STATE OF NEW YORK DEPARTMENT OF HEALTH

In the Matter of the Appeal of

BETH ISRAEL MEDICAL CENTER

Medicaid ID: 02994489

from a determination by the NYS Office of the Medicaid Inspector General to recover Medicaid Program

overpayments

Audit Number: 17-8064

Decision After

Hearing

Before: Natalie J. Bordeaux

Administrative Law Judge

Held at: New York State Department of Health

90 Church Street

New York, New York 10007

Hearing Dates: April 8 and 29, June 3, and September 23, 2019

The record closed March 16, 2020

Parties: New York State Office of the Medicaid Inspector General

800 North Pearl Street Albany, New York 12204

By: Kathleen Dix, Esq., Senior Attorney

Mount Sinai Health System for Beth Israel Medical Center Sally Strauss, Esq., Senior Associate General Counsel

Office of the General Counsel One Gustave L. Levy Place

Box 1099

New York, New York 10029-6574 By: Daniel J. Hurteau, Esq.

Nixon Peabody, LLP

677 Broadway 10th Floor

Albany, New York 12207

JURISDICTION

The New York State Office of the Medicaid Inspector General (OMIG) determined to seek restitution of payments made under the Medicaid Program to Beth Israel Medical Center (Appellant). The Appellant requested a hearing pursuant to Social Services Law § 22 and Department of Social Services (DSS) regulations at 18 NYCRR § 519.4 to review the OMIG's determination.

FINDINGS OF FACT

- 1. At all times relevant hereto, the Appellant was a hospital and health care center that operated an opioid treatment program (OTP) and was enrolled as a provider in the New York State Medicaid Program.
- 2. By letter dated December 20, 2017, the OMIG advised the Appellant that an audit would be conducted to review the Appellant's medical and fiscal records supporting its billings to the New York State Medical Assistance (Medicaid) Program for OTP services paid during the period January 1, 2014 through December 31, 2016. (Exhibit 1.)
- 3. During the period January 1, 2014 through December 31, 2016, the Appellant was paid \$82,093,297.20 by the Medicaid Program for 1,898,937 claims submitted for OTP services. The audit consisted of a review of a random sample of 100 of the 1,898,937 claims. (Exhibits 2, 3, 5 and 7.)
- 4. On January 31, 2018, an entrance conference was held with OMIG auditors and several senior members of the Appellant's staff. The auditors explained the audit process and outlined the audit scope. The Appellant was also given a description of the statistical sampling methodology used by the OMIG to select the random sample for the audit. (Exhibit 2.)

5. On May 17, 2018, an exit, or closing, conference was held, during which the auditors informed the Appellant that 31 claims in the audit sample were found to contain at least one error for a total sample overpayment of \$1,199.21. The Appellant was given a summary of those findings and provided additional information to the auditors. (Exhibits 3 and 3b.)

- 6. On June 15, 2018, the Appellant sent the auditors additional documentation regarding errors identified at the exit conference. (Exhibit 4.)
- 7. On August 7, 2018, the OMIG issued a draft audit report to the Appellant. After reviewing additional information supplied by the Appellant during and after the exit conference, the OMIG determined that the audited samples contained 12 violations of Medicaid Program requirements in 11 of the submitted claims and disallowed a total of \$407.90 in payments. The OMIG also advised the Appellant that the audit employed a statistical sampling methodology allowing for extrapolation of the sample findings to the universe of claims. By using the extrapolation, the OMIG determined preliminarily that the point estimate of the Medicaid overpayment received by the Appellant is \$7,745,764. (Exhibit 5.)
- 8. On September 28, 2018, the Appellant submitted its response to the OMIG's draft audit report, contesting the disallowances and the extrapolation methodology employed by the OMIG in its determination to recover \$7,745,764. (Exhibit 6.)
- 9. On November 7, 2018, the OMIG issued a final audit report which upheld the findings set forth in the draft audit report and advised the Appellant that the OMIG determined to seek restitution of Medicaid Program overpayments totaling \$7,745,764, derived by projecting the value of the 11 disallowed claims in the audit sample to the total 1,898,937 claims paid by the Medicaid Program during the audit period. (Exhibit 7.)
 - 10. The OMIG organized the 11 disallowed claims into the following categories:

1. Missing/Late Individual Treatment/Recovery Plan Review (Samples 16, 47, 48, 77, 87, 88, 92, and 100.)

- 2. Failure to Meet Brief Individual Counseling Requirements (Sample 49.)
- 3. Missing/Late Signature on Individual Treatment/Recovery Plan Review (Sample 80.)
- 4. Missing Signed Written Consent Form (Sample 87.)
- 5. Physician Examination not Updated Annually (Sample 99.) (Exhibit 7.)

ISSUES

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

APPLICABLE LAW

The Department of Health (Department) is the single state agency for the administration of the Medicaid Program in New York State. PHL § 201.1(v); SSL § 363-a. The OMIG is an independent office within the Department with the authority to pursue civil and administrative enforcement actions against any individual or entity that engages in fraud, abuse, or illegal or improper acts or unacceptable practices perpetrated within the Medicaid Program. Such actions may include the recovery of improperly expended Medicaid funds. PHL §§ 30-32.

By enrolling in the Medicaid Program, Medicaid providers agree to prepare and to maintain contemporaneous records demonstrating the right to receive payment under the Medicaid Program and to furnish such records and information, upon request, to the Department. Such records must be maintained for at least six years from the date of service. 18 NYCRR § 504.3(a). Medicaid providers agree to permit audits by the Department of all books and records or, in the Department's discretion, a sample thereof, relating to services furnished and payments received under the Medicaid Program, including patient histories, case files and patient-specific data. 18 NYCRR § 504.3(g), § 517.3(b), § 540.7(a)(8). In addition, Medicaid providers must

comply with the rules, regulations, and official directives of the Department. 18 NYCRR § 504.3(i).

