

**BEFORE THE OFFICE OF STATE ADMINISTRATIVE HEARINGS  
STATE OF GEORGIA**

NEW SERENITY, INC.,  
Petitioner,

v.

DEPARTMENT OF COMMUNITY  
HEALTH, HEALTHCARE FACILITY  
REGULATIONS DIVISION,  
Respondent.

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: Docket No.:  
: OSAH-DCH-HFR-NTP-1512293-64-Teate  
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DEC 30 2014

**INITIAL DECISION**

**I. INTRODUCTION**

*Kevin Wesley*  
Kevin Wesley, Legal Assistant

Petitioner New Serenity, Inc. (hereinafter "New Serenity") appeals a determination by Respondent the Department of Community Health, Healthcare Facility Regulation Division (hereinafter "the Department"), to revoke its permit to operate a Narcotics Treatment Program. A hearing was held on November 20, 2014 before the undersigned Administrative Law Judge at the Office of State Administrative Hearings in Atlanta, Georgia. Ms. Stacey Hillock, Esq., represented the Department. New Serenity was represented by Ms. Laura E. Austin, Esq. For the reasons indicated below, the Department's action is **AFFIRMED**.

**II. FINDINGS OF FACT**

1. New Serenity maintains and operates a Narcotics Treatment Program ("NTP"), a program that involves the administration of methadone, a controlled substance, for the purpose of treating drug addiction. Currently, New Serenity provides services to approximately eighty-five patients. Mr. Eustace Lewis is New Serenity's Program Administrator. (Testimony of Eustace Lewis; Exhibit R-21).
2. New Serenity operates its NTP under a permit issued to it by the Department on October 24, 2013. Prior to obtaining a permit from the Department, New Serenity was subject to an initial licensure survey on May 8, 2013. During this initial survey, the Department cited New Serenity for several violations of the Rules and Regulations for Narcotic Treatment Programs (hereinafter "NTP Rules"). New Serenity was able to obtain a permit only after submitting an acceptable plan of correction to the Department on October 23, 2013. (Exhibits R-5; R-21).
3. On May 28, 2014, Madelynn Speach, a surveyor with the Department, visited New Serenity to conduct an unannounced follow-up survey. This follow-up survey entailed a review of the facility's records as well as interviews with staff members and Mr. Lewis. At the time of the survey, New Serenity was providing NTP services to fifty-three clients. (Testimony of Madelynn Speach; Exhibit R-2).

4. During the follow-up survey, Ms. Speach cited New Serenity for nine (9) violations of the Rules and Regulations for Narcotic Treatment Programs (hereinafter "NTP Rules"). Specifically, Ms. Speach determined that New Serenity had committed the following NTP Rule violations:

- (1) In reviewing the facility's records, Ms. Speach noted a report of a Substance Abuse and Mental Health Services Administration (SAMHSA) inspection of New Serenity on May 16, 2014. According to the inspection report, inspectors observed violations of seven Federal Opioid Treatment Standards as set forth under Title 42, Part 8 of the Code of Federal Regulations during the May 16 inspection.<sup>1</sup> As a result of these violations, New Serenity was subject to federal regulatory action, including steps to formally revoke its certification. New Serenity's failure to comply with governing federal regulations constituted a violation of NTP Rule 290-9-12-.05(b).<sup>2</sup> (Exhibits R-2, R-3).
- (2) New Serenity failed to ensure that five clients admitted to its program were assessed by the Medical Director, Program Physician, and/or a

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<sup>1</sup> SAMHSA inspectors found New Serenity to be in violation of the following federal regulations:

- 42 C.F.R. § 8.12(d), which requires that "each [staff member] engaged in the treatment of opioid addiction . . . have sufficient education, training, and experience . . . to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional providers, including addiction counselors, must comply with the credentialing requirements of their respective professions."
- 42 C.F.R. § 8.12(e), which requires that a program physician ensure that the patient voluntarily chooses maintenance treatment, is informed of the facts concerning opioid use, and provides informed consent to treatment.
- 42 C.F.R. § 8.12(f)(2), which requires that a fully documented physical be administered before admission to the OTP [Opioid Treatment Program]. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.
- 42 C.F.R. § 8.12(f)(4), which requires that each patient be assessed initially and periodically . . . for education, vocational rehabilitation, employment medical, psychosocial, economic, legal or other supportive service needs.
- 42 C.F.R. § 8.12(g)(1), which requires that OTPs establish and maintain a recordkeeping system that is adequate to document and monitor patient care.
- 42 C.F.R. § 8.12(h), which requires that the initial dose of medication not exceed 30 mg and that the total dose for the first day not exceed 40 mg and that deviations from this standard be documented in the patient record.
- 42 C.F.R. § 8.12(i)(1), which states that patients may receive a single take-home dose when the clinic is closed for business, including Sundays and holidays.

