) Cross references at the ends of the two

invoices show the two orders were shipped together. (Exhibit 20, page D7-255; Exhibit 3, page A3-748; Transcript, pages 380-81.) The signed receipt shows only one of the invoice numbers (#11249851) but bears a handwritten notation that it is for two invoices. (Exhibit 20, page D-256.) The Appellant's documentation demonstrates that although the signed receipt did not contain both invoice numbers, both orders were delivered and signed for in the same shipment. (Transcript, pages 228-33, 374-82; Appellant reply brief, page 8.)

Sample 71 was an alternative finding with the same facts as sample 36. Two invoices were filled in one shipment. Both invoice numbers appear on the delivery receipt, the pertinent number being handwritten. (Exhibit 20, pages D7-482-484; Transcript, pages 388-90; Appellant brief, page 26.)

The Appellant was unable to produce a signed receipt for sample 49. After this audit was commenced in 2014, the Appellant obtained tracking information, but not a signed receipt, from the carrier that delivered the item in 2009. The carrier did not retain signed receipts for that many years. (Exhibit A-049, pages 3-19; Transcript, pages 235, 386-87.)

The Appellant argues that under the CMS Medicare Program Integrity Manual the carrier's tracking information would be acceptable. (Exhibit 3, pages A3-4&5; Appellant brief, page 25.) This Medicare policy does not preempt or supersede New York State requirements for Medicaid reimbursement. The Appellant cited no federal Medicaid regulation or policy that prohibits the New York Medicaid Program from requiring a receipt signed by the beneficiary of the service. The New York Medicaid requirement is clear, and a third-party carrier's electronic tracking records do not meet it.

The receipt produced for sample 117 documented an attempted and failed delivery, not a delivery. (Exhibit 21, page D-771.) As in sample 49, electronic tracking information the Appellant obtained from the carrier indicated delivery was made on a second attempt, but as in sample 49, the Appellant was unable to produce the signed receipt. (Exhibit A-117, pages 5-21; Transcript, pages 391-92.)

It was the Appellant's obligation to maintain and produce documentation demonstrating compliance with Medicaid claiming requirements. It is not an excuse that a third party did not maintain the documentation either. The Appellant knew or should have known at the time it submitted its claims that it did not have the required signed receipts, and so accepted the risk of being unable to produce them for audit.

The disallowances of samples 36 and 71 are reversed. The disallowances of samples 49 and 117 are affirmed. The total disallowance in this category is reduced from \$176.37 to \$12.37.

4. Order refilled more than 180 days after it has been initiated by the prescriber. One claim (sample 89) in the amount of \$163.20.

No order can be refilled more than 180 days from the original date ordered. 18 NYCRR 505.5(b)(4)(iii). The sample 89 order was dated March 14, 2011 and filled on September 26, 2011. (Exhibit 3, pages A3-787&788.) The Appellant did not dispute this disallowance (Transcript, pages 115, 122) and it is affirmed.

5. Ordering prescriber conflicts with claim prescriber. One claim (sample 57) in the amount of \$90.80. Alternative disallowance findings in samples 2 and 59.

All information submitted with a Medicaid claim must be true, accurate and complete. 18 NYCRR 504.3(h). A claim for a service ordered by one practitioner, documented as ordered by a different practitioner, is a significant violation of these

Medicaid requirements. Accurate reporting is not only material to the individual claim, it is essential to the Department's ability to oversee and administer the Medicaid Program as a whole.

The order the Appellant produced for sample 57 was not signed by the ordering practitioner identified on its Medicaid claim. The ordering practitioner identified on the claim was Dr. Chefitz, while the fiscal order was signed by Dr. Ude. (Exhibit 17, page D4-8; Exhibit 20, page D7-387&388; Transcript, pages 58-61, 395.)

The Appellant explained that the patient changed physicians after Dr. Ude authorized the order but before the signed fiscal order was returned to the Appellant. (Exhibit A-57, pages 3-4; Transcript, pages 241-42, 394-95.) By the time Dr. Ude's signed fiscal order came in, the Appellant had updated its claiming system to reflect the new physician (Dr. Chefitz), and so the Medicaid claim erroneously reported Dr. Chefitz as the ordering practitioner. (Exhibit 3, page A3-5; Appellant brief, page 27.) It remains the case that the ordering practitioner was not the practitioner reported on the Medicaid claim. (Transcript, pages 242-45.)

Alternative findings under this category were also made in samples 2 and 59. The sample 2 claim reported the order was made by Dr. Shah, but the fiscal order bore the name and identifying information of Dr. Morales. (Exhibit 17, page D4-8; Exhibit 20, page D7-11&18; Transcript, pages 396-97, 401.) The sample 59 claim reported the order was made by Dr. Singh, but the fiscal order bore the name and information of Dr. Khan. (Exhibit 17, page D4-8; Exhibit 20, page D7-402; Transcript, pages 404-405.)