When it is determined that a provider has submitted or caused to be submitted claims for medical care, services or supplies for which payment should not have been made, the Department may require repayment of the amount determined to have been overpaid. 18 NYCRR § 504.8(a)(1) and § 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 Medicaid provider is entitled to a hearing to review the OMIG's final determination to require repayment of any overpayment or restitution. 18 NYCRR § 519.4. The Appellant has the burden of showing by substantial evidence that the OMIG's determination was incorrect and that all claims submitted and denied were due and payable under the Medicaid Program. 18 NYCRR § 519.18(d)(1); SAPA § 306(1).

An OTP means one or more sites certified by the Office of Alcoholism and Substance Abuse Services (OASAS) where methadone or other approved medications are administered to treat opioid dependency, following one or more medical treatment protocols as defined in 14 NYCRR Part 822. It encompasses medical and comprehensive support services including counseling, educational and vocational rehabilitation. 14 NYCRR § 822-2.1(u)¹ and § 822.5(j)². OTPs are required to maintain a case record (either electronic or paper) for each patient who receives services. The case record must demonstrate a chronological pattern of delivered medical and treatment services consistent with the patient's prior treatment history, if any, and

¹ This provision expired on December 9, 2015.

² Effective December 9, 2015.

the patient's individual treatment/recovery plan and all reviews and updates. 14 NYCRR § 822-2.2(a)&(b)(4)³, § 822.10(a)&(b)(4)⁴.

OTPs that bill the Medicaid Program are subject to the additional requirements set forth in 14 NYCRR Part 841 and all applicable Medicaid requirements set forth by the Department.

14 NYCRR § 841.9.5

DISCUSSION

At the hearing, the OMIG presented the audit file and summarized the case, as required by 18 NYCRR § 519.17. The OMIG presented documents (Exhibits 1 - 15) and one witness, Charles Falkner, Principal Medical Facilities Auditor, who served as the Audit Supervisor of a three-person team that conducted this audit. (T 27-154.)

The Appellant presented seven exhibits (Exhibits A-G), and the following Mount Sinai Health System⁶ employees as witnesses: (1) , MD, MPH, Vice President of Behavioral Health (T 167-425, 432-35); (2) , Administrator of the OTP (T 435-506); (3) , Credentialed Alcoholism and Substance Abuse Counselor (CASAC)⁷ (T 517-37); (4) , CASAC (T 538-58); (5) , CASAC (T 558-72); (6) , CASAC (T 587-607); (7) , CASAC (T 607-27); and (8) , CASAC (T 628-53). Each party submitted two post-hearing briefs.

The Audit Findings

The purpose of this audit was to determine whether the Appellant prepared and maintained documentation to establish that OTP services for which it submitted claims to the

³ This provision expired on December 9, 2015.

⁴ Effective December 9, 2015.

⁵ This provision was in effect throughout the audited period and remains in effect to date.

⁶ Mount Sinai Health System was formed in September 2013 after the merger of Mount Sinai Medical Center and Continuum Health Partners, the then-current owner of Beth Israel Medical Center. (T 171-73.)

⁷ CASACs are also referred to as counselors in this decision.

Medicaid Program were rendered to patients in accordance with regulatory requirements. The OMIG organized the disallowed claims into five categories, which were explained in the audit report. Despite the categorical distinctions, ten of the eleven samples at issue were essentially disallowed for the same reason, i.e. inadequate documentation to support the claim.

Disallowance Category 1: Missing/Late Individual Treatment/Recovery Plan Review.

Within 30 days of admission to an OTP, a written comprehensive individualized patient-centered treatment/recovery plan for each patient based on the comprehensive evaluation must be developed by the responsible clinical staff and reviewed and approved by the multi-disciplinary team, as documented by their dated signatures. Each treatment/recovery plan must include a description of the type and frequency of counseling needed for implementation, including individual, group and family counseling in accordance with patient needs. 14 NYCRR § 822-5.5(d). Treatment/recovery plans are developed to "support the achievement and maintenance of recovery from chemical dependence and abuse, the attainment of economic self-sufficiency (including, where appropriate, the ability to sustain long-term productive employment), and improvement of the patient's quality of life." 14 NYCRR § 822-4.2(b)(3).9

The entire treatment/recovery plan, once established, must be thoroughly reviewed and revised at least every 90 calendar days for the first year and at least every 180 calendar days thereafter. Treatment/recovery plan reviews must be prepared by the responsible clinical staff member in consultation with the patient, and reviewed, signed and dated by at least three members of the multi-disciplinary team. The names of all reviewing individuals must be recorded in the treatment/recovery plan. A summary of the patient's progress in each of the

⁸ Although 14 NYCRR § 822-5.5 expired on December 9, 2015, it was in effect on all dates of service in claims disallowed in Categories 1 and 3.

⁹ 14 NYCRR § 822-4.2 expired on December 9, 2015. However, it was in effect for all dates of service in claims disallowed in Categories 1 and 3.

specified treatment/recovery plan goals must be prepared and documented in the patient's record as part of the treatment/recovery plan review. 14 NYCRR § 822-5.5(f).¹⁰ To obtain Medicaid reimbursement, OTPs must fully document the content and/or outcome of all services rendered, and those services must meet the standards established in Part 822 of Title 14, provisions which include the requirements for treatment/recovery plans and reviews. 14 NYCRR §§ 822-3.1(c) and (f).¹¹

All disallowed samples in this category involved claims paid for administration of maintenance medication to treat drug addiction. The OMIG audit team identified 8 instances pertaining to 8 patients (Sample #s 16, 47, 48, 77, 87, 88, 92, and 100) in which the required treatment/recovery plan review was not in place on the date of service for which the Appellant submitted its claim. (Exhibits 3, 5 and 7.) The auditors did not limit their review to documents that were formally identified as treatment/recovery plans and reviews. They were willing to accept other documents that contained the information required of a treatment/recovery plan review, e.g., treatment goals, incorporation of treatment goals in the treatment/recovery plan, patient medications, patient counseling schedules, and patient progress in other aspects of their lives. (T 127.) The auditors determined that supporting documentation for the disallowed claims did not reflect the involvement of at least three members of a multi-disciplinary team in timely treatment/recovery plan reviews. For reasons described below, the disallowances in this category are upheld.

