

**STATE OF NEW YORK
DEPARTMENT OF HEALTH**

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In the Matter of the Appeal of :
:
SPRINGVILLE PHARMACY INFUSION :
:
Medicaid ID #02395206 :
:
for a hearing pursuant to Part 519 of Title 18 of the :
Official Compilation of Codes, Rules and Regulations :
of the State of New York (“NYCRR”) to review a :
determination to recover Medicaid overpayments. :
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Decision After Hearing

Audit #15-4649

Before: Dawn MacKillop-Soller
Administrative Law Judge

Held At: NYS Department of Health
150 Broadway
Suite 510
Menands, New York 12204

Date of Hearing: September 8, 2016
Record closed: December 12, 2016

Parties: NYS Office of the Medicaid Inspector General
800 North Pearl Street
Albany, New York 12204
By: Thomas Coles, Senior Attorney
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Springville Pharmacy Infusion
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JURISDICTION

The New York State Office of the Medicaid Inspector General (“OMIG”), an independent office within the Department of Health (“Department”), has the authority to pursue civil and administrative enforcement actions against entities or individuals engaged in fraud, abuse, or unacceptable practices and to recover improperly paid funds pursuant to New York’s Medicaid Program. Public Health Law (“PHL”) §§ 30, 31, 32, 201(1)(v), Social Services Law (“SSL”) § 363-a. The OMIG determined to recover Medicaid Program overpayments made to Springville Pharmacy Infusion (“Appellant”). The Appellant requested a hearing pursuant to SSL 22 and Department of Social Services regulations at 18 NYCRR 519.4 to review the overpayment determination. (Exhibit 7.)

At the hearing, the OMIG submitted documents (Exhibits 1-8) and presented Sharon Conway, OMIG pharmacy supervisor (Transcript, p. 16), as a witness. The Appellant submitted documents (Exhibits A-C) and produced as a witness [REDACTED], Springville Pharmacy Infusion general manager and pharmacist. (Transcript, p. 61.) A transcript of the hearing was made. (Transcript, p. 1-111.) Each side submitted a post-hearing brief and the Appellant provided a reply brief. The Appellant has the burden of proving that the OMIG’s determination was incorrect and that all claims submitted and denied were due and payable under the program. 18 NYCRR 519.18(d)(1).

FINDINGS OF FACT

1. The Appellant, Springville Pharmacy Infusion, located in Orchard Park, New York, is a home infusion pharmacy enrolled as a provider in the New York State Medicaid Program that fills specialized products and therapies for patients with bleeding disorders. [REDACTED] is a [REDACTED] [REDACTED] product prescribed for [REDACTED]. (Transcript, p. 58, 62-63.)

2. The Office of the State Comptroller (O.S.C) conducted an audit of the Medicaid pharmacy claims paid to the Appellant for the period April 1, 2013 through September 30, 2013. The purpose of the audit was to confirm whether the Appellant's pharmacy claims were in compliance with Medicaid Program requirements for payment. (Exhibit 4; Transcript, p. 19.)

3. Among the claims reviewed was a refill dispensed on [REDACTED] 2013 for [REDACTED] doses of [REDACTED] under Rx numbers [REDACTED] and [REDACTED]. The Medicaid Program paid the Appellant \$113,268.40 on the refill. (Exhibit 4.)

4. In support of its claims, the Appellant submitted to the O.S.C. a copy of a telephone prescription order for [REDACTED] doses of [REDACTED] dispensed on [REDACTED] 2013 under Rx numbers [REDACTED] and [REDACTED]. The telephone order did not specify a refill. (Exhibit 1.)

5. After a review of the O.S.C.'s audit findings and documentation, the OMIG identified violations of Medicaid Program requirements as stated in the regulations, laws and guidelines in the submission of the [REDACTED], 2013 claims. In both instances, the Department determined that the claims "exceeded the authorized and/or allowed number of refills." (Exhibit 4.)

