IOWA DEPARTMENT OF PUBLIC HEALTH
DIVISION OF BEHAVIORAL HEALTH

FOLLOW UP INSPECTION TO DENIAL

PROGRAM:	*A New Leaf – Mental Health & Wellness Center (A New Leaf)* 5925 Council Street NW, Ste. 117 Cedar Rapids, Iowa 52302
LICENSED SERVICES:	Adult and Juvenile Level 1 Substance Use Disorder Treatment Services
DIVISION SURVEYOR:	Lori Hancock-Muck, Division of Behavioral Health
INITIAL NOTICE OF DENIAL FROM COMMITTEE:	April 14, 2021
CORRECTIVE ACTION APPROVAL:	June 21, 2021
FOLLOW UP REPORT:	July 5, 2022

SUMMARY OF DENIAL:
On April 14, 2021, the Substance Abuse/Problem Gambling Program Licensure Committee (Committee) denied A New Leaf's application for a substance use disorder treatment program license. The Committee's decision was based on the program's repeated failure to comply with corrective action plans, which is a violation of the terms and conditions of Consent Agreement DIA NO. 20DPH0008 (Agreement). The Agreement, executed on December 11, 2019, was a settlement of a contested case proceeding resulting from a denial that was issued September 11, 2019. As a mutually agreed upon informal settlement was reached, A New Leaf withdrew the pending contested case and agreed to comply with all terms and conditions of the Agreement, including agreeing to "comply with all corrective actions" in paragraph 9(B). One of the conditions of the Agreement was that in the event A New Leaf violates or fails to comply with any of the terms or provisions of the Agreement, the Committee may initiate appropriate action to deny, suspend, or revoke A New Leaf's license or to impose other appropriate discipline. On April 14, 2021, the Committee determined to proceed with the denial due to the program's

failure to achieve the minimum licensure weighting report rating required for a 270-day initial license, or a one-, two-, or three-year license; for repeated failure to comply with corrective action plans; and its violation of the terms and conditions of a consent agreement. The following violations were found during the licensure inspection and the complaint investigation that are grounds for a denial:

- *641 IAC 155.10(1) The Committee may deny an application for a license for any of the following reasons:*
  b. The applicant fails to achieve the minimum licensure weighting report rating required for a 270-day initial license or a one-, two- or three-year license.
- *641 IAC 155.11(125, 135) Denial, suspension or revocation of a license. The committee may suspend or revoke a license for any of the grounds for discipline pursuant to paragraph 155.10(1)"d".*
  155.10(1)d. Violation of any of the following grounds for discipline:
  (1) Submission of fraudulent or misleading information.
  (2) Violation by a program or staff of any statute or rule pertaining to programs, including violations of any provision of these rules, or failure to adhere to program policies and procedures adopted pursuant to these rules.
  (3)Failure to comply with licensure, inspection, health, fire, occupancy, safety, sanitation, zoning, or building codes or regulations required by federal, state or local law.
  (9) Conduct or practices determined to be detrimental to the general health, safety, or welfare of a patient, potential patient, concerned person, visitor, staff or member of the public.
  (11) Defrauding a patient, potential patient, concerned person, visitor, staff or third-party payor.
  (16)Failure to submit an acceptable written corrective action plan or failure to comply with a corrective action plan pursuant to rule 641-155.9(125,135) or 641-155.16(125,135).
  (17)Violation of an order of the committee or violating the terms or conditions of a consent agreement or informal settlement between a program and the committee.

The factual grounds for the denial are contained in the December 17, 2020 licensure inspection report and the January 26, 2021 complaint inspection report.

In accordance with IAC 641—155.11(2), A New Leaf submitted a written corrective action plan to address the areas of non-compliance found from the licensure inspection and complaint investigation. Following the Department approval of the plan, A New Leaf had 90 days to implement the plan. Following the 90 day implementation time frame, the Department conducted a follow up inspection to determine adherence with the corrective action plan measures.

