

JURISDICTION

The New York State Office of the Medicaid Inspector General (OMIG), an independent office within the Department of Health (the Department), determined to seek restitution of payments made under the Medicaid Program to Rite Aid of New York, Inc., formerly doing business as Eckerd Corporation Store 10839 (the Appellant). The Appellant requested a hearing pursuant to Social Services Law 22 and the former Department of Social Services (DSS) regulations at 18 NYCRR 519.4 to review the determination.

SUMMARY OF FACTS

An opportunity to be heard having been afforded the parties and evidence having been considered, it is hereby found:

1. At all times relevant hereto, Appellant Rite Aid of New York, formerly d/b/a Eckerd Store 10839, was a pharmacy and was enrolled as a provider (██████████) in the New York State Medicaid Program. The former Eckerd Store 10839 is located in Niagara Falls, New York.

2. In September 2008 the OMIG initiated an audit of the Appellant's records. The purpose of the audit was to determine whether the Appellant's records demonstrated compliance with Medicaid Program requirements. (Department Exhibit 5.)

3. During the period January 1, 2004 to December 31, 2007, the Appellant was paid \$7,878,373.59 by the Medicaid Program for 134,815 pharmacy services to Medicaid recipients. The audit consisted of a review of a sample of 200 of these services, paid in the total amount of \$11,081.77.

4. After reviewing the Appellant's documentation in support of its claims for Medicaid reimbursement for the 200 services in the sample, the OMIG identified violations of Medicaid Program requirements in the submission of 26 of the 200 claims, and disallowed payments in the total amount of \$890.48.

5. By final audit report dated May 4, 2009, the OMIG notified the Appellant that it had determined to seek restitution of Medicaid Program overpayments in the amount of \$600,250. (Department Exhibit 2.)

6. The OMIG's restitution claim was an extrapolation using a statistical sampling method in which the value of the 26 disallowed claims found among the sample of 200 claims was projected to the total of 134,815 claims paid by the Medicaid Program during the audit period. (Department Exhibits 7, 21.)

7. Prior to the commencement of this hearing, the OMIG amended its audit findings by withdrawing 7 of the 26 disallowed claims (samples 33, 41, 57, 62, 64, 115, 181). (Transcript, page 10.) At the hearing, the OMIG also withdrew the finding in sample 192. (Transcript, page 1585.) This reduced the total amount disallowed in the sample to \$433.06, and reduced the projected restitution claim to \$291,915.

8. The OMIG organized the charges disallowing the 18 claims remaining at issue in this hearing into four categories:

1. Missing prescription. Nine claims, disallowances in the total amount of \$397.06. (Samples 49, 52, 56, 129, 147, 150, 177, 184, 185.)
2. Ordering prescriber conflicts with claim prescriber. Eight claims, disallowances in the total amount of \$31.50. (Samples 3, 22, 71, 89, 117, 122, 170, 182.)
3. Imprinted or stamped name of prescriber missing on prescription. One claim, disallowance in the amount of \$4.50. (Sample 93.)
4. Additional findings. In samples 122 and 182, in addition to the primary finding (ordering prescriber conflicts with claim

prescriber), the OMIG made a secondary finding (missing supervising MD on prescription/fiscal order by physician's assistant).

9. Commencing with its March 11, 2009 response to the draft audit report (Department Exhibit 3a), the Appellant has consistently asserted its intention to challenge the validity of the extrapolation of the findings in the audit sample to the entire "universe" of the Appellant's paid Medicaid claims. The Appellant has repeatedly demanded access to the computer program used to select the audit sample from the universe of paid claims in order to, among other things, review whether it was properly designed to generate a statistically valid random sample. (Transcript, page 24.) The OMIG has refused to provide access to the program. (Transcript, pages 25-27.)

ISSUES

Was the OMIG's determination to recover Medicaid Program overpayments from Appellant Rite Aid of New York, Inc. correct? If so, what is the amount of the overpayment?

Was the OMIG entitled to extrapolate the audit sample findings to the audit universe?

APPLICABLE LAW

As is set forth in section 363 of the Social Services Law, the legislature established the Medicaid Program "to operate in a manner which will assure a uniform high standard of medical assistance throughout the state." The Department of Health acts as the single state agency to supervise the administration of the Medicaid Program in this state. SSL 363-a. Pursuant to Public Health Law sections 30, 31 and 32, the OMIG, an independent office within the Department of Health, 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.

Medicaid providers are required, as a condition of their enrollment in the program, to prepare and 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. The information provided in relation to any claim must be true, accurate and complete. All information regarding claims for payment is subject to audit. 18 NYCRR 504.3(a)&(h), 517.3(b), 540.7(a)(8).

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. Where its determination is based upon an alleged failure to comply with generally accepted professional or medical practices or standards of health care, however, the Department has the burden of establishing the existence of such practices or standards. 18 NYCRR 519.18(d).

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. The Appellant, however, may submit expert testimony and evidence to the contrary, or an 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 505.3 regarding drugs), 517 (provider audits), 518 (recovery and withholding of payments or overpayments) and 519 (provider hearings). Also pertinent are Department of Education regulations at 8 NYCRR 29.7 (unprofessional conduct – special provisions for the profession of pharmacy) and 8 NYCRR 63.6 (pharmacy – registration and operation).

The New York State Medicaid Program issues Medicaid Management Information Systems (MMIS) provider manuals, which are available to all providers and include, among other things, billing policies, procedures, codes and instructions. (Department Exhibits 11a-o, 12, 13a-b, 14a-b; www.emedny.org.) The Medicaid Program also issues a monthly Medicaid Update with additional information, policy and instructions. (Department Exhibit 10; Appellant Exhibit 235; www.emedny.org.) 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 (3d Dept. 1995); PSSNY v. Pataki, 58 A.D.3d 924, 870 N.Y.S.2d 633 (3d Dept. 2009).

DISCUSSION

The OMIG presented the audit file and summarized the case, as is required by 18 NYCRR 519.17. The OMIG presented documents,¹ two post hearing briefs and four witnesses: Dr. Karl Heiner is the statistical consultant who designed the sampling and estimation procedure used by the OMIG in this audit. (Transcript, pages 164-65, 233; Department Exhibit 7.) Sharon Conway, a registered pharmacist, is a pharmacy consultant in OMIG's pharmacy audit unit. (Transcript, page 373.) Kevin Ryan is director of OMIG's bureau of business intelligence, providing data analysis to OMIG staff. (Transcript, page 692; Department Exhibit 21.) Anne Markwardt is a Medicaid review analyst who conducts audits for the OMIG. (Transcript, page 842.)

The Appellant presented documents,² two post hearing briefs and eight witnesses: Dr. Michael D. Intriligator is a professor of economics and a statistical consultant who reviewed, on the Appellant's behalf, the sampling and estimation procedure used in this audit. (Transcript, pages 28-29, 61; Appellant Exhibits 202, 203.) Joseph Bova is director of continuing education at the Long Island University College of Pharmacy, and a member of the New York State Board of Pharmacy. (Transcript, pages 1129-30; Appellant Exhibit 204.) Richard Stoneking is the senior director of third party administration at Rite Aid Corporation. (Transcript, pages 1243-44.) Kenneth Robinson is a former vice president of managed care at Eckerd, who was involved in the integration of store 10839 into the Rite Aid Corporation. (Transcript, pages 1311, 1320-22.) Scott

¹ Department Exhibits 1, 2, 3a-b, 4-7, 7a, 8, 10, 11a-o, 12, 13a-b, 14a-b, 15, 18, 21-23, 26.