In these instances, the Appellant claims that the fiscal orders were in fact signed by the practitioners named on its Medicaid claims (Dr. Shah and Dr. Singh) and not by

the practitioners (Dr. Morales and Dr. Khan) whose names, addresses, telephone, NPI and license numbers appear on the fiscal orders it produced. (Transcript, pages 402-403, 405-406; Appellant brief, pages 27-28.)

Fiscal orders are required to show the name, address, and telephone number of the ordering practitioner. 18 NYCRR 505.5(b)(2). The signatures on these fiscal orders are illegible and there is nothing else on the orders to suggest they were made by Dr. Shah and Dr. Singh. Even if they were signed by Dr. Shah and Dr. Singh, these fiscal orders do not comply with Medicaid claiming requirements as they clearly purport to be orders by Dr. Morales and Dr. Khan. The Appellant compounds the confusion by maintaining that Dr. Morales and Dr. Khan actually were the practitioners who “prescribed and authorized Byram to dispense” the DME documented by fiscal orders it now maintains were signed by Dr. Shah and Dr. Singh. (Appellant brief, pages 27-28.)

The Appellant points out that it did not submit its claims to the Medicaid Program until it received the signed orders. (Transcript, pages 25, 32; Appellant brief, page 7.) This practice only underscores that it submitted each of these claims as ordered by one practitioner at a time when it had in hand an order identifying a different practitioner. The Appellant had itself prepared these fiscal orders for signature by practitioners it did not subsequently identify on its Medicaid claims. (Exhibit 20, pages D7-11, 388&402; Transcript, page 406.) The Appellant offered no persuasive reason why these errors were unavoidable or should be excused.

The OMIG did not extrapolate the sample 57 disallowance. (Exhibit 1, page A1-6.) Mr. Greco testified it was not extrapolated because “it was only one instance,” although the OMIG did make the same finding in samples 2 and 59. He then added the

additional reason “and they did have an order and a doctor did sign it.” (Transcript, page 62.)

The disallowances in samples 2, 57 and 59 are affirmed. Because samples 2 and 59 are alternative findings on claims also disallowed and affirmed in this decision under primary finding category 1 (no written order), the overpayment for these two claims is included in the total category 1 overpayment and is subject to extrapolation. The disallowance of sample 57 is affirmed without extrapolation in the amount of \$90.80.

6. Item billed does not match ordered item. Two claims (samples 22, 55) in the amount of \$57.96. Alternative disallowance finding in sample 79.

The Appellant’s records documented that it submitted claims in samples 22 and 55 for items that were neither ordered nor dispensed. The Appellant did not dispute these two disallowances. (Transcript, pages 119, 122.) At the hearing, the OMIG withdrew the alternative finding in sample 79. (Transcript, page 408.)

The disallowances of samples 22 and 55 are affirmed for a disallowance in this category in the total amount of \$57.96.

The overpayment in the sample

The amount disallowed for each claim in the audit sample was set forth in the schedules attached to the final audit report. (Exhibit 1.) The total disallowance in the sample was \$5,283.47. The disallowances of 56 claims in category 1, “no written order” in the amount of \$3,193.56, and of samples 36, 98 and 131 in categories 2 and 3, in the amount of \$432.52, are reversed in this decision. The total overpayment in the sample is accordingly reduced to \$1,657.39. The claims disallowed in this audit, as affirmed in this hearing decision, are overpayments because they were not supported by documentation

demonstrating compliance with Medicaid Program requirements. The OMIG is entitled to recover the overpayments. 18 NYCRR 518.1.

The statistical sampling method

The audit exit conference summary provided to the Appellant in connection with the March 27, 2017 exit conference (Exhibit 7), the draft audit report (Exhibit 4) and the final audit report (Exhibit 1) each set forth the manner in which the extrapolation was made. These documents identified the disallowed claims, the audit frame to which they were extrapolated, and the method of estimation. An extrapolation based upon an audit utilizing a statistical sampling method certified as valid will be presumed, in the absence of expert testimony and evidence to the contrary, to be an accurate determination of the total overpayments made. 18 NYCRR 519.18(g).

The OMIG submitted the required certification in the form of affidavits from Dr. Karl W. Heiner, the statistical consultant who designed the sampling and estimation methodology, and Kevin Ryan, the OMIG employee who implemented the methodology to establish the audit frame and select the random sample. (Exhibits 22, 23.) The Appellant called Sean M. Ennis to challenge the certification. His written report (Exhibit E) and testimony offered six criticisms on the statistical sampling and extrapolation issues. After Mr. Ennis testified, the OMIG called both Mr. Ryan and Dr. Heiner to answer the criticisms.

Dr. Heiner has Master's and Doctoral degrees in applied statistics. He has published extensively on the subject and taught it at the graduate level for decades. (Transcript, page 579-82.) He is thoroughly familiar with the extrapolation methodology in this case, having designed and monitored the sampling and estimation procedures used

in New York State Medicaid Program audits for thirty years. (Exhibits 22, 26.) The statistical sampling and estimation methodology he designed has consistently been upheld in New York State Medicaid Program administrative hearings and by the New York courts, including the New York Court of Appeals. Mercy Hospital v. NYS DSS, 79 N.Y.2d 197, 581 N.Y.S.2d 628 (1992); Enrico v. Bane, 213 A.D.2d 784, 623 N.Y.S.2d 25 (3rd Dept. 1995); Clin Path, Inc. v. NYS DSS, 193 A.D.2d 1034, 598 N.Y.S.2d 583 (3rd Dept. 1993).