RESULTS OF 90 DAY FOLLOW UP INSPECTION:

On October 6, 2021, A New Leaf was notified that an inspection was going to be conducted to determine compliance with the corrective action plan following the 90 day compliance period. Upon request, A New Leaf submitted documents to be reviewed, which included, a list of patient records to be accessed in the program's electronic health record, personnel records, clinical

oversight meeting minutes, specific policies and procedures, job descriptions, patient intake packet, and a current quality improvement plan.

2021 Complaint investigation rule violations:

The following includes each substantiated allegation cited from the January 26, 2021 Complaint Investigation report along with the current 90 day follow up inspection findings for the corrective action plan adherence.

- ***Patients and third party payor (Medicaid) were billed for treatment services, which consisted of email communications.*** In the complaint investigation report, it was determined that A New Leaf had billed third party payor (Medicaid) for treatment services, which included email communications. The corrective action plan stated the program had already discontinued its practice of e-mail based therapy and would cooperate with and comply with the direction of the Iowa Department of Inspections and Appeals Administrators, and any other Medicaid-compliance entity, with respect to the Medicaid telehealth billing matter at issue. Due to Department findings of possible improper Medicaid billing, a referral was made to Iowa Medicaid Fraud Control Unit (MFCU) and the Iowa Department of Inspections and Appeals on September 11, 2019.

For the 90 day follow up, the surveyor followed up with MFCU to determine the status of the referral. MFCU informed the surveyor that the referral was forwarded to the Program Integrity Unity at Iowa Medicaid Enterprise (IME). The Exclusions and Sanction Manager at IME informed the surveyor that a review was conducted in December 2021 and forwarded to Amerigroup. Amerigroup requested and was granted permission by IME to pursue a recoupment from A New Leaf in the amount of $2,484.88 for services rendered by non-licensed/non-certified staff who provided said services. The Department requested A New Leaf provide a summary response addressing the program's adherence to previous items of non-compliance. For this particular item, the program responded that the program "does not provide email based therapy, including treatment services consisting of e-mail communications." The surveyor did not find evidence in patient records review to suggest the program was continuing with this practice, however one patient noted on a satisfaction survey that "the part that was least helpful is that I cannot contact the counselor through the phone if I would need to, even if there is email, but sometimes phone call is better." The surveyor reviewed the program's website where it was noted, "You do not need any special equipment to access the e-Therapy program, these services can be provided, via telephone, *email*, or secure video conferencing." Although the patient records did not contain email correspondences documented as treatment services, the program's website and patient satisfaction survey comments suggested therapy services, provided via email, may still be occurring. It is unknown if the program is continuing to offer therapy services via email or whether the website contains incorrect information. As a result, the Department is unable to determine compliance with the corrective action plan.

FINDING: Undetermined

- ***Treatment services primarily consist of email communications.*** In the complaint investigation report, it was determined that the program had continued to deliver health care services through email communications despite direct guidance from the Department that "telehealth services means the delivery of health care services through the use of interactive audio and video, and does not include the delivery of health care services through an audio only telephone, electronic mail message, or facsimile transmission."

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the response noted the program was not providing email based therapy, including treatment services consisting of email communications. The surveyor did not find evidence in patient records review to suggest the program was continuing with this practice, however one patient noted on a satisfaction survey that "the part that was least helpful is that I cannot contact the counselor through the phone if I would need to, even if there is email, but sometimes phone call is better." The surveyor reviewed the program's website where it was noted, "You do not need any special equipment to access the e-Therapy program, these services can be provided, via telephone, email, or secure video conferencing." Although the patient records did not contain email correspondences documented as treatment services, the program's website and patient satisfaction survey comments suggest services, provided via email, may still be occurring. It is unknown if the program is continuing to offer therapy services via email or whether the website contains incorrect information As a result, the Department is unable to determine compliance with the corrective action plan.
FINDING: Undetermined

- ***Patients were billed for unexpected charges.*** In the complaint investigation report, it was determined that patients were being billed for unexpected charges for late submissions of treatment plan assignments. These charges were being submitted as "no call/no show fees".