6. By draft audit report dated January 15, 2016, in which the audit findings were detailed, the OMIG advised the Appellant that it had determined to seek restitution of Medicaid overpayments in the amount of \$113,268.40. The draft audit report afforded the Appellant an opportunity to respond to the OMIG's findings and to submit further documents to demonstrate entitlement to the payments it received within 30 days. (Exhibit 2.)

7. In a February 5, 2016 response to the draft audit report, the Appellant objected to the OMIG's proposed findings set forth in the draft audit report and submitted a printout from pharmacy computer records confirming that on [REDACTED] 2013, the Appellant dispensed a [REDACTED] refill under Rx numbers [REDACTED] and [REDACTED]. This computer record indicates that the refill was

from an order originally entered on [REDACTED], 2013. (Exhibit 3, 5D.)

8. On [REDACTED] 2016, the Appellant submitted a telephone prescription order that appeared to authorize the refill at issue. The Appellant also submitted pharmacy computer records to show a record of the [REDACTED] dispensed on [REDACTED] 2013. (Exhibit 5c, 6, 6a and 6c.)

9. By final audit report dated April 13, 2016, the OMIG reaffirmed the draft audit findings disallowing the claims for the refill dispensed on [REDACTED] 2013 and reaffirmed the overpayment determination. (Exhibit 4.)

10. On June 3, 2016, the Appellant requested an administrative hearing to contest the OMIG's final determination. (Exhibit 7.)

APPLICABLE LAW

1. The Department is permitted to require repayment of an overpayment when it has determined that a claim has been submitted that "should not have been made." 18 NYCRR 518.1(b).

2. Providers are subject to audit by the department and are required "to reimburse the department for overpayments discovered by audits in accordance with Parts 516 and 517." 18 NYCRR 504.8(1).

3. An overpayment subject to recovery by the Department includes "any amount not authorized to be paid under the medical assistance 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).

4. Under 18 NYCRR 504.3, a Medicaid provider's record keeping obligations under the Medicaid Program include:

- a. [to] prepare and to maintain contemporaneous records demonstrating its right to receive payment under the medical

assistance program and to keep for a period of six years from the date the care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider and to furnish such records and information, upon request, to the...New York State Department of Health.

[¶] . . . [¶]

- h. that the information provided in relation to any claim for payment shall be true, accurate and complete; and
- i. to comply with the rules, regulations and official directives of the department.

5. Fee-for-service providers “must prepare and maintain contemporaneous records demonstrating their right to receive payment under the medical assistance program.” 18 NYCRR 517.3(b)(1). Pursuant to 18 NYCRR 517.3(b)(2), “information for claims for payment...must be furnished, upon request, to the department.”

6. The procedural steps applicable to the issuance of a draft audit report are stated in 18 NYCRR 517.5 to include the following:

- (a) If, after affording the provider the opportunity for a closing conference upon completion of an on-site field audit and after consideration of any additional documentation and information presented in connection therewith...the department believes that overpayments have been made to the provider, a draft audit report may be issued identifying the items which are being disallowed and advising the provider of the basis for the proposed action and the legal authority therefor. When feasible, the draft report will also specify the amount of the overpayment.
- (b) The draft audit report...must afford the provider the opportunity to object to the proposed action within 30 days of receipt of the notice, must advise the provider that failure to object within the time provided may result in the adoption of the proposed action as the final agency action and must advise the provider that, pursuant to section 519.18 of this Title, the issues to be addressed at an administrative hearing will be limited to those matters contained in any objection to the proposed action.

(c) The report must be mailed to the provider's designated payment address or correspondence address or last known address and must be accompanied by a document identifying the person to whom objections to the report should be mailed. The provider's objections to the draft audit report must be mailed by the provider to that person within 30 days of receipt of the report which will be presumed in the absence of evidence to the contrary to be five days after the date on the draft report. Any objections must include a statement detailing the specific items of the draft report to which the provider objects and provide any additional material or documentation which the provider wishes to be considered in support of the objections.

7. In preparation for the issuance of a final audit report, the department must “consider the objections, any supporting documents and materials submitted therewith, the draft audit report, and any additional material which may become available.” 18 NYCRR 517.6(a).