² Appellant Exhibits 3a-b, 22a-b, 49a,c, e, 52a-c, 56a-b, 71a, 89a, 93a, 117a, 122a, 129a-b, 147a, 150a, 170, 177a-b, 182, 184a, c, 185a, 192a, 202-204, 208, 219, 235, 241, 248, 251-253, 255-256.

Kassay was the supervising pharmacist at store 10839 during the audit period. (Transcript, page 1340-41.) Edward Surowiec, Christina Pettapiece, and Anthony Heibel are pharmacists who worked at store 10839 during the audit period and dispensed some of the prescriptions under review. (Transcript, pages 1483-84, 1534, 1557-59.)

ALJ Exhibit I is a stipulation of facts between the parties.

The audit findings

The OMIG's final audit report set forth its reasons for each of several categories of disallowance and listed every disallowed claim. (Department Exhibit 2.) The final audit report incorporated the OMIG's conclusions after review of the Appellant's response to a draft audit report. (Department Exhibits 3a, 3b, 4.) These documents were exchanged between the parties in accordance with audit procedures set forth at 18 NYCRR 517.5 and 517.6(a).

The charges on which the 18 claims remaining at issue were disallowed are organized into four categories in exhibits attached to the final audit report.

1. Missing prescription. Audit report exhibit II, nine disallowances (samples 49, 52, 56, 129, 147, 150, 177, 184, 185) in the total amount of \$397.06.

Medicaid does not pay for prescriptions or supplies that are not obtained upon the written order of a practitioner that is valid under the Education Law. 18 NYCRR 505.3(b)(1)&(3). In these nine instances the OMIG charges that the Appellant has failed to produce a valid written order.

The Appellant objects to the OMIG's audit report characterization of these prescriptions as "missing," on the grounds that the Appellant did produce documents it claims justify the services. (Appellant brief, pages 6-8.) This quibble about terminology is of little significance. The Appellant's responsibility on audit, and burden of proof at

this hearing, was to produce a valid written order demonstrating its entitlement to payment from the Medicaid Program. 18 NYCRR 504.3(a), 519.18(d). The Appellant was clearly on notice that this was the issue, had the opportunity to produce, and has produced the documentation that it claims does demonstrate its entitlement to payment. The Appellant does not even suggest that there is additional documentation or evidence it could or would have produced for audit or at this hearing if the stated grounds for disallowance were “inadequately documented” rather than “missing” prescriptions.

The Appellant claims that in seven of these nine instances (samples 52, 56, 129, 147, 150, 184, 185) its documentation demonstrates the service was a valid telephone order for a new prescription for a patient who had previously had a prescription for the same medication. (Department Exhibit 3a, page 6.) In an eighth instance (sample 49) the Appellant claims that a valid order was received by fax. (Department Exhibit 3a, page 8.)

Telephone orders are permitted. 18 NYCRR 505.3(b)(4). All such orders must meet the requirements for a prescription under section 6810 of the Education Law. 18 NYCRR 505.3(b)(3). Telephone orders must be recorded by the pharmacy in the format required by Ed.L 6810(4), recording the time of the call and the initials of the person taking the call and the dispenser, prior to dispensing the drug. 18 NYCRR 505.3(b)(5).³

³ The Appellant suggests that the documentation requirements of Ed.L. 6810(4) apply only to “refills.” (Appellant brief, page 11.) Ms. Conway conceded that the Medicaid Program processes and handles renewals of expired prescriptions as new prescriptions, not “refills.” (Transcript, pages 542-43.) The statute makes no sense, however, if its use of the word “refill” does not include renewal of an expired prescription. There would be no reason or need for an ordering practitioner to contact a pharmacist to authorize a “refill” that had already been authorized on the original prescription. It is concluded that the meaning of the word “refill” in Ed.L 6810(4) is not identical with its meaning for Medicaid Program billing purposes. That is the way Ms. Conway understood it. (Transcript, pages 542-43.) These instances, where the Appellant claims the pharmacist was authorized by telephone to dispense a medication and additional refills and recorded that information on documentation of the previous prescription, precisely fit the Ed.L 6810(4) use of the word “refill.” *Schwamb v. Fireman’s Ins. Co. of Newark, New Jersey*, 52 A.D.2d 874, 383 N.Y.S.2d 52 (2d Dept. 1976), *affirmed* 41 N.Y.2d 947, 394 N.Y.S.2d 632 (1977), is consistent with this view.

The Appellant's pharmacists who filled these prescriptions all described the same procedure for telephone orders. When a customer who had no more refills on a prescription requested a new one, the pharmacist printed a "screen shot" of the Appellant's existing computer record of the previous order for the same drug. The pharmacist telephoned the ordering physician from the previous prescription to obtain authorization to refill it. The pharmacist then created labels for a new prescription, with a new prescription number, and affixed copies to the previously printed "screen shot" of the existing computer record. (Transcript, pages 1361-62, 1486-89, 1536-38.) The printed screen shot record of the earlier prescription, to which labels printed for the new prescription were affixed, was maintained as the Appellant's documentation of the service. The Appellant claims that, taken together, these documents satisfy Medicaid billing requirements. (Department Exhibit 3a, page 6.)

The Appellant's "screen shot" documentation in these instances does not satisfy Medicaid documentation requirements. There may be little to criticize in the described manner of providing these services. There is much to criticize, however, in the manner in which the services were documented. None of these "screen shot" records documents that there was a telephone call or any other communication with an ordering provider. The Appellant documented that these medications were dispensed, not that they were ordered. What is not documented is any indication how or even that an ordering provider was involved in the issuance of a new prescription.

The requirement that a telephone order be documented is not just some arcane rule peculiar to the Medicaid Program. Specific documentation requirements for

prescriptions have long been set forth in Ed.L. 6810, with which all pharmacists in New York have every reason to be familiar.

The Appellant attempted to characterize these claims as disallowed because the documentation did not always explicitly record such details as the word “telephone” or the time of the call. The Appellant then pointed out that the OMIG concededly does not always disallow a claim if such details as the time of call, initials of person taking the call, and the word “telephone” are not all documented. These are among the defects in the Appellant’s documentation. Therefore, according to the Appellant, a claim should not be denied because of these defects. (Appellant brief, pages 8-11; reply brief, pages 11-13, 17; Transcript, pages 556-67, 961, 964, 966-67, 977.)

The Appellant’s piecemeal approach to defects in the documentation attempts to portray the OMIG as splitting hairs while it ignores the real problem, which is that the Appellant’s records simply do not document in any way that these services were ordered by an authorized provider by telephone or by any other means. The requirement is not for specific words. It is for documentation demonstrating compliance with Medicaid Program requirements.

According to Mr. Bova, screen shots have been advocated by the Board of Pharmacy as the preferred method of recording oral prescriptions because they reduce the chance of transcription errors. (Appellant Exhibit 204, page 3.) The OMIG does not disagree with that view, and is not suggesting it is improper to use screen shots. (Transcript, pages 668-69.) The problem is that it was insufficient to use only screen shots as they were used in this case. The additional and crucial information that would

enable the screen shots to be identified as properly authorized telephone orders simply was not there.

The Appellant's arguments that certain handwritten notations added to the screen shots complete the documentation of these orders are unpersuasive. Notations of the number of refills to be allowed on the new prescriptions do not constitute documentation of contact with ordering providers. The Appellant's claim that they do depends on the testimony of its pharmacists at the hearing. The OMIG is not obligated to simply accept, in place of intelligible documentation, testimony at a hearing. That is what a documentation requirement means.