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¹⁰ Although 14 NYCRR § 822-5.5 expired on December 9, 2015, it was in effect on all dates of service for claims disallowed in Categories 1 and 3.

¹¹ 14 NYCRR § 822-3.1 included the requirements described above (as cited in this decision) and expired on December 9, 2015. However, this provision was in effect for all dates of service pertaining to claims disallowed in disallowance categories 1 and 3. The same requirements are included in 14 NYCRR § 822.6, a provision that has been in effect since December 9, 2015.

The Appellant's Broad Challenges to Disallowances in this Category

The Appellant contended that treatment/recovery plans and reviews are not a requirement for payment from the Medicaid Program, but are instead a "programmatic requirement" of an OTP. (Appellant's 1/27/20 Brief, p. 11.) It is the Appellant's position that a deficiency or failure of a programmatic requirement may be adequately addressed by OASAS taking action against an OTP's license, but is not an appropriate basis for disallowing a claim for a specific service that was rendered. (Exhibit 6, pp. 73-74.)

In support of this position, the Appellant cited 14 NYCRR § 822.6 ("Standards pertaining to Medicaid reimbursement"), subsection (c), which provides that "[t]he content and/or outcome of all services must be fully documented in the patient's case record consistent with section 822.11 of this Part." The Appellant contrasted this regulatory requirement with regulations pertaining to continuing day treatment programs which are overseen by the New York State Office of Mental Health¹², in which documentation of a treatment/recovery plan is a specific requirement for reimbursement. (Exhibit 6, pp. 73-74.) Thus, the Appellant argued that the silence of applicable regulations as to the import of treatment/recovery plans and reviews for purposes of Medicaid reimbursement signifies that reimbursement was not contingent upon the presence of these documents.

The Appellant's suggestion that all it was required to do was perform the billed service overlooks subsection (d) of 14 NYCRR § 822.6:

- (d) In order to qualify for reimbursement, each service must be documented as a covered Medicaid service in accordance with the following:
 - (1) the service must meet the standards established in this Part;

¹² As the Appellant suggested, those regulations, found in 14 NYCRR Part 587, are inapplicable to the Appellant's OTP. 14 NYCRR § 587.3.

(2) the service must meet the standards established in Part 841 of this Title;

(3) the service must be provided by appropriate staff as required in this Part.

As stated in subsection (d), in order to qualify for reimbursement for these services, the Appellant was required to document compliance with the requirements set forth in Parts 822 and 841. It is not entitled to payment on claims for which it failed to document that compliance.

The provision in effect for all dates of service in the disallowed claims in this category, 14 NYCRR § 822-5.5(f), required OTPs to conduct treatment/recovery plan reviews for patients at least every 90 calendar days for the first year of treatment and at least every 180 calendar days thereafter, prepared in consultation with the patient, and reviewed, signed and dated by at least three members of the multi-disciplinary team, with the names of all reviewing individuals recorded therein, and including a summary of the patient's progress in each of the specified treatment/recovery plan goals. Although treatment/recovery plans and reviews are not directly and individually reimbursable by the Medicaid Program, documented compliance with the requirement that such plans and reviews are in place when services are rendered is clearly a condition of payment by Medicaid for those services.

The Appellant also incorrectly asserted that it was only required to maintain documentation regarding medication administration, because the disallowances in this category all involved claims for this service and nothing more. As support for this contention, the Appellant cited 18 NYCRR § 504.3(a). (Appellant's 1/27/20 Brief, pp. 12-13.) The cited provision does not support the Appellant's position. The regulation requires a Medicaid provider to prepare and maintain contemporaneous records demonstrating its right to receive payment from the Medicaid Program, and specifically states that those records must include all information regarding claims for payment, for at least six years from the date of service. The

medical necessity of an OTP service such as medication administration cannot be established, and is not documented, without an appropriate treatment/recovery plan and treatment/recovery plan reviews.

Review of Disallowed Samples in this Category

These claims were disallowed because the Appellant failed to document a timely and properly conducted treatment/recovery plan review for each patient. The Appellant contended that "the existing documentation in the medical record taken together contain all the necessary elements of a treatment/recovery plan and, therefore, constitute an acceptable plan for purposes of payment and audit review." Yet, the Appellant also confirmed that its own internal policies require clinicians to complete treatment/recovery plans and reviews using a template. (Exhibit 6, pp. 72, 81-91; T 287-89.)

Although the Appellant's computer system allowed multiple signatures on electronic records, including progress notes (*see*, *e.g.*, Exhibit 6, p. 99), none of the documents submitted in lieu of timely, formal treatment/recovery plan reviews contained both the information necessary to constitute a treatment/recovery plan review and evidence that at least three members of the patients' multi-disciplinary team reviewed the patients' treatment goals and progress toward those goals. Rather, documentation prepared by individual staff members often showed no relationship to notes made by other clinicians.

Sample # 16:

This claim was submitted for a February 21, 2014 date of service, which fell within the patient's first year of treatment. The Appellant was therefore required to conduct a treatment/recovery plan review every 90 days. The Appellant failed to document a treatment/recovery plan review, signed by three members of the multi-disciplinary care team,

2013 for an date of service, CASAC reported working with the patient on the quarterly treatment/recovery plan review. (Exhibit 12, p. 221.) However, no such treatment/recovery plan review was provided to the OMIG audit team. The note for the date of service was not signed by at least three members of the patient's multi-disciplinary team. (T 68-70.)