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted a "Schedule of Service Fees" is located in the patient handbook which is provided to the patient at the time of the evaluation and receipt of this is documented in the patient record. The surveyor reviewed ten patient records and found that all records contained evidence that the patients had received the schedule of service fees which was included in the client handbook. The surveyor did not find evidence in patient records that patients were billed for submitting late assignments. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***Email communications relating to the patient were not included in the patient record.*** In the complaint investigation report, it was determined that email communications relating to patients were not included in the patient record.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program reported emails from and to patients were now placed in the patient's collaborative note section in the electronic health record. The surveyor reviewed ten patient records and found evidence that email correspondences were maintained in the patient records. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***Treatment is not individualized and is based on fixed (six sessions) of service.*** In the complaint investigation report, it was determined that treatment was not individualized and was based on a fixed length (six sessions) of service.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted it provides individualized care to patients with a number of sessions determined on a patient by patient basis. It was further noted that the patient's counselor determines the number of sessions based on the ASAM criteria and how the patient is progressing through their treatment plan. The surveyor requested the program submit a patient list to include dates of assessment and discharge. In reviewing this list, the surveyor determined that, although many patients received approximately six weeks of treatment, the length of treatment was not the same for every patient. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***Treatment plans are not developed collaboratively between patient and staff, and treatment plan reviews are not being conducted.*** In the complaint investigation report, it was determined that treatment plans were not developed collaboratively between patient and staff, and treatment plan reviews and revisions were not being conducted.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the treatment plan is developed collaboratively with the patient and is reviewed with the patient at least every 30 days or whenever clinically indicated and documented in patient progress notes. The surveyor reviewed ten patient records, three of which would have required a treatment plan. Although there was not documented evidence that the patient participated in the development of the treatment plan, the treatment plans included goals that aligned with each patient's assessed needs. One of the three treatment plans did not include a documented review or revision in the treatment plan. In this record, it was noted that the patient had a long term goal to stop use of alcohol, yet progress notes focused on the patient's marijuana use. This same record noted a short term goal to identify any patient weakness or unmet needs that may be challenging in sobriety. There were no other revisions made to the treatment plan even when progress notes documented new issues were identified during treatment. Although the Department finds the program to be in general compliance with the corrective action plan, it is recommended that A

New Leaf include documentation in the patient record that the patient participated in development of treatment plan goals and to revise treatment plans when clinically indicated.
FINDING: Compliance

- ***Unqualified staff, to include an 18 year-year-old high school student, provided licensed substance use disorder treatment services.*** In the complaint investigation report, it was determined that unqualified staff, to include an 18-year-old high school student, provided licensed substance use disorder treatment services.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the credentials and qualifications of all staff have been reviewed by the Executive Director, Jennine Seede. It was also noted that a checklist is located in each personnel file under the "General File Matters" section and applicable licenses, certificates, school transcripts, diplomas, etc. are also maintained in personnel records. The surveyor reviewed all personnel records for A New Leaf. Of the four personnel records, only the contracted Clinical Director, Stephen Steine, was licensed and certified. The remaining three staff were in the process of becoming licensed or certified to meet the qualifications of an addictive disorder professional. During the course of the follow up inspection, Jennine Seede became certified through Iowa Board of Certification (IBC) on December 1, 2021. Pursuant to 614 IAC 155.21(8)"b"(1)"6", staff, who are not deemed qualified, must be certified or licensed within two years of the date on which the person began to provide licensed program services. Ms. Seede began providing licensed program services on October 10, 2018 and became IBC certified almost four years later. The Department finds the program to be in partial compliance as Ms. Seede was not certified within the two year required time frame, but has since become certified. A review of all other personnel records, shows staff are currently on track to becoming certified within the two year required time frame.
FINDING: Partial Compliance