Mr. Ennis is a Certified Public Accountant (CPA) in Kentucky, with an MBA degree, who took “multiple classes on statistics” in business school. (Exhibit E, page 2; Transcript, page 442.) Describing himself as “a nationally recognized expert in sampling and statistics” (Exhibit E, pages 2, 9&10), he wrote:

I have prepared over 25 expert witness reports regarding the appropriateness of sampling and extrapolation procedures performed in U.S. Government overpayment cases. I have given testimony on 7 occasions, having been accepted as an expert in the field of accounting and statistics, specifically as it relates to extrapolation calculations... I have not authored any publications in the last ten years. (Exhibit E, pages 2-3.)

Mr. Ennis’ experience as a statistical consultant in “U.S. Government overpayment cases” does not include Medicaid audits. He had not testified about any Medicaid audit, let alone a New York State Medicaid Program audit, before this one. (Transcript, page 482.) His resume fails to suggest he has ever reviewed, evaluated or participated in any Medicaid audit, claiming experience in Medicare and “U.S. Government overpayment cases” but failing to even mention the word “Medicaid.” (Exhibit E, pages 9-10, 12.) Even in Medicare audits, his main area of experience, Mr. Ennis’ expert opinion on statistical issues has been rejected as not persuasive. Geriatric

Center of Mansfield, 2012 WL 1793280 (HHS Medicare Appeals Council). (Transcript, pages 494-97; Exhibit 30, page L-2.)

Mr. Ennis based much of his criticism on auditing guidelines that do not establish policy for this New York State Medicaid Program audit. He identified the CMS Medicare Program Integrity Manual as the “authority or authoritative literature that recommends the use of a sampling plan of government payer audits, like this one.” (Transcript, page 449.) He did not mention that the Medicare Manual itself states that failure to follow its guidelines should not be construed as necessarily affecting the validity of statistical sampling or the projection of an overpayment. Medicare Program Integrity Manual 8.4.1.1.

Mr. Ennis also failed to mention that there is a CMS Medicaid Program Integrity Manual which, as Dr. Heiner pointed out (Transcript, pages 589-90), makes clear that the methodology to be used in Medicaid audits is a matter of individual state, not federal policy. Medicaid Program Integrity Manual, Chapter 1. (Both manuals are available at www.cms.gov.) In New York, the Medicaid Program uses a methodology authorized by state law, Department regulations and the MMIS Provider Manuals, designed by Dr. Heiner and set forth in his certification. (Exhibit 22.)

To the extent Mr. Ennis’ opinions on statistical matters were inconsistent with Dr. Heiner’s, the opinions of Dr. Heiner are credited, both because of Dr. Heiner’s superior credentials and experience (*compare* Exhibit 26; Exhibit E, pages 9-10; Transcript, pages 487-94) and because his opinions were more convincing and intelligible. Mr. Ennis’ testimony was not persuasive and failed to overcome the presumption of validity

established by the certifications of Dr. Heiner and Mr. Ryan and further supported by their testimony at the hearing. 18 NYCRR 519.18(g).

Mr. Ennis' criticisms of this audit consisted of generalizations about statistical sampling and estimation processes which, to the extent they were accurate, did not expose any aspect of the OMIG's methodology that rendered its extrapolation invalid. He offered the uncontroversial opinion that it can be important to consider the particular details of the audit to be performed and to understand the appropriate way to approach it, followed by admissions that he did not consider the particular details of this audit and so was unable to say whether it was done appropriately. Mr. Ryan and the auditors who reviewed the sample claims, on the other hand, clearly did consider and engage with the particular details of how this audit was to be conducted, and Dr. Heiner provided the theoretical and methodological framework within which they worked. The Appellant's suggestion that Dr. Heiner somehow improperly delegated the carrying out of his audit methodology to them (Appellant brief, page 29 & reply brief, page 11) mischaracterizes and misrepresents his role both in the conduct of the audit and in certifying the validity of their work.

To the extent Mr. Ennis offered any accurate conclusions, they were mainly that the overpayment figure might have been determined within a narrower precision interval with a larger sample or possibly with a stratified sample. These general - and uncontroversial - observations do not establish that the extrapolation in this audit, as certified by Dr. Heiner, is invalid.

Mr. Ennis' six criticisms of the OMIG's audit were set forth in his supplemental report (Exhibit E) as follows:

1. *The [OMIG] Report lacks objectivity due to the lack of a sampling plan provided prior to commencement of testing procedures. (Exhibit E, page 4.)*

Mr. Ennis testified:

A sampling plan, I liken it to being a roadmap. You design it before you perform your sample, before you execute it. It contains critical factors such as; “Who are you auditing?” “What is the time frame that you are auditing?” “What type of claims are you auditing?” “Are you auditing all claims?” “Are you auditing just a certain procedure code of claims?”