Despite the Appellant's inability to locate the treatment/recovery plan review, Mr. testified that a timely treatment/recovery plan review was conducted. (T 612, 617.) The Appellant emphasized two progress notes that Mr. entered on and 2014. These notes were written over two months after the claimed service was provided. The entry does not document a treatment/recovery plan review. To the contrary, it explicitly documents that (because the patient failed to meet with him) a treatment/recovery plan review was not conducted, nor was the note signed by at least three members of the patient's multidisciplinary team. The entry reported a meeting with the patient on the patient's lack of progress in treatment, and identified abstinence as the patient's treatment goal. Although this entry also advised that a treatment/recovery plan review may be found in the patient's chart, no such document was provided to the auditors. The Appellant's argument that its documentation shows physician and nurse involvement in the patient's care does not address the reason for the disallowance. None of this documentation of ongoing patient care constitutes a treatment/recovery plan review. (Exhibit 12, pp. 221-23, 29.)

The Appellant also pointed to the patient's initial treatment/recovery plan dated 2013, which was created more than seven months before the date of service at issue in the audit. (Exhibit 12, pp. 230-38; T 284-87.) Evidence that a treatment/recovery plan was completed for

another quarter only establishes the Appellant's compliance with regulatory requirements for that period. It does not show the Appellant's continued adherence to those requirements for the date of service in this sample.

The Appellant did not prove that at least three members of the patient's multi-disciplinary team reviewed and signed off on the patient's treatment goals and progress towards those goals in the relevant 90-day period. This sample was properly disallowed.

<u>Sample # 47</u>:

Since this claim was for a ______, 2014 date of service (past the first year of the patient's admission), the auditors reviewed the patient's record to verify whether the Appellant conducted a treatment/recovery plan review at least every 180 days. While the auditors found some details in the submitted progress notes which satisfied certain elements of a treatment/recovery plan review, the OMIG found no evidence of multi-disciplinary involvement in the review, as required by 14 NYCRR § 822-5.5(f). (T 70-72.)

An unsigned copy of a patient treatment/recovery plan review dated was submitted to the OMIG during the audit. (Exhibit 6, pp. 101-10, Exhibit G.) At the hearing, CASAC testified with certainty that the original, hard-copy version of this treatment/recovery plan review was properly signed. (T 633-34.) However, the Appellant was unable to produce it and therefore did not establish the involvement of and signed approval by the patient's multi-disciplinary team (at least three members) in the treatment/recovery plan review process for the pertinent period.

For this Sample # 47, as for the other claims in this audit, the auditors looked beyond formal completion of discrete documents identified as treatment/recovery plan reviews to ascertain whether other submitted documents satisfied regulatory requirements for such reviews.

The Appellant offered various progress notes and other entries from the patient record. (Exhibit C; Exhibit 12, pp. 303-06.) The auditors correctly concluded that these other records did not constitute documentation within the relevant review period that summarized the patient's progress in specified treatment/recovery plan goals and showed the involvement of at least three members of the patient's multi-disciplinary team in reviewing the goals and patient progress.

Sample # 48:

This 2015 date of service was within one year of the patient's , 2014 date of OTP admission, thereby requiring the Appellant to maintain documentation of a quarterly treatment/recovery plan review in the patient's records. As with all disallowed samples in this category, the Appellant did not provide the formal treatment/recovery plan review during the audit.

The Appellant was required to contemporaneously prepare, maintain, and furnish the treatment/recovery plan review to the OMIG at the OMIG's request during the audit. 18

NYCRR § 504.3(a). 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). The OMIG was not obligated to reopen the audit when presented with new documents after it issued the final audit report. (OMIG's 3/16/20 Brief, p. 13.) The audit deadlines established by regulation afforded the Appellant a reasonable opportunity to submit supporting documentation to justify its right to receive payment for the sampled claim. Exhibit B was properly rejected by the OMIG because it was offered after the audit was completed. This administrative hearing is a review of that completed audit, not a continuation of the audit, and the untimely documentation will also not be considered in this decision.

At the hearing, Dr. contended that various patient records that were provided to the OMIG during the audit satisfied the requirements of a treatment/recovery plan review and showed multi-disciplinary involvement in the review. (T 214-28, 416-23; Exhibit C; Exhibit 6, pp. 113-16; Exhibit 12, pp. 337, 344, 353-54, 361-62.) However, the documents did not establish that at least three members of a multi-disciplinary team reviewed the patient's treatment goals and progress and signed off on a treatment/recovery plan review. Circumstantial evidence and testimony that a treatment/recovery plan review occurred because several clinicians were providing ongoing care and treatment fails to meet the requirements.

Although the documents produced by the Appellant during the audit were substantial in volume, only the document it had established by its own internal policies as the template to be used as a patient's treatment/recovery plan review (which the Appellant timely produced for most of the other patients in the 100-claim sample) discussed the information required by regulations, specifically, a summary of the patient's progress in every specified treatment/recovery plan goal <u>and</u> contained signatures of three members of the patient's multi-disciplinary team. Only the designated treatment/recovery plan review document identified possible obstacles to the patient's treatment progress and described the ways that clinical staff

will assist the patient with identified goals. (Exhibit B.) That information is not found in the other documents cited. This claim was correctly disallowed.

Sample # 77:

This ______, 2015 date of service occurred nearly 11 years past the patient's date of admission to the OTP. As such, the auditors reviewed the records for evidence that a treatment/recovery plan review was documented as having been performed within 180 days before the date of service. The auditors determined that the submitted documents did not describe the patient's treatment goals and did not reflect the involvement of the patient's multi-disciplinary team. (T 74-75.)

While the Appellant acknowledged its inability to locate the patient's treatment/recovery plan review, it again claimed that the submitted patient records provided all necessary information. (Exhibit 6; T 338, 347.) The Appellant submitted the treatment/recovery plan review for the prior period, along with patient progress notes, a medical problem list and a nursing periodic patient review. (T 345-47; Exhibit C; Exhibit 12, pp. 446-52.) Dr. testified that the patient's treatment goals were carried over and that the individuals completing the progress notes in the relevant time period were aware of the patient's treatment problems and goals. (T 338-39; Exhibit C; Exhibit 12, pp. 427-30, 435-36.)

The submitted records did not document a treatment/recovery plan review or the involvement and signatures of at least three members of the patient's multi-disciplinary team in the treatment/recovery plan review. This claim was properly disallowed.