Mr. Kassay pointed out that the sample 52 screen shot bears a handwritten notation "call tues," which is consistent with the four day delay between the printing of the screen shot and the filling of the prescription. (Appellant Exhibit 52a.) The sample 147 prescription was not dispensed until the day after the screen shot was printed, which is also consistent with the handwritten notation "w/c/b" on the screen shot. (Appellant Exhibit 147a.) Mr. Kassay and Ms. Pettapiece explained that these notations indicate the ordering provider was contacted by telephone but did not call back to authorize a new prescription until a later day. (Transcript, pages 1366, 1380-82, 1394, 1539, 1548-49.) These notations do not address the documentation problem, they illustrate the problem. Mr. Kassay testified:

Hearing officer: Why "WCB?"

Mr. Kassay: "Will call back." And then we put that aside, and then when I go back to it, that indicates to me that I have made the call and I am simply waiting for an answer. (Transcript, pages 1381-82.)

The Appellant documented that a call was expected, not that one was received. The Appellant produced nothing to document that these ordering providers actually did call back. It offers only the circular argument that if these prescriptions were filled they must have done so.

Ms. Pettapiece testified that handwritten notations in the form of her initials added to a label represented subsequent checking by her that the medication was accurately dispensed. (Transcript, page 1546.) Mr. Surowiec said that his handwritten initials on a label documented that he filled the prescription and that he double-checked it for accuracy. (Transcript, pages 1495-96.) Mr. Kassay interpreted his handwritten initials in the same way. (Transcript, pages 1367, 1377, 1414.) These initials appearing on the documents had an independent purpose that had nothing to do with documenting a telephone communication with an ordering provider. Sample 71, for example, is a written prescription that Mr. Surowiec initialed in the same manner as he did the “screen shot” orders allegedly taken by telephone. (Transcript, pages 1499-1500; Appellant Exhibit 71a.)

Mr. Bova, of the State Board of Pharmacy, found no deficiencies in these services, but he simply accepted, without requiring documentation of it, that these in fact were telephone orders and that there were conversations in which the ordering provider did authorize them. Mr. Bova explained that he arrived at this assumption by excluding what he considered to be the other possibilities – that the orders were written or electronic. (Transcript, page 1160.)

Taking the position that if a prescription is not documented by anything other than a record that it was dispensed, then it must have been a telephone order, does not

establish documentation of a telephone order. To accept this argument would render meaningless the entire idea and purpose of a documentation requirement.

Mr. Bova's testimony that he is satisfied these prescriptions were dispensed in compliance with state pharmacy regulations does not establish they are documented in compliance with Medicaid billing requirements. Mr. Bova simply ignored the Medicaid reimbursement issue, which is that these prescriptions, however they were presented, should not have been billed to Medicaid unless and until the Appellant received or prepared documentation demonstrating what they were and that they complied with Medicaid Program requirements. The Appellant's argument is essentially, and little more than that if it filled these prescriptions, it must have acted properly in doing so. This does not address the question whether it complied with the conditions under which it was entitled to bill the Medicaid Program for them.

In the eighth instance (sample 49) the Appellant produced a copy, not an original of a prescription and claimed that it had been received by fax. Department of Education regulations at 8 NYCRR 63.6(a)(7)(ii) permit pharmacies to fill prescriptions sent in by fax. There is nothing on the document in this instance, though, to indicate it was received by fax. (Transcript, pages 406-407.) The document produced by the Appellant is indistinguishable from a photocopy of a prescription. (Appellant Exhibit 49a.)

Mr. Kassay testified "I know this is not a Xerox and that it is a fax because I would not have a photocopied prescription in my store." (Transcript, pages 1443-44.) His argument, then, is that this must not be a photocopy because a photocopy is not acceptable. Therefore it must be a fax. (Transcript, pages 1344, 1443-44.)

Asked why, if the document is a fax, it does not show a fax “header” with a visible telephone number, Mr. Kassay said that it was the fault of the sender of the fax in not properly programming its fax machine to show that information. He said this has been a problem with ordering providers in Niagara Falls. (Transcript, page 1358.) If that is true, one reason the Appellant had and according to Mr. Kassay, the supervising pharmacist, still has a problem with faxed orders in this regard may well be that it has not seen to it that ordering providers or its pharmacists correct it.

Ms. Markwardt agreed that if the sample 49 document had a fax header indicating how it was received, the OMIG would have accepted it. (Transcript, page 996.) It does not follow from this, however, that the claim was disallowed because the document did not have a fax header.⁴ A fax header may not have been specifically required, but it is again a fallacy to conclude therefore that a document that does not have it does comply with requirements. What matters is whether a faxed order can be identified as such by the documentation. This order cannot be so identified. Even Mr. Bova acknowledged:

Well [sample 49] appears to be a fax prescription, and I would be able to tell that if I was reviewing this case and had the investigator ask the pharmacist what’s the genesis of the prescription and have to rely on the answer of the pharmacist in telling me that it was a fax prescription. (Transcript, page 1171.)

The Appellant did not maintain any documentation of the ninth service disallowed in this category (sample 177), not even a screen shot or copy of the prescription label. (Transcript, page 1405; Department Exhibit 3a, page 6; Appellant reply brief, page 20.) Well after the audit was completed, and shortly before this hearing commenced, the Appellant obtained a photocopy of a prescription from the ordering provider reported on

⁴ The prescription in question was dated June 17, 2005, and it was not until 2006 that the MMIS provider manual began to specifically require that a fax be from a secure unblocked number that must be visible. (Department Exhibit 13a, page 19 of 46; Department Exhibit 13b, page 19 of 45.)

its Medicaid claim. (Appellant Exhibit 177a.) It argues “[a]n original prescription obviously existed at some point in time; otherwise, Rite Aid would not have been able to produce the photocopy.” (Appellant brief, page 20n15.) Even if it is true, this assertion does not help the Appellant. It fails to establish when, if ever, an original was presented to the Appellant’s pharmacist, and it remains the case that the Appellant failed to maintain and produce a valid prescription or indeed any documentation for audit.

In seven instances (samples 49, 52, 56, 147, 150, 184, 185) the Appellant produced signed statements from ordering prescribers, prepared for the purpose of this audit, representing with varying degrees of certainty⁵ that they authorized the prescriptions in question. (Department Exhibit 3a, exhibit 2 thereto.) These statements, created long after the services were provided and solely for the purpose of this hearing, do not constitute contemporaneous documentation as required by the Medicaid Program. 18 NYCRR 504.3(a), 517.3(b).

In six instances (samples 49, 52, 150, 177, 184, 185) the Appellant offered contemporaneous records it obtained from the reported ordering providers. (Department Exhibit 3a, exhibit 2 thereto; Appellant Exhibits 52b, 177a.) In five of these (samples 49, 52, 150, 177, 185), the Appellant produced ordering physician records apparently noting, or at least arguably consistent with, a relevant prescription on an appropriate date.⁶

⁵ In sample 147, the statement obtained from the ordering provider actually states that he does not have any record of the order. (Transcript, pages 1385-86; Department Exhibit 3a, exhibit 2 thereto, tab 147.)

⁶ In the sixth instance (sample 184), the prescribing physician’s medical record was not even arguably consistent with the order in question. The ordering provider’s chart indicates the patient was receiving Colace on 1/3/07. The chart next documents that the patient was started on Colace on 8/21/08. There is nothing to suggest there was a telephone or any other kind of order for Colace to the Appellant or anyone else on or about 6/11/07.