(Exhibit R-3).

<sup>2</sup> The Department reorganized the NTP Rules under the Healthcare Facility Regulations Chapter of the Rules and Regulations of the State of Georgia effective September 29, 2013. The reorganization involved no substantive changes to the NTP Rules. Ms. Speach included the pre-amendment NTP Rule citations in her survey report. (Exhibit R-19).

- Medical Staff Member who was qualified to perform/coordinate the provision of such assessments prior to administering or prescribing any medication to those clients, in violation of NTP Rule 290-9-12-.12(1)(b). (Exhibit R-2).
- (3) New Serenity failed to conduct physical assessments of clients that included HIV, CBC, chemistry profile, Pregnancy, STD, and Mantoux TB tests in order to determine dependence on Opium, Morphine, Heroine, or any derivative or synthetic drug of that group and to determine each client's current DSM diagnosis as required by NTP Rule 290-9-12-.12(1)(b)5. (Exhibit R-2).
  - (4) New Serenity failed to complete a preliminary individual treatment plan for five patients within ten (10) days of their admission to the program and failed to complete individual treatment plans for those patients within thirty (30) days of their admission in violation of NTP Rule 290-9-12-.13. (Exhibit R-2)
  - (5) New Serenity failed to establish and implement policies and procedures for pre-employment and ongoing random drug testing for any of its employees in violation of NTP Rule 290-9-12-.10(4). The Department cited New Serenity for this Rule violation during an initial licensure inspection on May 8, 2013. (Exhibits R-2, R-5).
  - (6) New Serenity failed to provide staff training and/or orientation to four of its employees in violation of NTP Rule 290-9-12-.10(3). (Exhibit R-2)
  - (7) New Serenity's counselor, hired March 5, 2014, was not licensed or certified as an addiction counselor, had no prior experience as an addiction counselor, and was not receiving any proper clinical supervision or support. New Serenity's failure to ensure that the only counselor on staff was qualified to provide addiction counseling services constituted a violation of NTP Rule 290-9-12-.10(2)(e). (Exhibit R-2).
  - (8) New Serenity failed to maintain documentation that the program's medical director, Dr. Timothy Young, had a current license to practice medicine in the State of Georgia. The documentation of Dr. Young's licensure maintained by New Serenity indicated that his license expired on February 28, 2013. Although Ms. Speach later determined that Dr. Young's medical license was current, New Serenity's failure to maintain documentation of its medical director's current licensure violated NTP Rule 290-9-12-.10(2)(a). The Department previously cited New Serenity for violation of this rule during the initial licensure inspection. (Exhibits R-2, R-5, R-7).
  - (9) New Serenity did not have a clinical director on staff in violation of NTP Rule 290-9-12-.10(1)(b). New Serenity had previously been cited for this violation during an initial licensure inspection on May 8, 2013.<sup>3</sup> (Testimony of Madelynn Speach; Exhibits R-2, R-5).

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<sup>3</sup> New Serenity hired a clinical director pursuant to the plan of correction submitted to the Department on October 23, 2013. However, in a letter dated March 25, 2014, this clinical director notified the Department that he had resigned from New Serenity, and had performed no duties there since October or November of 2013. New Serenity

5. In a letter dated July 23, 2014, the Department notified Mr. Lewis of its determination to revoke New Serenity's permit to operate a Narcotic Treatment Program based upon the above-described NTP Rule violations. Mr. Lewis submitted a hearing request to the Department on or about July 25, 2014, whereupon the matter was referred to the Office of State Administrative Hearings for adjudication. (Exhibit P-2).

6. In the wake of the follow-up survey, New Serenity submitted multiple plans of correction to the Department. As of the date of this Decision, the Department has not accepted a plan of correction from New Serenity.<sup>4</sup> (Testimony of Madelynn Speach; Exhibits P-3, P-4, P-5, P-6, and P-7).