<u>Sample # 87</u>:

The 2015 date of service for this claim occurred within the first year of the patient's admission date. In support of the Appellant's assertion that a quarterly

treatment/recovery plan review was conducted, the Appellant's response to the draft audit report directed the auditors to a progress note for a counseling session that the patient received on 2015, which described the patient's revised goals and objectives, treatment progress, and health concerns. (Exhibit 6, p. 146; Exhibit 12, p. 496.) Although the auditors concluded that the submitted information might satisfy most of the criteria for a treatment/recovery plan review, they determined that the progress note did not reflect multi-disciplinary involvement in the review. (T 75-76.) Specifically, it failed to establish that at least three members of the patient's multi-disciplinary team reviewed and signed off on the patient's treatment goals and progress toward those goals.

Dr. testified that patient progress notes, when viewed in tandem with a 2015 nursing periodic patient review and a physician's medication administration order dated 2015, provided the information required in a treatment/recovery plan review and showed multi-disciplinary involvement in the review. (T 320-31; Exhibit C; Exhibit 6, pp. 145-47; Exhibit 12, pp. 487-92.)

The CASAC's , and , 2015 entries were detailed. They described the patient's treatment progress, along with treatment and life problems encountered. (Exhibit 6, pp. 145-47.) However, the documentation prepared by nursing and medical staff showed no relationship to the counselor's notes. While the , 2015 nurse's progress note and nursing periodic patient review summarized the patient's medical conditions, those documents did not describe, or even mention, the patient's treatment goals and thus cannot be considered a review of the patient's treatment/recovery plan. (Exhibit 6, p. 147; Exhibit 12, pp. 487-92.) The , 2015 medication administration order provided no information to signify

that the ordering physician reviewed the patient's treatment goals and progress toward those goals. (Exhibit 12, p. 486.) As such, this claim was properly disallowed.

Sample # 88:

This 2014 date of service was outside of the patient's initial year of treatment, thus necessitating a treatment/recovery plan review at least once every 180 days. In support of its position that a treatment/recovery plan review was timely conducted, the Appellant pointed to a progress note for a 2013 counseling session, in which the counselor reported reviewing the patient's progress and treatment goals, along with a nursing periodic patient review conducted on 2013. (Exhibit 6, pp. 75, 153-58; Exhibit 12, p. 511; Exhibit C.) The auditors found no evidence that at least three members of the patient's multi-disciplinary care team were involved in a treatment/recovery plan review. (T 76-77.)

At the hearing, Dr. directed attention to progress notes with dates of service ranging from 2013 through 2014, a nursing periodic patient review conducted on , 2014, and a physician's medication administration order valid from , 2013 through , 2014. (Exhibit C; Exhibit 6, pp. 153-56; Exhibit 12, pp. 509, 514-15; T 232-36.) Those documents did not show that these individuals reviewed the patient's treatment goals and progress toward those goals. The submitted records established the involvement of only one member of the patient's multi-disciplinary team in a treatment/recovery plan review. This claim was properly disallowed.

Sample # 92:

This _____, 2014 date of service was beyond the patient's first year of admission and required a treatment/recovery plan review at least once every 180 days. In its response to the draft audit report, the Appellant emphasized a progress note pertaining to a _____, 2014

counseling session, which explained that the CASAC met with the patient to devise a semi-annual treatment/recovery plan. Additionally, the Appellant pointed to an annual treatment review, which evaluated the patient's physical health. (Exhibit 6, p. 75.) At the hearing, Dr. asserted that submitted documentation showed multi-disciplinary input in the patient's care. (T 248-56; Exhibit C; Exhibit 6, pp. 159-60; Exhibit 12, pp. 539-42.)

The documents submitted to the OMIG audit team did not describe the patient's treatment goals and progress toward those goals. Moreover, the Appellant's contention that the documentation separately prepared by a counselor, a registered nurse, and a physician were evidence of multi-disciplinary approval of the patient's treatment/recovery plan review is rejected. For instance, no correlation was shown between a prepared medication administration order for the patient and a treatment/recovery plan review conducted four months later. This claim was properly disallowed.

Sample # 100:

This ______, 2012 date of service was more than one year after the patient's date of admission to the OTP. The auditors therefore reviewed patient records for evidence that a treatment/recovery plan review was conducted at least every 180 days around the date of service. From the records submitted, the auditors were unable to discern the patient's treatment goals and found no evidence of multi-disciplinary involvement in the patient's treatment/recovery plan review. (T 78.)

Dr. opined that the submitted documents contained sufficient information to constitute a treatment/recovery plan review. Specifically, she cited an 2012 progress note prepared by CASAC in which he reported the following: "Writer met with

patient today and developed his Semi[-]Annual Treatment Plan Review. We reviewed patient's progress and lack of progress". (T 293-94; Exhibit C; Exhibit 12, pp. 618-19.)

To show the involvement of at least three multi-disciplinary team members in the patient's treatment/recovery plan review, Dr. pointed to a physician's involvement in a physician's order made in physician's involvement in a physician's review that the Appellant claims was developed in physician's prescription did not mention the patient's treatment goals and progress and does not establish the physician's review of the patient's semi-annual treatment/recovery plan. The possibility that the patient's medication would be adjusted in response to a treatment/recovery plan review if needed (T 298-99) does not substitute for documentary evidence that the physician reviewed the patient's treatment goals and progress towards those goals. (OMIG's 3/16/20 Brief, p. 19.) The documents for this sample did not show that at least three members of the multi-disciplinary team reviewed the patient's treatment/recovery plan. This claim was properly disallowed.

<u>Disallowance Category 2:</u> Failure to Meet Brief Individual Counseling Requirements.

¹³ 14 NYCRR § 841.14 was in effect for the entire period audited and remains in effect to date.

(Exhibit 12, p. 383.) The Appellant conceded this error. (Exhibit 6; Appellant's 1/27/20 Brief, p. 26.) This sample was properly disallowed.

<u>Disallowance Category 3:</u> Missing/Late Signature on Individual Treatment/Recovery Plan Review.