The Appellant argues that the OMIG should recognize contemporaneous documentation from a third party as a substitute for documentation maintained by the billing provider. Ms. Markwardt, the auditor, agreed that during the audit she initially thought that the OMIG did. She was later advised as the audit progressed that OMIG policy is that the provider who submits the claim is required to prepare and maintain the necessary records. (Transcript, pages 877-78, 970-71; Department Exhibit 6, audit workpaper b-9-19.) Ms. Conway also confirmed that OMIG policy is not to accept third party documentation in place of documentation required to be maintained by the billing provider. (Transcript, pages 594, 662.)

Billing providers are not required just to produce contemporaneous records, they are specifically required to “prepare and to maintain” contemporaneous records that must be “kept by the provider.” 18 NYCRR 504.3(a), 517.3(b). The OMIG’s position that records prepared and maintained by a third party fail to meet the billing provider’s obligation is completely consistent with the language in the regulations and is reasonable. The Appellant’s own pharmacy consultant, Mr. Bova, argued in his written report on behalf of the Appellant:

Whether an existing telephone prescription with all required information properly prepared by a pharmacist is considered “missing” should not hinge on whether the prescribing doctor also happened to maintain a separate record of the telephone prescription, something over which the pharmacist has no control. (Appellant Exhibit 204, page 3.)

The sketchy and poor quality of the third party evidence brought forward in this case illustrates why the regulations on this point are rational and reasonable.

All nine disallowances in this category, in the total amount of \$397.06, are affirmed.

2. Ordering prescriber conflicts with claim prescriber. Audit report exhibit IV, eight disallowances (samples 3, 22, 71, 89, 117, 122, 170, 182) in the total amount of \$31.50.

In eight instances, the OMIG determined that the prescription was not authorized by the provider the Appellant identified on its Medicaid claim to be the ordering provider. In these instances the OMIG disallowed the service fee portion of the claim rather than the entire amount paid by Medicaid to the Appellant.

All information submitted with a Medicaid claim must be true, accurate and complete. 18 NYCRR 504.3(h). Billing providers certify with each claim that no material fact has been omitted from the claim. 18 NYCRR 540.7(a)(8). (Department Exhibit 15.) A claim for a service ordered by one provider, submitted with the representation it was ordered by some other provider, is a significant violation of these Medicaid requirements. The Appellant's argument (brief, page 28) that the identity of the ordering provider is not "material" to a Medicaid claim is rejected. 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. (Transcript, pages 415-17.)

The Appellant argues that if these were valid prescriptions for eligible Medicaid recipients written by authorized providers they are not overpayments in the ordinary sense of the word and so should be reimbursed under the Medicaid Program. (Appellant brief, page 26.) "Overpayment," however, has a specific definition in DSS regulations that includes amounts paid as the result of improper claiming or mistake. 18 NYCRR 518.1(c). Even if the ordering provider and patient acted properly, the Appellant did not.

These claims were submitted with the representation that they were validly ordered by an identified provider. This representation was not accurate.

Visiting Nurse Service of NY v. NYS Dept. of Health, 5 N.Y.3d 499, 806 N.Y.S.2d 465 (2005), was cited by the Appellant but does not support its position. (Appellant brief, page 26.) The court of appeals holding in that case was (ironically for the Department) consistent with what the court recognized as a “broad definition” of the term overpayment.

The Appellant also cites a previous decision issued by this bureau in support of its position that these are not overpayments. (Appellant brief, page 24.) In Bronx Prescription Center South (DOH administrative hearing decision issued April 1, 1998) the Department disallowed claims on the grounds that the prescriptions were written by providers excluded from the Medicaid Program. The disallowances were reversed because the Department failed even to make a prima facie showing that the prescriptions were written by excluded providers. That is not the charge in this case.

In four of these instances (samples 3, 117, 122, 182) the Appellant’s Medicaid claim identified a health care facility, rather than an individual, as the ordering prescriber. (Appellant Exhibits 3a, 117a, 122a, 182a; Department Exhibit 6, audit workpapers d-2.) The Appellant’s argument that under 18 NYCRR 505.3(b) and 512.2(a) a pharmacy always has the option to submit a claim identifying either the ordering provider or the facility in which the order was written has been rejected by the appellate division and it is rejected here. PSSNY v. Pataki, *supra*. The MMIS provider manual specifies:

For orders originating in a hospital, clinic or other health care facility, the facility’s MMIS ID Number may be entered only when the prescriber’s MMIS ID or State License number is unavailable. (Department Exhibit 12, page 3-21.)

MMIS manual billing guidelines applicable to these prescriptions also state:

If the Medicaid ID or State License number of an authorized prescriber is not on the prescription, it is the pharmacist's responsibility to obtain it. (Department Exhibit 14a, page 19; Department Exhibit 14b, page 20.)

The Appellant's argument (brief, page 30) that these Medicaid Program requirements violate the State Administrative Procedure Act or conflict with 18 NYCRR 512.2 was also rejected in PSSNY v. Pataki, and it is rejected here.

Even if a prescription was written at a hospital or other health care facility, the facility's number should be used for billing only when the pharmacy is unable to identify the ordering prescriber. The Appellant has the burden of establishing that it made some attempt to obtain and submit an individual prescriber's number. The Appellant has not met that burden in these instances because there is no evidence that it made any attempt to do so.

In the remaining four instances (samples 22, 71, 89, 170), the order was signed by one provider, but billed as if ordered by another. (Appellant Exhibits 22a, 71a, 89a, 170a; Department Exhibit 6, audit workpapers d-2.) In sample 89, the Appellant suggests that its employee who typed in the license number made a one digit typographical error, which caused the service to be billed under a different provider with a similar number. (Appellant brief, page 22.) This explanation is plausible, but even if accepted it does not establish the Appellant is entitled to payment. Overpayments include payments made as a result of improper claiming or mistake. 18 NYCRR 518.1(c).

The sample 22, 71 and 170 prescriptions were written by Dr. Tanhehco, whose name and license or DEA number is imprinted on them. (Appellant Exhibits 22a, 71a, 170a.) The Appellant's Medicaid claims identified Dr. Hak Ko. (Department Exhibit 6,

audit workpapers d-2.) Mr. Kassay suggested that the names Tanhehco and Hak Ko could have been confused over the telephone. (Transcript, page 1415.) These were written prescriptions, not telephone orders, and they were all imprinted with Dr. Tanhehco's name.

The Appellant claims that Dr. Tanhehco and Dr. Hak Ko were both on staff at the same hospital. (Appellant brief, page 23.) This is not a justification for interchanging them on a Medicaid claim. OMIG auditors do allow interchanging numbers among members of the same practice, for example when the names of both providers are imprinted on the prescription. That rationale does not apply to staff at a hospital. Dr. Tanhehco and Dr. Ko were not in practice together, nor did both their names appear on the written orders in question. As Ms. Conway and Ms. Markwardt both explained, this is a significant distinction that justifies a difference in treatment. (Transcript, pages 461, 465, 627, 1045, 1119-21.)

In any event, in all of these instances the Appellant obviously knew who the individual prescriber was. The correct ordering provider name appears on the Appellant's own pharmacy labels. (Appellant Exhibits 3a, 22a, 71a, 89a, 117a, 122a, 170a, 182a.) Only the Medicaid claims were inaccurate. The Appellant itself expressed a plausible and even probable explanation for the errors, which is that the Appellant's billing records inaccurately assigned one provider's MMIS or license number to another provider. (Transcript, page 631.)

Mr. Heibel explained that most if not all of these instances were probably the result of having the wrong MMIS or license number associated with a name in the Appellant's provider profiles. (Transcript, page 1569.) Mr. Surowiec said the error

could have been made at the time an ordering provider's profile was created in the computer system. (Transcript, page 1505.) A facility's MMIS or license number could have been assigned to an individual, or one ordering provider's number could have been assigned to another. The error would then remain in the Appellant's billing system.