8. The parties are limited at the hearing to “issues and documentation... directly relating to the final determination. An appellant may not...raise any new matter not considered by the department upon submission of objections to a draft audit or notice of proposed agency action.” 18 NYCRR 519.18(a).

9. Telephone orders for prescription drugs are permitted. Education Law 6810(4) and 18 NYCRR 505.3(b)(4).

10. Pursuant to Education Law 6810, the following requirements apply to telephone prescription orders:

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription.

[¶] . . . [¶]

4. (a) An oral authorization for the refill of a prescription, other than a prescription for a controlled substance, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist

receiving such oral authorization for the refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of the practitioner authorizing the refill of the prescription. An oral prescription or an oral authorization for the refill of a prescription for the drug, other than a controlled substance, may be communicated by an employee of the prescribing practitioner; provided, however, the pharmacist shall:

(i) contemporaneously reduce such prescription to writing;

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made available for inspection and copying by a representative of the department.

11. A Medicaid provider's documentation responsibilities for telephone prescription orders include the pharmacist recording the following:

(T)he time of the call and the initials of the person taking the call and the dispenser, prior to dispensing the drug...(and) label the drug as he/she would a written prescription, and make a good faith effort to verify the practitioner's identity, and validity of the prescription if the practitioner is unknown to the pharmacist. 18 NYCRR 505.3(b)(5).

12. The New York State Medicaid Program issues Provider Manuals that include Medicaid billing policies, guidelines, procedures and instructions. The Department also issues Medicaid Updates with additional policies, rules and guidelines. (See, www.eMedNY.org; Exhibit 4.) Under the Medicaid Program Prescription Manual ("MPPM") guideline, "(a) prescription or fiscal order may not be refilled unless the prescriber has indicated on the prescription or fiscal order the number of refills." Version 2006-1, Section I, p.5; See also, Medicaid Update, November, 2015, Version 2015-1, Section I, p. 7; www.eMedNY.org.

ISSUE

Has the Appellant established that the OMIG's determination to recover overpayments in the amount of \$113,268.40 was not correct?

ANALYSIS AND CONCLUSIONS

Audit findings

The OMIG charges that for date of service [REDACTED] 2013, the amounts disallowed are \$91,206.50 and \$22,061.90 for prescription numbers [REDACTED] and [REDACTED] respectively, for a total amount of \$113,268.40. The charge on which the two claims were disallowed are contained in one category in the final audit report: Prescription/Fiscal Order Refilled in Excess of Prescriber's Authorization and/or Refilled in Violation of Medical Regulations. (Exhibit 4.) This case involves a determination of whether the Appellant maintained and produced contemporaneous documentation of a telephone prescription order for the [REDACTED] refill it dispensed on [REDACTED], 2013, from the original order it created on [REDACTED] 2013.

Documentation provided during the on-site audit.

The parties do not dispute, and this case does not involve, whether the patient received the medicine that the practitioner intended him to have. The issue here is whether under the Medicaid Program and Department of Education regulations, the refill prescription is supported by a contemporaneous written order authorized by a practitioner. The Appellant claims that it had a "valid prescription/physician order with the requisite number of refills at the time the drug product [REDACTED] was dispensed." (Appellant's brief, p. 3; Transcript, p. 15.) The evidence failed to establish this. The only documentation that the Appellant submitted to the O.S.C. in support of its [REDACTED] 2013 claims was an original telephone prescription order dated [REDACTED], 2013 that did not specify that a refill was ordered. (Exhibit 1.)

The Medicaid Program permits telephone prescription orders made pursuant to the authorization requirements under Education Law 6810. 18 NYCRR 505.3(b). The Medicaid Program relies on pharmacy providers to make the effort to document refills directly on

prescription orders. Education Law 6810(2) and 505.3(d)(1). This reliance is based on the MPPM guidelines that specifically compel documentation of the “number of refills” on the face of the prescription order. Version 2006-1, Section I, p.5; *See also*, Medicaid Update, November, 2015, Version 2015-1, Section I, p. 7; www.eMedNY.org. The Appellant’s participation in the Medicaid Program created a contractual obligation to abide by these rules, which are the “official directives of the department.” Lock v. NYS Dept. of Social Services, 220 AD2d 825, 827 (3rd Dept. 1995); 18 NYCRR 504.3(i).