Treatment/recovery plan reviews must be prepared by the responsible clinical staff in consultation with the patient, and reviewed, signed and dated by at least three members of the multi-disciplinary team. The names of all reviewing individuals must be recorded in the treatment/recovery plan. 14 NYCRR § 822-5.5(f). 14

The OMIG found that records pertaining to Sample # 80, a claim with a 2012 date of service, contained adequate information to constitute a treatment/recovery plan review. However, the records did not include dated signatures of at least three members of the multi-disciplinary team who reviewed the patient's treatment/recovery plan, as required by 14 NYCRR \$ 822-5.5(f). (Exhibit 12, p. 454-72; T 79-80.) Although the OMIG auditors elected to distinguish this finding in a disallowance category independent of Category 1 (Missing/Late Individual Treatment/Recovery Plan Review), these categories could have been combined because they are based upon a failure to comply with the same regulation.

At the hearing, the Appellant presented a copy of an unsigned treatment/recovery plan review which the OMIG auditors deemed insufficient for regulatory requirements. (Exhibit F.)

CASAC explained that the Appellant was unable to locate the signed version. (T 592-94.) Other submitted documents also failed to establish the involvement and approval of at

¹⁴ As previously noted, this provision expired on December 9, 2015.

¹⁵ Although this provision expired on December 9, 2015, it was in effect for the Sample # 80.

least three members of the multi-disciplinary team in the treatment/recovery plan review. (Exhibit C; Exhibit 6, pp. 131-42; Exhibit 12, pp. 460-72.)

As it argued in response to Disallowance Category 1, the Appellant asserted that a treatment/recovery plan review is not a basis for denying payment on a claim. For the reasons delineated in Disallowance Category 1, the Appellant's argument is again rejected here. This claim was correctly disallowed.

<u>Disallowance Category 4</u>: Missing Signed Written Consent Form.

A physician must ensure that a prospective OTP patient provides written consent to participate in opioid treatment, which shall include notice of the risks and benefits of a prescribed medicine. The prospective patient must sign the informed written consent prior to treatment being initiated at admission. 14 NYCRR § 822-5.4(e).¹⁶

The auditors identified two errors in Sample # 87, even though the sample was only disallowed once. In addition to finding that the Appellant did not conduct a treatment/recovery plan review for this patient in the relevant quarter, the OMIG determined that the records did not contain an informed written consent signed by the patient. (Exhibit 7.)

Although the Appellant was unable to locate a consent form for this patient (who was admitted to the OTP on October 30, 2014), it asserted that the patient signed a consent form and consented to treatment because the patient continued to receive the Appellant's OTP services. (Exhibit 6, p. 77; T 335-38.) Acceptance of the Appellant's assertion that the patient gave consent to treatment by continuing to receive treatment (T 335-36) requires assumptions not permitted by and contrary to the consent regulation. The Appellant's claim that progress notes recounting a discussion of treatment risks are the equivalent of the patient's signed, written

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¹⁶ This provision expired on December 9, 2015. The date of service under review is

informed consent is also meritless. (Appellant's 1/27/20 Brief, pp. 4, 25.) The progress notes, whether viewed individually or collectively, did not constitute an informed, written consent signed by the patient. This claim was properly disallowed.

<u>Disallowance Category 5</u>: Physician Examination not Updated Annually.

The prescribing professional at an OTP must conduct a full physical examination, including required laboratory tests or screens, and any other test as clinically indicated or as may be required, during the first week after admission to determine the patient's overall health. A prescribing professional must annually repeat the physical examination required at admission. A patient may choose to have a licensed practitioner outside the OTP complete the annual physical examination to determine health condition and OTP clinical staff shall make diligent efforts to record all required results, including ordered tests, in the patient's case record. 14 NYCRR § 822.8(e)(1).¹⁷

The OMIG disallowed Sample # 99 pertaining to a claim for opioid maintenance medication administration on _______, 2016 because the patient records did not include documentation to establish that a physician examination was conducted annually. (Exhibit 7, p. 202.) Specifically, the submitted patient records showed that a physician examination was conducted on _______ 2014 and then on _______, 2016, slightly more than two years later. (Exhibit 12, pp. 544, 553-56.)

In its response to the draft audit report, the Appellant confirmed its inability to locate documentation of the required physician examination. However, the Appellant contended that periodic nursing reviews establish that "the patient's physical health issues" were being addressed. (Exhibit 6, p. 78.) The Appellant also argued that a physician examination must have

¹⁷ These requirements were included in the cited provision on 2015 and were applicable to the claim's date of service. That version of 14 NYCRR § 822.8 was repealed, and a new version added, on March 27, 2019.

been performed in 2015 because the Appellant was able to produce the 2014 and 2016 physician examinations for this patient. (Appellant's 1/27/20 Brief, pp. 25-26.) There is no documentation to support this claim. A nursing review is not a physician examination, nor does conjecture establish that a physician examination was performed.

The Appellant also contested this disallowance on the grounds that it did not bill the Medicaid Program for a physician examination of this patient for the year 2015 (the year in which no examination was performed). (Exhibit 6, p. 78; Appellant's 1/27/20 Brief, p. 4; T 348.) This admission only supports the conclusion that the required examination was not conducted. Without the annual physician examination, the Appellant was unable to demonstrate its complete verification of the safety of continued medication administration to this patient. Reviews conducted by nursing staff do not supplant the regulatory requirement for an annual physician exam for OTP patients, as set forth in 14 NYCRR § 822.8(e)(1). This claim was properly disallowed.

The Appellant's Broader Challenges to the Audit Disallowances

In its January 27, 2020 brief, the Appellant contended that the OMIG's audit protocol was improper and constituted proposed rulemaking or an interpretation of applicable regulations for which the Appellant should have been informed. (Appellant 1/27/20 Brief, pp. 26-27.)