It identifies effectively your approach, so what level of confidence and what level of precision. It identifies other factors to consider, stratification. It identifies any – it’s the opportunity for an independent statistician to understand the plan before it is executed. (Transcript, pages 449-50.)

The answers to all of these questions are readily apparent from the information the OMIG provided to the Appellant at every step in this audit. The answers to most of them are readily apparent from even a cursory review of the April 9, 2013 audit notification letter that first advised the Appellant an audit would be conducted. (Exhibit 10.) Pursuant to 18 NYCRR 517.3(f), “an on-site entrance conference at which the nature and extent of the audit must be discussed” was also held between the auditors and the Appellant’s representatives on May 13, 2014, before data retrieval for the audit began. (Exhibit 9.) There is no evidence the Appellant raised questions about the “audit plan” before the audit commenced.

The audit plan, as Dr. Heiner explained, was quite straightforward: a simple random sample of 150 claims was selected from an audit frame constructed from all DME claims that the Department’s billing and payment records show were paid by the Medicaid Program to the Appellant during the three-year audit period. (Transcript, pages 613-14.) The findings from the audit sample were extrapolated by a mean per unit point estimate to all of the claims. (Exhibit 22, page E-3.) This was the same audit plan the

OMIG has consistently followed in hundreds of similar audits. (Transcript, pages 517, 545.) The approach is consistent, principled, well established and has been repeatedly challenged in and affirmed by the courts, including the New York Court of Appeals. Mercy Hospital, *supra*; Sarfo v. Glass, 243 A.D.2d 824, 663 N.Y.S.2d 894 (3rd Dept. 1997); Tsakonas v. Dowling, 227 A.D.2d 729, 642 N.Y.S.2d 342 (3rd Dept. 1996); Lala v. Dowling, 226 A.D.2d 933, 640 N.Y.S.2d 933 (3rd Dept. 1996); Piasecki v. DSS, 225 A.D.2d 310, 639 N.Y.S.2d 319 (1st Dept. 1996); Polanco v. DSS, 212 A.D.2d 443, 622 N.Y.S.2d 932 (1st Dept. 1995); Kuchment v. DSS, 222 A.D.2d 806, 634 N.Y.S.2d 849 (3rd Dept. 1995); Enaw v. Dowling, 220 A.D.2d 942, 632 N.Y.S.2d 715 (3rd Dept. 1995); Lock v. DSS, 220 A.D.2d 825, 632 N.Y.S.2d 300 (3rd Dept. 1995); Enrico v. Bane, *supra*; Ghosal v. Bane, 204 A.D.2d 215, 612 N.Y.S.2d 399 (1st Dept. 1994), *lv. denied* 84 N.Y.2d 805, 618 N.Y.S.2d 6; Ogunkoya v. DSS, 204 A.D.2d 122, 612 N.Y.S.2d 7 (1st Dept. 1994); Newman v. Dowling, 210 A.D.2d 552, 619 N.Y.S.2d 794 (3rd Dept. 1994); State v. Khan, 206 A.D.2d 732, 615 N.Y.S.2d 771 (3rd Dept. 1994); Roggeman v. Bane, 206 A.D.2d 622, 614 N.Y.S.2d 593 (3rd Dept. 1994), *lv. denied* 84 N.Y.2d 809, 621 N.Y.S.2d 518; Adrien v. Kaladjian, 199 A.D.2d 57, 605 N.Y.S.2d 33 (1st Dept. 1993); Lalani v. Bane, 199 A.D.2d 80, 605 N.Y.S.2d 48 (1st Dept. 1993); Clin Path, *supra*; Metzies Shoe Brooklyn NY Corp. v. DSS, 151 A.D.2d 675, 542 N.Y.S.2d 731 (2nd Dept. 1989).

The March 7, 2017 exit conference summary and the August 11, 2017 draft audit report each included a section entitled “Sampling Methodology” that described the statistical sampling methodology used. (Exhibit 4, pages A4-4&5; Exhibit 7, pages B1-13&14.) This plan included an explanation of how the universe of claims was extracted

from payment records; how it was refined and corrected to create the audit frame of unique claims from which the sample was selected; the computer program used to obtain the random sample and an offer to provide that program upon request; explanation of how the program was implemented to select the sample; and explanation that a series of statistical tests was done to verify the random characteristics of the sample. The exit conference summary and the draft and final audit reports all identified the method of extrapolation (mean per unit point estimate) and the confidence level, and calculated a lower confidence limit.

All of the records needed to verify the implementation of this plan, including the universe of claims payment records, the audit frame, the sample, and the computer programs used were available to the Appellant. (Exhibits 15, 16, 24, 25, 32.) The OMIG also presented Mr. Ryan and Dr. Heiner at this hearing to explain the details and answer questions.