██████████, the Appellant’s general manager and pharmacist, admitted that at the time she recorded the original telephone prescription (Exhibit 1), it did not authorize a refill. The Appellant argues that ██████████ “had forgotten” to note the refill, but a pharmacist “corrected the missing refill information prior to dispensing the drug product” to the patient. (Appellant’s brief, p. 6; Transcript, p. 69.) While this explanation may seem to make sense, it is not documented. In particular, it fails to establish that a refill was documented on the prescription itself when the order was made, as required under 18 NYCRR 504.3 and 517.3(b). This prescription does nothing more than confirm that the order made on ██████████ 2013 failed to authorize the refill that was dispensed on ██████████ 2013. It also underscores the importance in these documentation requirements, which the Appellant acknowledges, to avoid harm to patients caused by medications that are not received “when...needed” or conversely, medications that are taken that were never ordered. (Transcript, p. 63, 101.)

Documentation submitted in response to the draft audit report.

At the conclusion of the on-site audit and closing conference and following the issuance of the OMIG’s draft audit report, the Appellant submitted its response to the draft audit report and attached a copy of a “verbal order” that showed ██████ doses of ██████ on ██████ 2013 “with one

additional refill.” ██████ testified that this document “is not the prescription” and it was “created when (she) found out about the audit.” (Transcript, p. 75.) Despite this, the OMIG incorrectly refers to this document in its brief as a “physician order.” (Department’s brief, p. 5, 7, 8.) This document represents a computer printout to show the medicine maintained and dispensed to the patient. (Exhibit 5D.) Like the other evidence produced in this case, it fails to contain complete and accurate information recorded at the time of the medical services to show that the refill was ordered. 18 NYCRR 504.3, 517.3(b).

Documentation submitted in March 2016.

On March 15, 2016, a month after the deadline for submission of documents, the Appellant submitted to the OMIG a telephone prescription order that appeared to be a copy of the first order submitted, with the addition of a “1” in the refill section. (Exhibit 5c, 6a.) The Appellant had the burden of showing that on ██████, 2013, the “1” refill on this physician order was recorded at the same time as, or contemporaneous to, the telephone prescription order made on ██████ 2013, which it failed to do. 18 NYCRR 504.3, 517.3(b); Education Law 6810(4).

The timing of this order’s submission to the OMIG raises questions of its authenticity. This order seemed to be a copy of the first order produced, with the refill authorization added later, and the Appellant failed to show otherwise. ██████ never referenced this order in a February 27, 2015 email correspondence to an O.S.C. staff member confirming that she had provided “all necessary information on this claim.” (Exhibit C.) The evidence showed that ██████ was unfamiliar with this order – the only telephone prescription order that substantiated the refill – until after she learned about the audit, which suggests that the authorization for the refill may have been entered “after-the-fact” on this copy of the telephone prescription for purposes of bolstering the Appellant’s defense that it had a valid prescription order all along. (Transcript, p. 100, 102.)

Even Ms. Conway characterized this order as an “exact duplicate...except for the refills.” (Transcript, p. 29.) Regardless, this prescription order constitutes “new” material under 18 NYCRR 519.18(a), which the Appellant is prohibited from raising because it was not included as part of its February 5, 2016 objections in its response to the draft audit report. (Exhibit 3.)

This version of the telephone order was not submitted to the OMIG until March 15, 2016, which was 60 days after the issuance of the draft audit report, making it untimely under 18 NYCRR 517.5(b). Sharon Conway, OMIG registered pharmacist, credibly testified that this order was received for the first time “in the March response.” (Transcript, p. 50.) Even after the Department’s multiple requests to submit documentation to establish an authorized refill order, the Appellant failed to produce this prescription until three years after the refills were dispensed. Under 18 NYCRR 504.3(a), 517.3(b) and Education Law 6810(5), this order should have been furnished to the Department, upon request, as part of its records that were made at the time of the pharmacy order that are complete and accurate and that fully disclose the nature and extent of the services provided. At the very latest, it was required to be produced with the February 5, 2016 response to the draft audit report. 18 NYCRR 517.3(f) and 517.5(b); *See also* Community Related Services, Inc. v. NYS Dept. of Health, 2010 N.Y. Misc. LEXIS 5057, 2010 NY Slip Op 32926(U) (Sup. Ct., N.Y. Co. 2010.)