The Appellant was repeatedly advised that the purpose of the audit was to:

determine whether [the Appellant's] claims for Medicaid reimbursement complied with applicable Federal and State laws, regulations, rules and policies governing the New York State Medicaid Program and to verify that:

- Medicaid reimbursable services were rendered for the dates billed;
- appropriate rate or procedure codes were billed for services rendered;
- patient related records contained the documentation required by the regulations; and

• claims for payment were submitted in accordance with Department regulations and the appropriate Provider Manuals. (Exhibits 3, 5 and 7.)

The Appellant failed to identify any provision in the audit protocol that was inconsistent with the applicable regulations, or any instance in which the OMIG applied an audit protocol inconsistently with the regulations.

Throughout the audit, the Appellant repeatedly advised the OMIG of its difficulties with locating missing records because of its then-reliance upon a third-party vendor and the improvements in record storage made as a result of this audit. (Exhibits 3 and 4.) At the hearing, (the OTP's Director of Clinical Services during the period audited), provided an overview of the Appellant's OTP clinic staff responsibilities and testified as to the Appellant's efforts to locate the missing documents. (T 439-57, 476-89, 496-97.)

Compliance with documentation requirements is a fundamental condition of the Appellant's enrollment as a Medicaid provider and its receipt of Medicaid payments. The Appellant's voluntary enrollment in the Medicaid Program signified its agreement to maintain contemporaneous records to demonstrate its right to receive payment for services in compliance with all applicable laws, rules, and regulations. 18 NYCRR § 504.3. Providers' compliance with their contractual agreements is essential for the OMIG to oversee the appropriateness of billions of dollars in public funds paid under the Medicaid Program.

The Appellant also claimed that it has incurred substantial costs of at least \$300,000 plus ongoing expenses to improve its document storage processes in response to the audit findings. (T 489-91.) According to the Appellant, these voluntary changes show that it has learned from the audit findings and should be the extent of any penalty imposed. (Exhibit 4, pp. 25-26.) The stated amount of \$300,000 is less than 4 percent of the actual overpayment identified in this

audit, and less than .4 percent of the total Medicaid payments received by the Appellant during the audit period.

It is undisputed that this audit triggered the Appellant's reevaluation and overhaul of its document retention processes. Oversight of the Medicaid Program to ensure provider compliance with program requirements is an important function of the OMIG, as the Appellant's steps taken to bring itself into compliance show. The Appellant, however, had an ongoing and independent obligation to correct any inadequate compliance with documentation requirements. Making the changes did not account for or excuse the failure to produce the documents which the Appellant was required to provide for this audit. Those missing documents precluded the Medicaid Program (a substantial payor for the Appellant's OTP) from verifying that the care rendered to Medicaid recipients, for which the Medicaid Program paid, was medically necessary.

The Appellant emphasized that the OTP was audited by both OASAS and the Joint Commission in the year 2018, with both entities reviewing patients' treatment/recovery plans. (Appellant's 1/27/20 Post-Hearing Brief, p. 9; T 462-67.) However, the outcome of reviews by OASAS and the Joint Commission are neither dispositive nor instructive in this audit. Each organization has a distinct role in monitoring the Appellant's compliance with various standards and regulatory requirements. The Joint Commission accredits healthcare organizations. (T 495; see also https://www.jointcommission.org/about-us/facts-about-the-joint-commission/.) The Appellant requires the approval of OASAS to provide OTP services in the State of New York. MHL Art. 32; 14 NYCRR Part 810.

The OMIG provides neither OTP accreditation nor operating approval. It is legally authorized, on the Department's behalf, to conduct audits to review Medicaid payments. 18

NYCRR § 504.8(b) and § 518.3. As a condition of receiving Medicaid payments, the Appellant

was required to prepare, maintain and provide documentation to the auditors to establish that the sampled OTP services for which it submitted claims to the Medicaid Program were appropriate and necessary. 18 NYCRR §§ 504.3(a)&(g). When the Appellant was unable to provide the required supporting documentation during the audit for certain sampled claims, those claims were properly disallowed, and overpayments were identified.

The OMIG's Extrapolation of the Audit Findings to the Appellant's Universe of Claims

The OMIG extrapolated its sample findings of 11 disallowed claims totaling \$407.90 to the Appellant's total 1,898,937 claims for which it received a total payment of \$82,093,297.20 from the Medicaid Program in the period at issue. The OMIG's use of statistical sampling methodology for extrapolation of the sample findings was explained to the Appellant in the exit conference summary (Exhibit 3), the draft audit report (Exhibit 5), and the final audit report (Exhibit 7.) During the exit conference, the Appellant was also given a compact disk (CD) containing information about the universe of claims in the audit period and sample information about the claims selected for audit. (Exhibit 3.)

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 may submit expert testimony challenging the extrapolation by the Department or an actual accounting of all claims paid in rebuttal to the Department's proof. 18 NYCRR § 519.18(g).

The OMIG submitted the required certifications in the form of affidavits from Dr. Karl W. Heiner, the statistical consultant who designed the sampling and estimation methodology used, and Theresa Gulum, the OMIG employee who applied the methodology to establish the

audit frame and select the random sample. (Exhibits 14 and 15.) The Appellant offered neither expert testimony nor an actual accounting of all claims to establish error in the extrapolation.

Although it did not challenge the statistical methodology employed by the OMIG in its extrapolation, the Appellant did object to the OMIG's extrapolation of its audit findings to the Appellant's entire universe of claims on the grounds that the audit revealed only 12 disallowances on 11 claims out of 100 reviewed claims. (Exhibit 6, pp. 78-79; T 165-67; Appellant Brief 1/27/20, pp. 27-28.) The Appellant offered no expert testimony or persuasive argument why these facts invalidate the extrapolation.

The Appellant also argued that extrapolation of the sample findings is unjust in this matter because four of the five audit categories yielded only one finding in each of those categories. According to the Appellant, the single claim disallowances in Categories 2, 3, 4, and 5 should not have been included along with the extrapolation computation for the eight disallowed claims in Category 1 because the inclusion of those disallowances resulted in a disproportionate "penalty". (Exhibit 6, pp. 78-79; Appellant's 1/27/20 Brief, p. 27.) The Appellant offered no expert testimony or persuasive argument to support this assertion.