7. As described in the most recent Plan of Correction submitted to the Department, New Serenity hired a new Clinical Director, Mr. Willie Dean, in July 2014 to oversee the clinical aspects of its program. Although New Serenity has been unable to hire a licensed counselor, two of its staff members are currently participating in a 180-hour certified addictions counselor (CAC) training program, with both staff members scheduled to complete the program by July 2015. The current medical license of Dr. Young, who remains New Serenity's medical director, is maintained in the facility's personnel records. Additionally, New Serenity submitted to the Department that it had amended its policies to rectify the deficits in personnel records, client records, informed consent, individual treatment plans, drug screening, medical assessments, and staff member training/orientation identified during the follow-up survey. (Testimony of Brenda Lewis; Testimony of Willie Dean; Testimony of Dr. Timothy Young; Exhibits P-7, P-8, P-9, P-11, P-12, P-13).

8. New Serenity also submitted a plan of correction to SAMHSA and is awaiting an accreditation review. SAMHSA has not accepted a plan of correction from New Serenity however, and, according to an e-mail sent to New Serenity by SAMHSA on or about September 29, 2014, the program remains out of compliance with federal regulations. (Exhibit P-18).

9. At the hearing on this matter, New Serenity acknowledged that it was not in compliance with NTP Rules at the time of the follow-up survey. It asserted, however, that all of the deficiencies identified during the follow-up survey had been corrected and that the extensive corrective measures implemented by the facility merited reversal of the agency's determination to revoke its NTP permit. New Serenity further contended that, given the dearth of similar programs in the area, revocation of its permit would impose a hardship on the community. (Testimony of Brenda Lewis; Testimony of Heustace Lewis; Testimony of Willie Dean).

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failed to notify the Department of a change in its clinical director within the ten-day time period prescribed by the Department's rules. (Testimony of Madelynn Speach; Exhibits R-2, R-5, R-6).

<sup>4</sup> The Department has yet to review the most recent plan of correction submitted by New Serenity. (Testimony of Madelynn Speach; Exhibit P-7).

### III. CONCLUSIONS OF LAW

1. As the Department seeks to revoke New Serenity's permit, the Department bears the burden of proof. Ga. Comp. R. & Regs. 616-1-2-.07(1) (2014). The standard of proof is a preponderance of the evidence. Ga. Comp. R. & Regs. 616-1-2-.21(4) (2014).
2. The Department is the licensing authority for narcotic treatment programs in the State of Georgia. O.C.G.A. §§ 26-5-10 (2014); Ga. Comp. R. & Regs. 111-8-53-.01 et seq. (2013). As the licensing authority, the Department is responsible for enforcing the regulations governing narcotic treatment programs. O.C.G.A. §§ 26-5-10 (2014); Ga. Comp. R. & Regs. 111-8-53-.01 et seq. (2013); see also Ga. Comp. R. & Regs. 111-8-25-.04 to -.05 (2013).
3. Pursuant to its general licensing and enforcement authority, the Department may impose sanctions against a program upon a finding that the program has failed to comply with licensing requirements or the Department's rules. Ga. Comp. R. & Regs. 111-8-25-.04 (2013). Moreover, "[u]pon the discovery of *any* violation of [NTP Rules], the Department may proceed to suspend or revoke a program's license." Ga. Comp. R. & Regs. 111-8-53-.08(2) (2013) (emphasis added). In determining the appropriate sanction, "the Department may consider whether the violations can be corrected, the program's history of compliance, the nature and seriousness of the violations, the impact of the violations on the safety and welfare of the program's patients and the surrounding community and any other relevant circumstances." Id.
4. In the present case, the Department discovered nine NTP Rule violations at New Serenity during a follow-up survey. These violations were of a serious nature, and risked compromising the safety and welfare of the program's patients. Although New Serenity introduced evidence that it had corrected many of the deficiencies, it remains out of compliance with federal regulations and has yet to submit a plan of correction that has been accepted by the Department.

### IV. DECISION

**IT IS HEREBY ORDERED** that the Department's revocation of New Serenity's permit to operate a Narcotic Treatment Program is **AFFIRMED**.

**SO ORDERED**, this 30<sup>th</sup> day of December, 2014.

  
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STEVEN W. TEATE  
Administrative Law Judge