In view of this material, it is difficult to understand how Mr. Ennis can claim “there was not a sampling plan provided” (Transcript, page 449) or suggest he did not have “the ability to replicate the entirety of the sampling process” or that “critical components were not provided to Byram.” (Exhibit E, page 4; Transcript, page 451; Appellant brief, page 31 & reply brief, page 11.) Rather than come to grips with the abundance of information available about this audit, Mr. Ennis resorted to objecting that the OMIG did not prepare a written account, detailed enough to suit him, of everything it was going to do before even starting the audit. The OMIG’s methodology is not invalidated or even made suspect simply because Mr. Ennis did not think “an approved,

signed sampling plan” that he could understand was “provided prior to commencement of testing procedures.” (Exhibit E, page 4; Transcript, pages 450-52.)

2. *It is unclear whether claims subjected to self-reported repayments, recouments and payments with offsetting refunds were properly excluded.* (Exhibit E, page 5.)

The Appellant offered no evidence to challenge the presumption of accuracy in the Department’s Medicaid payment records. 18 NYCRR 519.18(f). This criticism instead questioned how the audit frame was established from these records and whether it included inappropriate claim items.

It is not at all “unclear whether claims subjected to self-reported repayments, recouments and payments with offsetting refunds were properly excluded.” Mr. Ryan did perform the work of adjusting the Department’s accurate “universe” of electronic payment records to an appropriate audit frame in accordance with the OMIG’s written Sampling Methodology. (Exhibit 4, pages A4-4&5.) At the hearing, he addressed the questions Mr. Ennis raised and explained how the payment records were reduced to one record for each claim and corrected in just the ways Mr. Ennis suggested. Mr. Ryan removed entries for such things as claims previously recovered, voided claims, self-disclosures and zero dollar claims, in order to establish an appropriate audit frame with one record for each paid claim. (Transcript, pages 518-20, 548-53.)

Although Mr. Ennis suggested that claims should have been removed from the audit frame for various reasons, his actual criticism was that he was “unable to verify that the [OMIG] selected the sample from the correct population file.” (Exhibit E, page 5.) The Appellant was provided with the list of 134,770 claims in the audit frame, and of the claims that had been removed from it. (Exhibits 24, 25, 32.) If Mr. Ennis or the Appellant were aware of ways in which the audit frame might be inaccurate or unreliable

because it included additional items that did not belong in it, they could have reviewed the claims and identified the inappropriate items. Arguing that they did not actually review and verify the accuracy of the frame hardly meets the Appellant's burden of proving it was inaccurate.

There was one type of claim in the sample to which Mr. Ennis did specifically object, although without offering any figures regarding how many such claims were included in the audit frame. He argued that for "dual eligibility" patients where the primary coverage was Medicare, the Medicaid claim should not be included in the audit. (Transcript, pages 452-53.) He admitted he was unaware of any authority for the view that if it sought and received payment for a service from a primary payor source, a provider's claim for an additional payment from Medicaid "is not something that is auditable." (Transcript, page 453.) The Appellant cited no authority for this assertion other than Mr. Ennis himself. (Appellant brief, page 35 & reply brief, page 10.) Mr. Greco correctly pointed out that if a claim is submitted to Medicaid and a payment is made by Medicaid, the provider must comply with Medicaid requirements to be entitled to that payment. (Transcript, page 220.) Any such payment is subject to audit. 18 NYCRR 517.3(b)(2).

Mr. Ennis compounded his confusion about "dual eligibility" claims by asserting that the OMIG's withdrawal of some of its initial sample disallowances "artificially increased the point estimate." (Transcript, pages 453-55.) Several "dual eligibility" claims in the sample (samples 6, 8, 15, 35, 42, 45, 58, 82, 122, 146) were initially questioned but later allowed in the audit. (Exhibit 1, page A1-22; Exhibit 2.) Mr. Ennis' assertion that the audit frame must be proportionally reduced if proposed sample

disallowances are withdrawn is incoherent and completely inconsistent with the estimation methodology, which automatically adjusts the extrapolation to reflect withdrawals of sample disallowances whenever they occur. Dr. Heiner explained this in his certification and at the hearing. (Exhibit 22, point 17; Transcript, page 641.)

3. *Sampling approach lacks objectivity as the sample size of 150 claims is unsupported as being statistically valid.* (Exhibit E, page 3.)

Mr. Ennis wrote that "The [OMIG] Report and approach lack objectivity by not providing the necessary details standard in sampling for all Medicaid overpayment audits." (Exhibit E, page 5.) He did not identify what "necessary details" about this audit were not provided to the Appellant, nor did he identify the authority he relied on for what is "standard in sampling for all Medicaid overpayment audits."