As already noted, the OMIG's distinction between Category 1 ("Missing/Late Individual Treatment/Recovery Plan Review") and Category 3 ("Missing/Late Signature on Individual Treatment/Recovery Plan Review") was unnecessary because the categories require review of the same regulatory provision. Furthermore, Sample # 87 was disallowed (albeit only once) for reasons found in two distinct categories: Category 1 and Category 4 ("Missing Signed Written Consent Form"), thereby prompting the disallowance of this sample in either category. The Appellant's failure to account for these events illustrates the vagueness of its complaint. The Appellant failed to submit any expert testimony to challenge the presumption of accuracy

established by the certifications of the extrapolation methodology. Bare assertions of unfairness fail to overcome that presumption. 18 NYCRR § 519.18(g).

The Appellant argued that stratified sampling (analysis of each category of claims separately) is the industry standard for statistical sampling and is used by the federal government. According to the Appellant, the OMIG's extrapolation of audit findings did not comport with guidelines propounded by Centers for Medicare and Medicaid Services (CMS) as delineated in the Medicare Program Integrity Manual, Chapter 8¹⁸. (Exhibit 6, pp. 78-79; Appellant's 1/27/20 Brief, pp. 28-29.) The Medicare Program Integrity Manual is not binding authority in an audit of claims paid by the Medicaid Program. (OMIG's 3/16/20 Brief, pp. 4-5.) In fact, the Medicare Manual itself states that failure to follow its guidelines should not be construed as necessarily affecting the validity of statistical sampling or the projection of an overpayment. Medicare Program Integrity Manual § 8.4.1.1, accessible at:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf.

There is also a Medicaid Program Integrity Manual, which pertains to Medicaid audits and defers to state Medicaid policies regarding extrapolation. Medicaid Program Integrity Manual § 1.7.3, effective 4-3-18, accessible at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mpi115c01.pdf. New York State Medicaid audits employ the statistical sampling method described in Dr. Heiner's certification and authorized by state law and Department regulations.

The OMIG's authority to determine overpayments by extrapolation based upon audit findings is well-settled. Yorktown Medical Laboratory, Inc. v. Perales, 948 F.2d 84 (2d Cir. 1991); Mercy Hospital of Watertown v. New York State Dept. of Social Services, 79 N.Y.2d 197

¹⁸ Chapter 8 of this manual was most recently revised on September 27, 2019.

(1992); Enrico v. Bane, 213 A.D.2d 784 (3d Dep't 1995); State v. Khan, 206 A.D.2d 732 (3d Dep't 1994); Clin Path, Inc. v. New York State Dep't of Social Servs., 193 A.D.2d 1034 (3d Dep't 1993). The OMIG's selection of 100 claims from 1,898,937 paid claims afforded both the OMIG and the Appellant an efficient means by which to establish whether the Appellant had created and maintained the requisite documentation to justify its right to the Medicaid payments received for OTP services in the period reviewed.

The fact that the audit resulted in a disallowance rate of 11% (11 samples disallowed out of 100 reviewed samples) shows the Appellant's overall sound implementation of procedures. Given the large number of claims submitted by the Appellant and total Medicaid payments received, even a small percentage of identified errors yields a seemingly large overpayment recovery. Yet the overpayment of \$7,745,764 amounts to only 9.4% of the total amount that the Appellant received from the Medicaid Program during the period audited, a percentage below the error rate. (OMIG's 3/16/20 Brief, p. 2.) Despite being given the claims universe from which the samples were selected, the Appellant offered no evidence to show that review of total Medicaid payments received for the period audited would result in a lower overpayment amount.

The Appellant also contended that it is unjust, amidst a growing opioid epidemic, to impose an overpayment of \$7,745,764 upon a large OTP that serves disenfranchised members of the general population. (Appellant's 1/27/20 Brief, p. 30.) It is New York State policy to make uniform, high-quality medical care available to everyone, regardless of age, national origin, or economic standing. 18 NYCRR § 504.1(a). The Appellant's rendering of OTP services to vulnerable individuals only underscores the import of this audit in assessing whether the Appellant's OTP patients received care in accordance with all legal requirements. (OMIG's 3/16/20 Brief, p. 8.)

The Appellant claims that the OMIG's recovery of the overpayment using extrapolation methodology will result in the closure of one clinic serving anywhere from 400 to 1500 patients. (Appellant's 1/27/20 Brief, p. 1.) That business decision is irrelevant to this review of a documentation audit and a resulting Medicaid overpayment. (T 433-35.)

Although the OMIG made no allegation of fraud in this audit, the Appellant contended that the overpayment demand constituted a "penalty" and "abusive and retaliatory practices", with the goal of extracting "maximum financial capital." (Appellant's 1/27/20 Brief, pp. 29-30; Appellant's 3/16/20 Brief, p. 5.) The Appellant's citing of 18 NYCRR Part 516 as authority is misplaced. Providers engaged in defrauding the Medicaid program are subject to penalties as such are described in Part 516 and sanctions as described in Part 515. There is no penalty, nor is any sanction imposed in this audit, which was conducted pursuant to Part 517. The OMIG is authorized to recover overpayments in such an audit without finding fraud. 18 NYCRR § 518.1 and § 518.3. The Appellant did not explain its basis for alleging that the OMIG's recovery of overpayments of public funds identified in this audit is an abusive or retaliatory practice.

The OMIG did not determine that the Appellant's submission of nearly two million claims and/or receipt of over \$82 million from the Medicaid Program in a three-year period was excessive. No evidence has been offered to show that the OMIG acted outside of its legal authority in extrapolating the audit findings or that its determination was not correct. As such, the OMIG's determination is sustained.

DECISION

The OMIG's determination to recover Medicaid Program overpayments from the Appellant was correct and is affirmed. The overpayment amount is \$7,745,764.

Dated: Menands, New York April 24, 2020

/Natalie J. Bordeaux/
Natalie J. Bordeaux
Administrative Law Judge