- ***Notification was not provided to the Division regarding change in clinical oversight.*** In the complaint investigation report, it was determined A New Leaf did not provide timely notification of a change in clinical directors.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted that Stephen Steine continues to serve as the clinical director and there had been no changes to clinical oversight since the approval of the corrective action plan. Through the surveyor's inspection of the program, it was confirmed there had been no changes in clinical oversight. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***Lack of clinical oversight.*** In the complaint investigation report, it was determined the program had no licensed or certified staff on site to provide clinical oversight and that there were inconsistent staff meetings without any direct supervision of clinical activities.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the clinical director, Stephen Steine, holds regular oversight meetings, for which A New Leaf maintains documentation. It was further noted that Mr. Steine sends invitations for ongoing Zoom meetings every other week, and that Ms. Seede maintains the meeting minutes. Upon request, the program submitted clinical oversight meeting minutes to the surveyor. The surveyor found evidence that the clinical director regularly conducted clinical supervision meetings with appropriate minutes maintained. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

2020 Licensure Inspection Report Violations:

The following includes each rule violation cited from the December 17, 2020 inspection report along with the current 90 day follow up inspection findings for the corrective action plan adherence.

- ***641 IAC 155.17 License Revision.*** The program did not submit a written request to the division at least 30 days prior to a change in clinical oversight staff. This was noted as a violation of the terms and Consent Agreement DIA NO: 20DPH0008.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted that Stephen Steine continues to serve as the clinical director, and there had been no changes to clinical oversight since the approval of the corrective action plan. Through the surveyor's inspection of the program, it was determined that there had been no changes to the clinical oversight staff. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(3) Clinical Oversight.*** The program did not have a designated treatment supervisor to oversee the provision of licensed program services. This was noted as a violation of the terms and Consent Agreement DIA NO: 20DPH0008.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the clinical director, Stephen Steine, holds regular oversight meetings, for which A New Leaf maintains documentation. It was further noted that Mr. Steine sends invitations for ongoing Zoom meetings every other week, and that Ms. Seede maintains the meeting minutes. Upon request, the program submitted clinical oversight meeting minutes to the surveyor. The

surveyor found evidence that the clinical director regularly conducted clinical supervision meetings with appropriate minutes maintained. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(5)"c". Staff Development and Training.*** The program's personnel records did not contain documentation that staff completed orientation with the required elements. This was noted as a violation of the terms and Consent Agreement DIA NO: 20DPH0008

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the personnel files were reviewed and updated and included documentation of staff orientation. The surveyor reviewed all personnel records for A New Leaf and found all four records contained evidence of an orientation with all required elements. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(5)"e". Staff Development and Training.*** The program did not document on-site training.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted A New Leaf has not had any on-site training, and that any future trainings would be documented as described in the corrective action plan. The surveyor's inspection found no evidence that on-site training had occurred. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(7)"b". Fiscal Management.*** The program did not have policies and procedures to ensure proper fiscal management and did not submit an annual fiscal audit.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program had updated its fiscal management policies and that a fiscal audit would be submitted as required. The surveyor reviewed the program's fiscal management policies and found the policies to be in compliance. The program also submitted a fiscal audit for 2019 and 2020 to the Division on May 17, 2021. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(8)"b". Personnel.*** The program did not have written job descriptions for each staff position and the program did not review job descriptions when there was a change in a staff position.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted written job descriptions were reviewed and updated, and that personnel records contained copies of each staff member's job description. It was further noted that there had not been any changes to existing staff member's positions since the corrective action plan was implemented. The surveyor reviewed personnel records and each record contained updated job descriptions. The Department finds the program to be in compliance with the corrective action plan.