The Appellant suggested a 150-claim sample was inappropriate because an undated DME audit plan found in the OMIG audit file outlined an audit using a 200-claim sample and a two-year audit period. (Exhibit 14; Transcript, pages 178-80, 562-63.) The Appellant finds itself arguing both that "the [Exhibit 14] Audit Plan does not contain all of the elements needed to qualify as a sampling plan" and that the OMIG "blatantly disregarded and deviated from the [Exhibit 14] Audit Plan in this case... This alone creates substantial questions as to the accuracy of the statistical sampling." (Appellant brief, pages 31-32.) These arguments require some interesting contortions: If the Exhibit 14 Audit Plan were conceded to be an adequate plan to support a sampling and extrapolation audit, the Appellant would be hard pressed to explain why the audit description and Sampling Methodology in the exit conference memo and draft audit reports, which outline in far greater detail the sampling and extrapolation procedure actually followed in this audit, are inadequate. (Exhibits 4&7.) If the Exhibit 14 Audit

Plan does not “qualify as a sampling plan,” it is difficult to understand why the OMIG should be faulted for not following it.

The Appellant offered no authority or persuasive reason obligating the OMIG to use a 200-claim sample in this or any other audit. Mr. Ryan testified, “[t]he sample size is pretty standard for our audits. We usually use 100, 150 and occasionally 200.” (Transcript, pages 536, 569-70.) The Appellant’s suggestion that the OMIG’s selection of a 150 rather than a 200-claim sample in this case evidences an inappropriate attempt to “manipulate” the sample or to “skew the statistical sampling to serve their own purposes” (Appellant brief, pages 29, 31) is not supported by any credible or intelligible reasoning and is not persuasive.

As Mr. Ennis himself testified “[t]he higher the sample size, the more normal the distribution, so the more accurate the results. That is always a competing factor.” (Transcript, page 459.) The OMIG, which is tasked with recovering improperly expended Medicaid funds, is entitled to consider costs of auditing, including sample size, as a “competing factor” in allocating limited resources to fulfill its oversight responsibility for thousands of providers, millions of claims, and billions of dollars in public expenditures. Medicaid audits based on samples of 100 claims and even 50 claims have been upheld by New York courts. Tsakonas v. Dowling, *supra*; Piasecki v. DSS, *supra*; Enrico v. Bane, *supra*; Adrien v. Kaladjian, *supra*; Clin Path, *supra*.

Mr. Ennis’ admissions that he was unable to determine whether the sample size was large enough to be statistically valid hardly constitute persuasive expert opinion that it was not valid. (Exhibit E, page 5; Transcript, page 456.) Dr. Heiner’s certification and his testimony that the 150-claim random sample was statistically valid (Exhibit 22;

Transcript, page 615) were based on the same information available to the Appellant and Mr. Ennis. His expert opinion is credited over Mr. Ennis' agnosticism on the issue.

4. *The sample size is insufficient based on industry standard precision levels.* (Exhibit E, page 5.)

This objection also criticizes the size of the sample, but in a more confused manner. Mr. Ennis admitted "I have no ability to evaluate the [OMIG]'s method for sample size determination other than comparison to the Medicare approved approach." (Exhibit E, page 5.) That the "Medicare approved approach" is the only one with which he is familiar does not make it the "industry standard" or a requirement for this Medicaid Program audit.

Mr. Ennis' analysis of the sample size was based upon his use of RAT-STATS, a software package for statistical sampling and analysis available from the U.S. Department of Health and Human Services, Office of Inspector General (OIG). (*See* RAT-STATS at www.oig.hhs.gov.) RAT-STATS is referenced in the Medicare Program Integrity Manual as one of "a number of well-known, reputable software statistical packages (SPSS, SIS, etc.) and tables that may be used for generating a sample." Medicare Program Integrity Manual 8.4.4.2. (Transcript, page 456.)

Mr. Ennis conceded that no state requires nor does even the OIG require the use of RAT-STATS. (Transcript, pages 477-78.) Dr. Heiner did not use RAT-STATS in designing the OMIG's audit sampling and estimation methodology as there are, in his view, better programs for the purpose. (Transcript, page 588-89.) In designing an audit methodology for the New York State Medicaid Program, Dr. Heiner used a statistical software program that included a random number generator provided by Sun Microsystems, Inc. in the JAVA programming language. (Exhibit 22, page E-2.) This

information, along with an offer to provide copies of the program and source codes upon request, was provided to the Appellant in both the exit conference summary and the draft audit report. (Exhibit 4, pages A4-4&5; Exhibit 7, pages B1-13&14.) Mr. Ennis did not offer any critique of the statistical software used by Dr. Heiner, other than eventually to admit that it did generate a valid random sample and withdraw his initial criticism on this point. (Exhibit 27, page H-6; Exhibit E, page 2.)

This is not to say that Mr. Ennis' use of RAT-STATS to analyze this audit was inappropriate. (Transcript, pages 498-99.) The evidence establishes, however, that RAT-STATS, the tool Mr. Ennis chose to use, supports rather than calls into question the validity of the random sampling and statistical estimation methodology designed by Dr. Heiner and implemented in this audit.