As Mr. Surowiec pointed out, the dispensing pharmacist's primary concern is to serve the customer by filling the order. (Transcript, pages 1520, 1521.) When a pharmacist accessed the Appellant's records in order to dispense a medication, it was usually done using the ordering provider's name, address or telephone number. (Transcript, pages 1412-13, 1425, 1566.) The computer screen called up by the pharmacist did not show the MMIS provider or license number associated with that provider. (Transcript, pages 631, 1413, 1503, 1567.) The pharmacist had little reason and apparently was not required to take additional steps to verify the MMIS or license number the system associated with the provider's name. (Transcript, pages 1425-26.)

Medicaid claims, on the other hand, are submitted by MMIS or license number, and not by name. (Transcript, pages 626, 702, 1021-22.) If the MMIS or license number in the Appellant's record was inaccurate, a claim would still go through and be accepted, or "captured," by Medicaid as long as the number was a valid number for some provider. (Transcript, pages 441-42, 631-32.) The pharmacist could then generate medication labels showing the true ordering provider and fill the prescription with confidence that Medicaid had approved payment for it. The Appellant, not the dispensing pharmacist, prepared and submitted a Medicaid Program claim that identified the wrong provider. (Transcript, pages 1250-51.)

The Appellant's record keeping system allowed a number, as long as it was valid for some Medicaid provider and so would be accepted by Medicaid for billing purposes, to be assigned to an unrelated ordering provider and then maintained in its system. The error would be perpetuated each time the ordering provider's name was used. For example, Dr. Hak Ko's number was reported instead of Dr. Tanhehco's on three claims (samples 22, 71 and 170) in just this audit sample. Even if the errors were inadvertent to begin with, it is not reasonable to excuse the Appellant for claiming errors its own recordkeeping system enabled it to make, and that, once made, its system perpetuated.

The Appellant suggested that these claims should not be disallowed because, as is set forth in a Medicaid Update of August 2001 (Appellant Exhibit 235), providers have the right to adjust claims to correct certain errors. (Appellant brief, page 27; reply brief, page 25.) The short answer to this argument is that the Appellant did not submit any corrections or adjustments. As Ms. Markwardt pointed out, "any adjustments made in response to the audit would be a method of circumventing the audit findings." (Transcript, page 1049.)

The Appellant may have had little reason to correct its claims in the absence of this audit because the claims were paid as submitted. After being advised of the audit findings, however, the Appellant was on notice that there was a problem. The draft and final audit reports were both issued within the six year time limit for submitting corrected claims. The Appellant apparently did not submit any corrections. It is hardly a defense to the audit findings to now argue that it could have corrected its inaccurate Medicaid claims (or submitted them properly in the first place) but did not do so.

Although neither fraud nor abuse is charged, and there is no reason to conclude it occurred in this case, the Appellant's billing system has an obvious potential for abuse. Once a valid provider's number is obtained and entered into the Appellant's system, a dispensing pharmacist can use it to bill and be paid by Medicaid for services ordered by anyone. Only if there is an audit will improper claiming be revealed. The OMIG and the Appellant both have good reason to take this problem seriously. The Appellant, however, not the Medicaid Program, is the one responsible for it.

All eight disallowances in this category, in the total amount of \$31.50, are affirmed.

3. Imprinted or stamped name of prescriber missing on prescription. Audit report exhibit V, one disallowance (sample 93) in the amount of \$4.50.

Every prescription written in New York State must bear the prescriber's signature and, in addition, be imprinted or stamped legibly and conspicuously with the printed name of the prescriber who has signed the prescription. Ed.L 6810(8). No ordering prescriber's name is imprinted on the prescription in sample 93. (Appellant Exhibit 93a.) In this instance the OMIG limited the disallowance to the Appellant's service fee.

The Appellant argues that the imprint requirement can be overlooked because the signature was allegedly legible to the dispensing pharmacist, and so the "intent" of the imprint requirement is met. (Appellant brief, page 33.) The intent of legislation is not irrelevant, but it does not replace compliance with the clear requirement of the law that was enacted. The statute clearly and unambiguously requires both a stamp and a signature.

The Appellant's argument (brief, page 31) that the requirement is met by the name appearing on the printed label after the medication was dispensed is rejected as

again amounting to a claim that the documentation requirements were met because the service was provided. As Ms. Conway said, a dispensing label is made from an input of data from an authorized prescription and is generated after the pharmacist has determined it is appropriate to fill it. (Transcript, page 618.) Mr. Stoneking also testified that the label is generated after the authorized prescription is presented by the patient and after the claim for payment is submitted to and approved by the Medicaid Program. (Transcript, pages 1248-49.) The label is not the authorized prescription itself and it is bootstrapping to say so. (Transcript, pages 396-97.) The Appellant's argument would again render the documentation requirement essentially meaningless.

The Appellant's argument (brief, page 32) that a previous decision issued by this bureau supports a different finding herein is rejected. Brighton Pharmacy, Inc. (DOH administrative hearing decision issued January 22, 2009) is not about nor does it even mention the requirements of Ed.L 6810(8).

The disallowance in sample 93, in the amount of \$4.50, is affirmed.

4. Additional findings. Audit report exhibit VI, two disallowances (samples 122, 182.)

In samples 122 and 182 an additional criticism was that these prescriptions were written by physician's assistants but did not identify the supervising physician. The final audit report cited no legal authority for this charge, as is required under 18 NYCRR 517.5(a) and 517.6(b)(1), nor did the OMIG address it at the hearing or in its briefs. These additional findings are dismissed.

Medicaid Program overpayments

The claims disallowed in this audit, as affirmed in this hearing decision, were not authorized to be paid under the Medicaid Program because they were not supported by

documentation demonstrating compliance with Medicaid Program requirements. The OMIG is entitled to recover the overpayments made.

The OMIG's determination in this case is not punitive: The OMIG does not seek to impose any sanction under 18 NYCRR Part 515 (provider sanctions) or penalty under Part 516 (monetary penalties). This audit is about the recovery of Medicaid Program overpayments pursuant to 18 NYCRR Part 517 (provider audits). Contrary to the Appellant's suggestion (brief, page 3), the OMIG is not required to establish unacceptable practices in order to recover overpayments. Also contrary to the Appellant's claim (reply brief, pages 2-3) the OMIG is not required to proceed under 18 NYCRR Part 515 in order to recover overpayments that are the result of unacceptable practices. Overpayments are defined in Part 518 (recovery of overpayments), which is applicable to both Part 517 and Part 515. 18 NYCRR 518.1(c)&(d).

The findings in the 200 claim audit sample were selected from the "universe" of claims that the Department's billing and payment records show were paid by the Medicaid Program to the Appellant during the four year audit period. 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 519.19(f). The Appellant did not challenge or offer any evidence to rebut this presumption. The Appellant did claim it was given lists showing universes of two slightly different sizes, but the evidence establishes that the shorter list, the one used in the extrapolation, simply – and appropriately - omitted

duplication of claims that appeared more than once on the longer list because they had been canceled, reissued or corrected. (Transcript, pages 342, 704-706.)

The draft audit report (Department Exhibit 4) and the final audit report (Department Exhibit 2) each set forth the manner in which the extrapolation was made. Each report identified the disallowed claims, the universe 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. Heiner, the statistical consultant who designed the sampling and estimation procedure and the computer program that implemented it, and Kevin Ryan, who used the procedure to select the audit sample. (Department Exhibits 7, 21.)