FINDING: Compliance

- ***641 IAC 155.21(8)"c". Personnel.*** The program did not have annual written performance evaluations for each staff member. This was determined to be an area of non-compliance at prior inspections as well.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted a standardized form was used to complete annual performance reviews for each staff member, which was documented in personnel records. It was further noted that staff had an opportunity to comment at the time of their performance review. The surveyor reviewed personnel records, and two of the records would have required a performance review to be documented. Both records did contain completed performance reviews within the required annual timeframe. Both performance reviews included opportunities for the staff to provide comments. The Department finds the program to be in compliance with the corrective action plan.

FINDING: Compliance

- ***641 IAC 155.21(8)"d". Personnel.*** Personnel records did not include verifications of training, experience, and or professional credentials.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted personnel files were reviewed and confirmed compliance for documented credentials required for the position held by each staff. It was also noted that there had been no changes to staffing since the submission of the corrective action plan. The surveyor reviewed all personnel records. Of the four records, the only staff person credentialed was the clinical director. The clinical director's personnel record did contain verification of professional credentials. The Department finds the program to be in compliance with the corrective action plan.

FINDING: Compliance

- ***641 IAC 155.21(10)"f" Patient Records.*** Patient records were not in compliance with 42 CFR Part 2. Patient consents to disclose substance use disorder treatment information did not

contain patient signatures; were not limited to the amount and kind of information to be disclosed; and required sections of the consents were left blank.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program "only accepts ink-signed release forms and the forms used by A New Leaf have been revised." The surveyor reviewed ten patient records. Nine of the ten records contained consents that remained in non-compliance with 42 CFR Part 2. The surveyor found consents were not limited in the amount and kind of information to be disclosed and did not specify substance use disorder treatment information to be released to third parties. The surveyor also found a typed versus actual patient signature on a consent to disclose information to third parties. The Department finds the program to be in non-compliance with the corrective action plan.

FINDING: Non-Compliance

- ***641 IAC 155.21(11)"b" Assessment and Admission.*** The program did not implement a uniform assessment process with the information gathered. Several patient records did not contain a thorough drug use history.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program continues to obtain patient drug use history at the time of the evaluation and additional revisions were made to policies and procedures. The surveyor reviewed ten patient records, all of which contained thorough drug use histories. The Department finds the program to be in compliance with the corrective action plan.

FINDING: Compliance

- ***641 IAC 155.21(11)"e" Assessment and Admission.*** The program did not inform patients of the costs to be borne by the patient, the program service hours, or safety and emergency procedures.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted a patient handbook is provided to the patient at the time of admission, and this handbook contains the required elements. The surveyor reviewed program policies and procedures, which also noted that upon admission the patient would be informed of the required elements, and that this would be documented in the patient record. The surveyor also reviewed the patient handbook and found all required admission orientation information was included in the handbook. The surveyor also reviewed ten patient records, three of those were admitted to treatment and would have required to be informed of the orientation information. The surveyor had difficulty finding this evidenced in two of the three records. Some records noted that not all paperwork was signed due to COVID but it was not clear if this paperwork included the patient handbook. As it was difficult to determine whether all patients were provided with a copy of the

patient handbook, the Department finds the program to be in partial compliance with the corrective action plan.
FINDING: Partial Compliance

- ***641 IAC 155.21(12)"b" Treatment Plans.*** Treatment plans did not minimally contain a summary of assessment findings; the type of frequency of planned treatment activities; the staff responsible for the patient's treatment; or culturally and environmentally specific considerations.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program utilizes a treatment plan template that was approved by the Department and includes the requirements. The surveyor reviewed ten patient records, three of which were patients admitted to treatment and would have required a treatment plan. All three records did contain treatment plans with the required elements. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(12)"c" Treatment Plans.*** Treatment plans were not developed in partnership with the patient; copies of treatment plans were not provided to patients; nor were treatment plan reviews conducted in accordance with the time frames specified in the management-of-care review process.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program utilizes a treatment plan template that was approved by the Department and includes the requirements. Of the ten records that the surveyor reviewed, three of those were admitted to treatment and would have required a treatment plan. Although there was no documented evidence that the patient participated in the development of the treatment plan, the treatment plans included goals that aligned with each patient's assessed needs. One of the three treatment plans did not include a documented review or revisions in the treatment plan. In this record, it was noted that the patient had a long term goal to stop use of alcohol, yet progress notes focused on the patient's marijuana use. This same record noted a short term goal to identify any patient weakness or unmet needs that may be challenging in sobriety. There were no other revisions made to the treatment plan even when progress notes documented new issues were identified during treatment. Although the Department finds the program to be in general compliance with the corrective action plan, it is recommended that A New Leaf include documentation in the patient record that the patient participated in development of treatment plan goals and to revise treatment plans when clinically indicated.
FINDING: Compliance