Mr. Ennis used RAT-STATS and the OMIG's audit findings to retroactively (Transcript, page 620) calculate, based on the standard of deviation in the sample findings, a sample size that would be large enough to achieve 5% and 10% precision levels. He concluded that sample sizes of 1,617 and 408, respectively, were required. (Exhibit E, pages 6, 16.) He agreed, however, that RAT-STATS does not dictate levels of precision. Those parameters were chosen by him as the user of the program. (Transcript, page 476.)

Mr. Ryan testified "I would agree that a larger sample would give increased precision, but there is no industry standard for Medicaid audits." (Transcript, page 554.) Mr. Ennis' testimony was completely consistent with this opinion. He admitted, contrary to his report's assertion "the sample size is insufficient based on industry standard precision levels," that there is no industry standard, let alone a Medicaid standard, that

dictates precision levels that a sample size must achieve in statistical sampling audits. (Transcript, page 476.)

Criticisms of the OMIG's overpayment estimate expressed in terms of confidence intervals and precision levels do not invalidate the point estimate relied on by the OMIG to determine the overpayment. As Dr. Heiner testified, a larger sample might give more precision in the sense of narrowing the confidence interval, but "[i]t's not more accurate. You might say it's more precise." (Transcript, page 598.) Like the court in Clin Path:

We reject petitioner's extended arguments that the accuracy of the audit method was discredited by the opinion of its expert witness, who stated that a sampling of 1,300 to 1,400 cases was necessary to get "accurate" results and that 2,400 cases were needed to get results suitable for legal proceedings. Our courts have upheld the validity of audits based upon a much smaller sampling of cases... Clin Path, *supra*.

5. *The [OMIG's] extrapolation results are inconsistent with the RAT-STATS variables sampling output, which is the standard approach used in Medicare and Medicaid overpayment audits.* (Exhibit E, page 6.)

Mr. Ennis' report stated: "In my experience in designing, executing and evaluating sampling plans, Medicare and Medicaid have consistently utilized the variables sampling method in RAT-STATS." (Exhibit E, page 6; Transcript, pages 456-58.) It is unclear what experience he relied on to assert that Medicaid audits have "consistently utilized" RAT-STATS. This is the first Medicaid audit about which he has testified and his resume contains no mention of "designing, executing and evaluating" any Medicaid audit plans. He alleged only that "I've seen it with the states of Kentucky, Tennessee, Connecticut." (Transcript, page 458.) Nor is it clear why this statement matters, as Dr. Heiner confirmed that the New York Medicaid Program does not use RAT-STATS. (Transcript, page 590.)

In any event, Mr. Ennis admitted at the hearing that his claim “The [OMIG’s] extrapolation results are inconsistent with the RAT-STATS” was simply wrong. There is no inconsistency. His report mistakenly compared numbers derived from a 95% confidence interval with numbers derived from a 90% confidence interval. (Exhibit E, page 6; Transcript, pages 479-80, 625-27.)

6. *There is a lack of stratification when there was a variation caused by the significant number of claims in the population.* (Exhibit E, page 6.)

Mr. Ennis’ report stated “In this case the [OMIG] chose to not stratify the population (or at least there is no mention to any stratification in its report).” (Exhibit E, page 7.) It is uncontroverted that the OMIG did not use stratified sampling in this audit (although Mr. Ennis was apparently not even able to be sure about this).

Mr. Ennis conceded that stratification is not always required. (Transcript, pages 462, 480-81.) However, according to Mr. Ennis, “the high number of claims and variation in payment amounts between those claims suggests that stratified sampling would have been a more appropriate approach.” (Exhibit E, page 7.)

Mr. Ennis’ statement “there was a variation caused by the significant number of claims in the population” is simply confused. As Dr. Heiner explained, variation in claims is not caused by and has nothing to do with the number of claims in a population. It has to do with differences among the claims. A “high number of claims” in a population is not the issue in considering whether to stratify. (Transcript, pages 627, 630-31.)

Dr. Heiner agreed that the extent of “variation in payment amounts between those claims” is relevant to a consideration of stratification. (Transcript, page, 628, 630-31.) But Dr. Heiner also pointed out that the reason for such a consideration, and the aim of

stratification, is to tighten the confidence interval, not to establish the validity of or even change the point estimate. (Transcript, page 629.) Mr. Ennis essentially conceded the same point:

It will increase the accuracy of a sample. Usually what you see is you will still get the point estimate, but then your range, your confidence levels, will come in. Your lower-level limit won't be as low and your higher-level limit won't be as high, so you get a more accurate result. (Transcript, pages 461-62.)

As Mr. Ryan pointed out, stratification, which tightens the confidence interval, does not necessarily work to a provider's advantage because the OMIG typically offers to settle audits for the low end of a 90% confidence interval:

If we want to maximize our recoveries and we have a particularly egregious provider, we will consider stratification because it would normally result in a higher low point. (Transcript, page 569.)

Dr. Heiner made the same point, saying that there is "no statistical answer" to a consideration whether to stratify or not:

If you stratify and the stratification doesn't help you, which is often times the case, then you are going to get roughly the same answer that you get if you just take the simple random sample. If it does help you, it's going to tighten the confidence interval and raise the lower-end of the confidence interval. This means if you go to the provider and ask if they want you to check the lower-end, it hurts them to stratify. One might say why stratify?... its not going to change the point estimate... The expected value of the point estimate is still the same. It's just the interval might be made tighter. (Transcript, pages 632-33.)