The Appellant, however, has a right under DSS regulations to challenge the accuracy of the extrapolation. 18 NYCRR 519.18(g). The New York Court of Appeals has recognized the importance of this right:

We emphasize that, as the regulation governing the use of statistical sampling dictates, the provider, who at all times bears the burden of proving entitlement to the Medicaid funds, must be given a fair opportunity to challenge the accuracy of the estimate by attacking the reliability of the methods or standards employed... Mercy Hospital of Watertown v. NYS Dept. of Social Services, 79 N.Y.2d 197, 581 N.Y.S.2d 628 (1992).

The OMIG has refused in this case to allow the Appellant to review the computer program the OMIG used to select the audit sample.

The OMIG argues that “the software is not part of the audit file” and so is not required to be disclosed under 18 NYCRR 519.13 or 519.14. (OMIG brief, page 22.)

This argument is irrelevant to the issue whether the Appellant was entitled to review it pursuant to 18 NYCRR 519.18(g) and Mercy Hospital.

The OMIG also points out that it provided the same documents to the Appellant that it provided to its own statistician to enable him to prepare his certification. “As such, they should also have been sufficient for Rite Aid’s expert to assess the very same things that the department’s statistician was assessing.” (OMIG brief, pages 12n7, 20-21.) What this *non sequitur* overlooks is that the OMIG’s statistician did not need to review and assess the random sampling program. He is the one who “designed and approved” it in the first place. (Department Exhibit 7, point 18.)

The OMIG seemed at times to claim the sampling program was exempt from disclosure pursuant to 18 NYCRR 519.13(b) on the grounds that it constituted an “investigative technique.” (OMIG brief, page 23n22.) The OMIG did not explain how disclosure of a random sampling program, if indeed it is a random sampling program, could compromise the OMIG’s investigations or give providers an improper advantage, and it is not apparent to this tribunal.

The OMIG claimed that a part of the program, the random number generator, was not written by Dr. Heiner and was “proprietary” information to Sun Microsystems, the company from which he obtained it. (Transcript, page 269; OMIG brief, page 23n23.) The OMIG then also argued, somewhat confusingly, that the Appellant has not been prejudiced because the Sun Microsystems random number generator is “proprietary but available at no cost on the open market.” (Transcript, page 270; OMIG brief, page

20n18.) According to the OMIG, this means “Rite Aid had the opportunity – at no cost to themselves – to generate these exact numbers.” (OMIG brief, page 20n18.)⁷

While the OMIG claimed in its post hearing brief that the Appellant “was aware” the Sun Microsystems program had been used, it failed to cite any evidence for or offer any reason to believe this claim. (OMIG brief, page 20n18.) Sun Microsystems is not mentioned in either Dr. Heiner’s or Mr. Ryan’s certification. Dr. Intriligator does not appear to have been aware of its connection with this audit. (Transcript, pages 80-81, 105-106; Appellant Exhibit 202.) This information came out when it was volunteered by Dr. Heiner during his cross examination at this hearing, after Dr. Intriligator had already testified. (Transcript, pages 260, 269-70.)

In any event, it is not necessary for the purposes of this hearing decision to reach the question whether the OMIG was able to provide or even disclosed its use of the Sun Microsystems random number generator, because the alleged “proprietary” material is only one part of Dr. Heiner’s computer program. (Transcript, page 279.) The OMIG has refused even to allow access to those portions of the program that Dr. Heiner did write.

Instead of providing access to the random sampling program, the OMIG relies on three “batch tests” that Dr. Heiner’s program automatically performed on the audit sample after it was generated. The OMIG claims that these tests are sufficient to establish the validity of the random sample, and takes the position that because these tests can be done on the sample numbers without knowing the program that generated them, it is not necessary to allow access to the program. (Transcript, pages 179, 182; OMIG brief, page 23.)

⁷ This assertion is difficult to reconcile with the OMIG’s simultaneous claim that “obtaining the software program would not assist Rite Aid in reproducing those numbers.” (OMIG brief, pages 22-23n21.)

The tests do not prove that the sample in this case was a random sample generated by a procedure generally accepted as statistically valid for estimation purposes. As Dr. Heiner himself said, all they establish is that the numbers “look like” a random sample. (Transcript, pages 181, 188, 237, 795.) The sample has the appearance of being random because it displays certain characteristics one might ordinarily expect to find in a random sample, such as an absence of any obvious pattern or markedly uneven distribution in the numbers selected. These tests cannot determine retroactively whether the sample was indeed selected by means of a statistically valid random number generator.

Passing the three batch tests does not establish that a sample was randomly selected. Nor, indeed, does failing any of the three tests establish that a sample was not randomly selected. In fact the first sample or “run” generated by the OMIG in this case did fail one of the tests. (Transcript, pages 183-84; Department Exhibit 21, exhibit b-2 thereto.) That failure does not mean that the first run generated by the program was not randomly selected. (Transcript, pages 183, 240-41.)

As Dr. Heiner explained, he wrote these tests into the sampling program to avoid the use of a sample that “doesn’t appear to be random, so they don’t encounter difficulties in a hearing.” (Transcript, pages 177-78, 188, 242.)

Dr. Heiner did testify and certify that the “linear congruential” method of generating a random sample was applied in the OMIG’s program. (Transcript, page 260; Department Exhibit 7.) He agreed, however, that there are different ways of writing such a program. (Transcript, pages 272-74.) Dr. Heiner conceded that a sample generator could be created that did not produce a random sample. (Transcript, page 236.) Dr. Intriligator testified, and Dr. Heiner agreed, that a sampling program could be written to

generate a skewed sample, or that could select for certain types of claims. (Transcript, pages 82, 244, 246, 251-52.) Dr. Heiner further agreed that one could simply sit down and write a list of sample numbers that passes his batch tests. (Transcript, pages 240-41.) In short, passing or failing these after the fact tests proves nothing about how the sample was generated.

Dr. Heiner offered a “philosophical” view of random sequence generators to explain his opinion why in this situation what is random and what looks random “amount to the same question.” (Transcript, page 239.) He pointed out:

Any random sequence[s] that you use are sequences that look random, because you have to have a method of generating them. If you had a method generating them, then, philosophically, they can’t be random. (Transcript, page 276.)

However intriguing this observation might be, it is no excuse for refusing to provide access to the program used to generate the sample in this case. (Transcript, pages 184-85, 234-35, 243, 276.) Dr. Heiner’s own certification states:

Random number generators are really medical [sic]⁸ algorithms that can be programmed into a computer. However, not all of these automated generators produce adequate random sequences. (Department Exhibit 7, paragraph 17.)

The issue is not the “philosophical” one whether any computer can generate more than the “pseudorandom” samples generally accepted and used for statistical purposes. (Transcript, pages 276-77.) The issue is the Appellant’s entitlement to review what was done in this case given that even Dr. Heiner agrees “it’s true that one could write some program to generate numbers that wouldn’t produce random numbers.” (Transcript, page 236.) The Appellant is entitled to review whether the program used to generate the

⁸ This statement apparently originates from an article by Dr. Heiner in the Spring 1984 Jurimetrics Journal, in which “medical” appears as “mathematical.”

sample in this case was designed to, in Dr. Heiner's words, "produce adequate random sequences."

The OMIG argues that even if the program were provided it would not enable the Appellant to generate a sample that reproduced the OMIG sample because other variables, such as the "seed" used and the particular computer equipment the program is run on, affect the result. (OMIG brief, page 23.) That is not the point. The issue is whether the program, upon examination, proves to be a program that can produce an "adequate," that is, statistically valid sample. The Appellant is entitled to examine it for that purpose. (Transcript, page 79.)