Under 18 NYCRR 517.3(b), once notified of the OMIG’s intent to audit, the Appellant, as a fee-for-service provider, had an unequivocal obligation to safeguard its records. The purpose in this requirement is for the Appellant to turn over all prescription records to the OMIG in a timely fashion to justify its receipt of payments. 18 NYCRR 517.5(b) and Education Law 6810(5). Although 18 NYCRR 516.6(a) contemplates a window of opportunity after the response to the draft audit report for the submission of “any additional material which may become available,”

this provision speaks specifically to items not otherwise accessible during the audit period, which would not include this prescription order. If this order was created on the same date that the medication was dispensed, as the Appellant claims it was, it should have been available. (Transcript, p. 70, 91, 102; Appellant’s brief, p. 2-3, 6.)

Other issues

In addition to the prescription order submitted on March 15, 2016, the Appellant provided the OMIG with a [REDACTED] prescription dated [REDACTED] 2013 and a computer screen shot. While these materials show a record of the [REDACTED] dispensed to the patient, they fail to document that a refill was authorized on [REDACTED], 2013. (Exhibit 6b, 6c.) Moreover, the [REDACTED] 2013 prescription is not relevant to the claims at issue in this case. The parties do not dispute that a new prescription for [REDACTED] was required on [REDACTED] 2013 due to a change in units, which routinely vary “plus or minus ten percent.” (Transcript, p. 57, 67-68.) The OMIG incorrectly argues that the [REDACTED] 2013 is the “original prescription order” and that the [REDACTED] 2013 prescription order (Exhibit 1) required the same prescription numbers for billing purposes under 18 NYCRR 505.3(d)(3). (Department’s brief, p. 6-7.) The evidence showed the opposite to be true: The new prescription on [REDACTED] 2013 became the “original prescription order,” triggering new prescription and billing numbers, which is exactly how these claims were billed. (Exhibit 8.)

Conclusion

The Appellant argues that based on the evidence, “it should be enough for a reasonable mind to conclude or accept as ultimate fact that Appellant had a valid prescription/physician order with the requisite number of refills at the time the drug product [REDACTED] was dispensed.” (Appellant’s brief, p. 7.) In order to defend the payments it received, the Appellant was obligated under 18 NYCRR 504.3(a) and 517.3(b)(1) and (2) to maintain and produce, upon request, all

fundamental records made contemporaneous with the services provided, which it failed to do. *See also* Education Law 6810(5). The belated evidence offered by the Appellant after the fact or post-draft audit response fails to satisfy the Medicaid Program documentation requirements. If the Appellant's argument were accepted "as ultimate fact," the Legislature's intent in 2006 to amend the PHL for the purpose of empowering the OMIG to enforce, among other things, "expenditure accountability," would have no merit. (Mem of Assembly Rules Comm, Bill Jacket, L 2006, ch 442.) Medicaid providers are required by contract to render "high quality medical care" and ensure that "public funds will be properly utilized" while adhering to Medicaid's rules, regulations and requirements. 18 NYCRR 504.1(a), 504.3(i).

The Appellant failed to meet its burden of proving entitlement to payment for the claims disallowed by the OMIG. 18 NYCRR 519.18(d)(1). The disallowances are affirmed.

DECISION:

The OMIG's determination to recover Medicaid Program overpayments from Springville Pharmacy Infusion is affirmed. The overpayment is in the total amount of \$113,268.40.

This decision is made by Dawn MacKillop-Soller, who has been designated by the Commissioner of the New York State Department of Health to make such decisions.

Dated: _____, 2017
Albany, New York

Dawn MacKillop-Soller
Administrative Law Judge