- ***641 IAC 155.21(12)"d" Treatment Plans.*** Treatment plan reviews were not documented in the patient record. This was determined to be an area of non-compliance at prior inspections as well.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program documents the treatment plan activities in the patient record. For the ten patient records the surveyor reviewed, three of those were admitted to treatment and would have required a treatment plan. All 3 records did include documentation in the patient record of treatment plan reviews The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(14)"a" Patient Record Contents.*** Patient records did not contain results of laboratory tests or correspondences related to the patient, to include electronic communications.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program stores laboratory results and email communications in the patient record. The surveyor reviewed ten patient records and found evidence that laboratory test results and email communications were maintained in patient records. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(15)"c" Drug Screening.*** The program did not comply with the Clinical Laboratory Improvement Act (CLIA) requirements for on-site drug screening.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the program outsources all drug testing. The surveyor reviewed ten patient records and found that the program utilized a College of American Pathologists approved laboratory for its drug testing. The program does not appear to be conducting on site drug testing that would require a CLIA waiver. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(19) Management of Care and Discharge Planning.*** The program did not utilize The ASAM Criteria for continued service and discharge decisions.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted individualized care is provided to patients with the number of sessions

determined on a patient-by-patient basis and The ASAM Criteria is utilized for all admission, continued stay, and discharge decision making. The surveyor reviewed ten records and found appropriate use of The ASAM Criteria for determining continued stay and discharge decisions. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(19)"a" Management of Care and Discharge Planning.*** The program did not conduct care coordination to meet patient needs and promote effective outcomes.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted referrals are provided to meet the needs of the patients, and the referrals and communications with other agencies are maintained in the patient record. The surveyor reviewed ten patient records and found several consents to disclose information for referral purposes. In addition to patient records, the surveyor also found evidence of care coordination being conducted through a review of clinical oversight notes. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(19)"b" Management of Care and Discharge Planning.*** The program did not conduct management-of-care activities within the timeframes required for outpatient level of care. This was determined to be an area of non-compliance at prior inspections as well.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted continued stay ASAM reviews were completed at least every 30 days from the date of admission and every 30 days thereafter until the date of discharge. The surveyor reviewed ten patient records and three of those records would have required ASAM continued stay reviews. Of those three records, one record had two ASAM reviews that were untimely. Department finds the program to be in non-compliance with the corrective action plan.
FINDING: Non-Compliance

- ***641 IAC 155.21(19)"d" Management of Care and Discharge Planning.*** The program did not conduct discharge planning to include determining the patient's continued need for licensed program services and development of a plan to address ongoing patient needs post discharge. This was determined to be an area of non-compliance at prior inspections as well.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted discharge planning was documented in progress notes and in ASAM reviews by using language that clearly describes the plan to address ongoing patient needs before discharge can occur. It was also noted that post-discharge planning is discussed with the patient prior to

discharge and documented in the patient's progress note and ASAM review. The surveyor reviewed ten records and three of those records would have required discharge planning. All three records contained evidence of discharge planning documented in the progress notes. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