The OMIG's refusal to provide the information needed to review and evaluate the random sampling program that was used in this case renders the right to challenge it meaningless. The OMIG has presented, as Dr. Intriligator called it, a "black box" inside of which is alleged to be a computer program that OMIG claims generated a statistically valid random sample. (Transcript, page 105.) The OMIG's position that it has no obligation to allow the Appellant to examine that program makes no sense if the Appellant is also explicitly granted the right to challenge it. It calls to mind Chico Marx protesting "Who you gonna believe, me or your own eyes?"

The OMIG's refusal to allow the Appellant to examine the program used to select the sample is especially mystifying because, as the Appellant asserted and the OMIG did not deny, the program designed by Dr. Heiner has been disclosed to providers in the past. (Transcript, pages 268-69, 286-89.)

The finding herein is in no way an invalidation of the sampling and estimation procedure described by the OMIG in its certifications and at the hearing. The procedure

used by the OMIG is authorized by the regulations and has consistently been upheld by the courts, including the New York Court of Appeals. Mercy Hospital v. NYS DSS, *supra*; Clin Path v. NYS DSS, 193 A.D.2d 1034, 598 N.Y.S.2d 583 (3d Dept. 1993). A finding that the OMIG has deprived the Appellant of a fair opportunity to exercise its right to challenge the validity of the procedure as it was applied in this particular case is not a finding that the procedure itself was improper or invalid.

The decision herein regarding the extrapolation is based solely on the foregoing. It is noted, however, that there is also little to applaud in the OMIG's manner of disclosing other information even if it did technically comply with its obligations under the regulations. In particular, the OMIG was unwilling to provide the Appellant with the "universe" in such detail as would, according to the Appellant, enable it to more easily identify individual claims in its own records. The OMIG refused to do so until at or shortly after the October 30, 2009 prehearing conference. (Transcript, pages 742-45, 749-51, 765-66; Department Exhibit 21; Appellant Exhibits 219, 256.)

The OMIG apparently provided such "discovery" as is required by 18 NYCRR 519.13. However, in a case that involves over 134,000 claims, it is not always reasonable to demand that a provider digest so much material within seven days. The unreasonableness of the OMIG's approach to this hearing is exemplified by its suggestion that the Appellant could, from the initial claims list provided, have gone back to examine all of its original remittance statements and, one by one, matched up 134,815 claim reference numbers used by Medicaid with the corresponding but different numbers in its own internal records. (Transcript, pages 743-44, 813, 831-33, 1285-86; OMIG brief, pages 24-25.) The OMIG had the ability to facilitate this cross-referencing by providing

the more detailed “universe” requested by the Appellant. There was little reason for the OMIG to drag its feet and be uncooperative in doing so simply because “the department was not required to share any of these documents with Rite Aid until the prehearing conference.” (OMIG brief, page 12n7; Transcript, pages 817-21.)⁹

Although the Appellant was not given the opportunity to review the entirety of the estimation procedure, it did have access to most of what was done, and to the audit file. The Appellant’s argument that information in the audit file that it characterized as evidence of “data mining” could be used to skew the audit sample proves nothing. (Appellant brief, page 50; reply brief, pages 29, 32.) The OMIG categorizes and organizes provider information in different ways for various purposes in order to enable it to make various sorts of inquiries. It is entitled to do so, and it is not surprising that such information might appear in an audit file. It does not follow nor is there any evidence that a determination to access such information inappropriately influenced the selection of this audit sample. (Transcript, pages 851, 1069-72.)

The Appellant presented Dr. Intriligator to criticize the sampling and estimation procedure. Dr. Intriligator and Dr. Heiner did not disagree on much. The significant difference was that Dr. Intriligator considered the OMIG’s estimation not precise enough, while Dr. Heiner opined that it was valid for the purpose and so met the regulatory requirement.

Dr. Intriligator agreed that the use of a statistical sampling and extrapolation methodology in Medicaid audits is “[a]bsolutely[,] in fact the only way to arrive in proper

⁹ This is not to suggest that the OMIG had an obligation to organize or provide information in a form chosen by the Appellant. The issue in this case is that the OMIG actually redacted the first version of the universe it provided. All the Appellant requested was the unredacted version of this information in a form in which the OMIG already had and eventually did provide it.

decisions...” (Transcript, page 48.) His criticisms of this audit were essentially 1) that there were various methods, none of which the OMIG is required to use, by which the audit and resulting overpayment calculation could and should have had greater precision; and 2) that the audit was not conducted and documented in conformity with Medicare requirements that do not apply in this Medicaid audit. (Appellant Exhibit 202.)

Dr. Intriligator’s report criticized the OMIG for failing to first audit a “probe sample.” (Appellant Exhibit 202, page 17.) He then conceded at the hearing that failure to do so did not invalidate the audit. (Transcript, page 119.) Neither DSS regulations nor OMIG audit protocols require probe samples.

Dr. Intriligator opined that the tolerance level for accuracy in this case, expressed as a “coefficient of variation,” was too high. A 27 percent coefficient of variation in this case¹⁰ was, in Dr. Intriligator’s view, “totally unacceptable.” (Transcript, pages 96, 138.) The Appellant failed to establish either why the coefficient of variation is too high, other than because Dr. Intriligator said so, or what it must be in this case.

Dr. Intriligator described ways in which the margin of error in the audit could have been narrowed. He suggested the use of stratified samples (Appellant Exhibit 202, pages 14-16), although neither applicable regulations nor OMIG policies (Appellant Exhibit 251) require their use. Dr. Heiner agreed that stratification might give a more precise estimate by narrowing the confidence intervals. A stratified sample, however, yields at best a more precise estimation. It is not a necessary condition for a valid estimation. (Transcript, pages 210-11.)

¹⁰ 40 percent as corrected to reflect withdrawals at the hearing. As the OMIG pointed out, the coefficient of variation can only be calculated retroactively, after the audit is completed and the findings are made. (OMIG brief, page 35n42.)

Dr. Intriligator said that “there should be some floor in terms of sample size.” (Transcript, page 58.) He failed, however, to specify what it is and agreed that even the Medicare protocols brought forward by the Appellant do not specify or require any minimal sample size, leaving it up to the reviewing agency to decide what is appropriate. (Transcript, pages 57-58.) In Dr. Heiner’s opinion a sample size of 200 was “fine” for this audit. (Transcript, pages 328-29.) Courts of this state have upheld the use of smaller samples than this for Medicaid provider audits. See, *e.g.*, Clin Path, *supra*.

From the OMIG’s point of view, determining sample size includes considerations of effectiveness, balancing the amount that may be recovered against the cost of auditing. As Dr. Heiner pointed out, the benefit of greater precision can be outweighed by the cost of applying a more rigorous standard. (Transcript, page 347.) Dr. Intriligator agreed “it depends on the resources that [the reviewing agency] has which, of course, are important.” (Transcript, page 58.)

The OMIG has limited resources to devote to audits of thousands of Medicaid providers. It is responsible for monitoring the claims of over 246,000 Medicaid Providers in New York State, including over 12,000 pharmacies. The OMIG has roughly 280 auditors to do so. (Transcript, pages 845-46.) These realities matter. Cost of auditing considerations, deterrence objectives and corrective pressure aimed at influencing both individual providers and the provider community are all rational considerations in determining sample size.¹¹

¹¹ Mr. Stoneking testified that as a result of Medicaid audits of a number of its pharmacies, Rite Aid has taken significant steps to address the problem raised in category 2, “ordering provider conflicts with claim prescriber.” (Transcript, pages 1251-55.) Inducing corrective action by providers is a legitimate and important purpose of audits like this.