Conceding "[t]hat doesn't necessarily mean that every time stratification makes sense," Mr. Ennis criticized the OMIG for failing to document a "stratification analysis" without himself offering any such analysis of the abundant data available in the audit file. (Transcript, pages 462-63.) He did not review the audit findings to learn the amounts of the payments or the nature of or reasons for the disallowances. (Transcript, pages 466-68.) He did not attempt to quantify, or even characterize with any precision, the extent of

the variation between claims in the audit frame. He did not present any analysis to demonstrate that the OMIG's use of a simple unstratified sample raises any question about the validity of the mean per unit point estimate it relies on.

As Mr. Ennis failed to actually "determine whether the sample should be stratified" or "consider what would be the best approach based on the underlying data" (Exhibit E, pages 6-7), his suggestion that stratification should have been considered was just that, a suggestion. As in his criticism alleging there was no "audit plan," he resorted to suggesting the OMIG should have proved more, in a hearing where the burden of proof is on the Appellant. 18 NYCRR 519.18(d)&(g).

The Medicaid Program overpayment

The overpayment in the sample, as adjusted in this hearing decision, is in the total amount of \$1,657.39. The amount of the disallowance for extrapolation is reduced by the disallowance in sample 57 (\$90.80) to \$1,566.59. Dr. Heiner's certification, and the final audit report, set forth how the extrapolation was done. (Exhibit 1, page A1-10; Exhibit 22, page E-3.) The overpayment in the sample (\$1,566.59) is divided by the number of claims in the sample (150) to provide an average overpayment per sampled claim of \$10.4439. The overpayment per sampled claim is multiplied by the 134,770 claims in the population (the universe as corrected into an appropriate audit frame).

Application of the estimation procedure set forth in the audit report and in Dr. Heiner's certification – $(\$1,566.59 \div 150) \times 134,770$ – yields an overpayment (rounded to the nearest dollar) in the total amount of \$1,407,524. The \$90.80 disallowance in sample 57 brings the total to \$1,407,615. A restitution claim in that amount is authorized pursuant to 18 NYCRR 518.1 and 518.3.

Mr. Ennis argued that a lower confidence figure, not the point estimate, should be the measure of the overpayment, saying the lower confidence figure is “the recommended approach.” (Transcript, pages 458-59.) For this claim, he again cited the Medicare Program Integrity Manual, which he conceded (Transcript, page 486) is not mandated for use in New York or any other state’s Medicaid Program audits, and which in any event does not rule out the point estimate. Medicare Program Integrity Manual 8.4.5.1.

A lower confidence figure is variable, in fact basically arbitrary, because it is dependent on the confidence interval chosen after the point estimate is established. (Exhibit 22, page E-3; Transcript, pages 597-98, 655.) Dr. Heiner agreed that calculating a lower confidence figure can have its purposes, including as a principled means of proposing settlements. (Transcript, pages 632-33.) This is how the OMIG does use the 90% lower confidence figure, offering to accept that amount to resolve an audit while also asserting its intention to defend the point estimate at any hearing. (Exhibit 1, pages A1-3&8.)

The mean per unit point estimate relied on by the OMIG in this hearing is “unbiased, which means that it does not tend to either overestimate or underestimate the population characteristics” and is “a statistically valid projection of what the disallowance would be if the entire universe were audited.” (Exhibit 22, page E-3.) Even Mr. Ennis admitted “[t]he point estimate is just the best guess for that particular sample.” (Transcript, page 460.) It was not arbitrary or capricious for the OMIG to use it, nor has the Appellant met its burden of proving that it was not “an accurate determination of the total overpayments made.” 18 NYCRR 519.18(g).

The Appellant objects to the OMIG's extrapolation methodology on the grounds that "accuracy is relevant and critically important" and the audit was not designed to ensure accuracy. (Appellant brief, page 30.) When asked on cross-examination: "In your design of the OMIG sampling procedures, is one of the goals to maximize the accuracy?" Dr. Heiner readily answered "No." (Transcript, page 639.) His answer was entirely appropriate. The Appellant is not entitled to the largest or best sample or most precise estimation possible. It is entitled to a random sample and a statistically valid estimate of what the auditors would have determined to be paid in error had they reviewed all 134,770 claims under audit. All the evidence supports the conclusion that it did receive these things.

DECISION: The OMIG's determination to recover Medicaid Program overpayments is correct and is affirmed.

The overpayment in the audit sample is \$1,657.39. The overpayment to be extrapolated is \$1,566.59.

The OMIG is entitled to recover restitution in the amount of \$1,407,615.

This decision is made by John Harris Terepka, who has been designated to make such decisions.

DATED: Rochester, New York
December 16, 2019

_____/s/_____
John Harris Terepka
Bureau of Adjudication