- ***641 IAC 155.21(20)"f" Quality Improvement.*** The program did not evaluate the effectiveness of the quality improvement plan at least annually.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the effectiveness of the quality improvement plan was documented annually and revised when appropriate. It was further noted that "a cover page has been prepared to accompany the quality improvement plan to document evaluation and revision." The surveyor reviewed the program's quality improvement plan. The plan noted a procedure to review the indicators and monitors quarterly and to make recommendations for change when indicated. The indicators and monitors included reviewing medical records for regulatory compliance. The surveyor also reviewed the cover page which included the program evaluation along with any revision to the quality improvement plan. The cover page noted the quality improvement plan was evaluated on August 16, 2021, and it was noted the plan was "adjusted to reflect changes made to the treatment plan form." The surveyor's review of the evaluation did not clearly show an evaluation of the effectiveness of the plan; rather it simply noted a date and a change to a form. Although the Department finds the program to be in general compliance with the corrective action plan, it is recommended that the program thoroughly document the evaluation of the quality improvement plan to detect trends, patterns of performance, and potential problems that affect patient care and program operations.
FINDING: Compliance

- ***641 IAC 155.25(1) OWI Evaluations.*** The program did not collect information on the patient's family history of substance abuse. This information is required in accordance with 641 IAC chapter 157.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted the patient's family history of substance abuse, blood alcohol content, history of arrests, history of mental health, and any information regarding prior OWI arrests are obtained from the patient at the time of the evaluation and documented in the patient record. The surveyor reviewed ten records and five of those records were OWI evaluations where family history of substance abuse was not assessed until after admission. To be in compliance, this information is required to be collected and documented at the time of the assessment/evaluation. The Department finds the program to be in non-compliance with the corrective action plan.
FINDING: Non-Compliance

- ***641 IAC 155.38(3) Baseline TB Screening Procedures for Facilities.*** The program did not have evidence that staff received a baseline TB screening upon hire.

For the 90 day follow up, the Department requested A New Leaf provide a summary response addressing the program's adherence to previous areas of non-compliance. For this item, the program noted all staff have documentation in their personnel records of TB test results. It was also noted that there has been no changes in staffing since the approval of the corrective action plan. The surveyor reviewed all personnel records and found evidence of TB test results in all records. The Department finds the program to be in compliance with the corrective action plan.
FINDING: Compliance

RECOMMENDATIONS:
The Department determined, the program demonstrated the following compliance after the 90 day corrective action plan implementation time frame:

2021 Complaint investigation rule violations

- ***6 of 9 corrective action plans are in compliance.***
- ***1 of 9 corrective action plans are in partial compliance.***
- ***0 of 9 corrective action plans are in non-compliance.***
- ***2 of 9 corrective action plans have undetermined compliance findings.***

2020 Licensure Inspection Report Violations:

- ***19 of 23 corrective action plans are in compliance.***
- ***1 of 23 corrective action plans are in partial compliance.***
- ***3 of 23 corrective action plans are in non-compliance.***

As the Department finds A New Leaf to be in compliance/partial compliance with 27 of the 32 corrective action plan measures, the Department recommends the Committee not proceed with the denial and recommends a two year license be issued with effective dates from July 7, 2020 to July 7, 2022, contingent upon the program's adherence with the following:

- Submission of a corrective action plan addressing all current findings of non-compliance (3 items), partial compliance (2 items), and undetermined (2 items) within 30 days of the Committee's approval of the recommendations. The corrective action shall have Department approval.

- The program shall submit required re-application materials to seek a subsequent license. Upon receipt of the re-application materials, the Department shall inspect the program to verify application information and determine compliance with all law, rules, and regulations.

Failure to adhere with any of the above recommendations will be grounds for denial of a license pursuant to rule 641–155.10(1)(d)(16) and will result in the Committee reconvening to determine to deny, suspend, or revoke the program's license pursuant to rule 641–155.11(3). If the

Committee determines, at that time, to deny, suspend, or revoke the program's license, the program shall be given written notice by restricted certified mail and may request a contested case hearing on the determination.