Dr. Intriligator conceded that the acceptable degree of precision required in any estimation depends upon the particular environment in which it is applied, and acknowledged, as Dr. Heiner said, that different entities can appropriately require different standards. (Transcript, pages 96, 216-18, 318-19.) The OMIG is not required to use a probe sample, a stratified sample or a sample of any specific size. The test is statistical validity, and Dr. Intriligator, while offering reasons why the OMIG's audit was unacceptably imprecise to him, failed to establish that the audit findings were inaccurate or statistically invalid.

The Appellant has failed to establish that the OMIG violated its own policy or applicable regulations in its conduct of this audit. (Transcript, pages 115-117.) The Appellant has also failed to establish that OMIG policies or applicable regulations violate any generally accepted professional standard or applicable legal requirement, or that their application in this case constituted an abuse of discretion.

Dr. Intriligator also argued that the OMIG failed to show the sample was representative. The Appellant, not the OMIG, had the burden of proof on this issue. 18 NYCRR 519.18(d)&(g). Dr. Intriligator complained that the average dollar value per claim in the sample did not precisely match the average dollar value per claim in the universe. (Appellant Exhibit 202, page 14; Transcript, pages 121-22.) Dr. Heiner's explanation why the slight difference in this case is not unexpected and does not invalidate the sample is credited. (Transcript, pages 189-92, 214.) Even Dr. Intriligator conceded that it would be unlikely for the average dollar value per claim in the sample to exactly match that in the universe. (Transcript, page 122.) It is further noted that the

variance in this case does not suggest any unfairness to the Appellant, because it worked in the Appellant's favor. (Transcript, pages 121-22, 192, 365.)

Dr. Intriligator pointed out in his report that the ratio of "services" to "cases" in the universe was approximately 30 prescriptions per patient, whereas 177 different patients were found in the 200 claim sample. (Appellant Exhibit 202, page 14; Transcript, page 140.) He suggested that, but failed to explain how or why this raises a question about the representativeness of the sample. He displayed confusion about what "cases" even meant, and acknowledged that in his report he was simply quoting terms used by the OMIG that were not explained to him. (Transcript, pages 140-43, 153-54, 724.)

Dr. Heiner explained that "there is a problem with the logic there." The sample taken was of claims, not patients. A comparison of the proportion of patients to claims in the sample to the proportion of patients to claims in the universe is "not relevant. It's not logical to tell you anything about that." A more relevant point is that the 177 patients in the sample, like the 4,174 patients in the universe, had an average of 30 claims each, and Dr. Intriligator agreed the sample was representative in this respect. (Transcript, pages 159, 223-25.)

Dr. Intriligator said there were "other tests you could do" (Transcript, pages 125-26), but failed to identify others that he did or that supported the view that the sample was not representative.

Dr. Intriligator also criticized the OMIG's audit as not adequately documented. (Appellant Exhibit 202, page 22.) Dr. Intriligator relied, however, on Medicare audit protocols (Appellant Exhibit 248) for documentation requirements that do not apply to

this Medicaid audit. The Medicare protocols cited by the Appellant themselves state that deviation from them does not render a sampling procedure invalid nor does it necessarily affect the validity of the statistical sampling or the projection of an overpayment. (Transcript, pages 109-110, 296; Appellant Exhibit 248, section 3.10.1.1.) Furthermore the Medicare rules brought forward by the Appellant and relied on by Dr. Intriligator are not inconsistent with any requirement set forth in the Department's regulations.

Dr. Intriligator claimed that another flaw in the OMIG's audit was a failure to consider what he called "non-sampling errors" such as clerical errors or errors in the review of sampled claims. (Appellant Exhibit 202, page 29; Transcript, page 103; Appellant brief, pages 58-59.) The correction of such errors is one purpose of this hearing. (Transcript, page 218-19.) The OMIG's withdrawal of several disallowances illustrates this.

Dr. Intriligator pointed out that the OMIG disallowed only the Appellant's service fee, not the entire cost of the prescription, in certain instances. This, he claimed, was an inconsistency. (Appellant Exhibit 202, pages 29-30; Transcript, pages 103, 143-44.) Any difference in the treatment of individual disallowances in the sample is carried over into and will be projected in the same way to the universe. (Transcript, pages 220-21.) The "inconsistency" is not an inconsistency in the estimation methodology itself, as Dr. Intriligator himself conceded. (Transcript, page 145.) The OMIG's determination to require restitution of only the service fee in some instances actually benefited the Appellant.

The Appellant complains the OMIG did not consider possible underpayments for some claims. (Appellant Exhibit 202, page 30; Transcript, pages 104-105; Appellant

brief, page 59.) The OMIG is responsible for detecting Medicaid fraud and abuse and identifying and recovering Medicaid Program overpayments. PHL 30, 31, 32. OMIG is not charged with auditing to detect and correct underpayments to providers. Providers have their own avenues of redress for underpayments, and the responsibility to pursue them. For this reason the Appellant's offer of evidence to show underpayments in the sample was denied as not relevant to the OMIG's determination. (Transcript, pages 1327-33.) Possible underpayments in the universe are also irrelevant to the audit determination. (Transcript, pages 220-22.) 18 NYCRR 519.18(a).

The Appellant argues that using the mid point estimate, rather than the low end of the 95 percent confidence interval mentioned in the audit report, is unfair. Dr. Heiner did not agree that "using the lower confidence bound was more fair." (Transcript, page 310.) He testified instead that the point estimate is unbiased, and that "the unbiased estimate has the provider and the State sharing the risk of the sampling error. So, in that sense, it is fair if both sides are equally sharing –" (Transcript, page 307.)

The lower confidence figure is variable, in fact basically arbitrary, because it is dependent upon the confidence interval chosen. The OMIG referenced a 95 percent interval in the audit report. There is no apparent reason, however, why the confidence interval could not have been set at 90 percent, 75 percent or any other interval, and the lower confidence figure would vary accordingly. Confidence intervals are not specified or even mentioned in the DSS regulations or OMIG protocol applicable to this audit.

The point estimate, on the other hand, is the best estimate of what the auditors would have determined to be paid in error had they reviewed all 134,815 services in the universe of claims. (Transcript, pages 205, 212.) It was not arbitrary or capricious for

the OMIG to use it, and the Appellant has failed to meet its burden of proving that it was inaccurate in this case.

Conclusion

The amount disallowed for each claim in the audit sample is set forth in the exhibits attached to the final audit report. All 18 disallowances remaining at issue, in the total amount of \$433.06, are affirmed herein. A restitution claim in that amount is authorized under 18 NYCRR 518.1 and 518.3.

The OMIG's restitution claim based upon its extrapolation of the audit sample findings to the "universe" of claims in the audit period, however, will not be affirmed. The right to present expert testimony and evidence to challenge an extrapolation is specifically granted to providers under DSS regulations. The court of appeals has pointedly endorsed the importance of this right. Mercy Hospital, *supra*. The OMIG has nevertheless refused to disclose details of the procedure by which it selected the allegedly random sample in this case. Without access to those details, the Appellant's right to "challenge the accuracy of the estimate by attacking the reliability of the methods or standards employed" is meaningless. Consequently, the OMIG's determination to extrapolate the findings in the sample to the "universe" of claims is reversed.

The Appellant's demand in its brief (pages 60-63) for an award of attorneys' fees is not justified by the facts or the law and it is denied.

DECISION: The OMIG's determination to recover Medicaid Program overpayments is affirmed. The overpayment is in the total amount of \$433.06.

The OMIG's determination to extrapolate the overpayment in the audit sample to the "universe" of claims in the audit period is reversed.

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

DATED: Rochester, New York
July 7, 2010

_____/s/_____
John Harris Terepka
Bureau of Adjudication