

**NC DHHS – NC DMH/DD/SAS
Outpatient Opioid Treatment Program (MH/DD/SA)
Endorsement Check Sheet Instructions**

Introduction

Prior to site and service endorsement, business verification must take place. In the process of business verification, the business information presented on the DMA CIS (Community Intervention Services) application is validated. At that time, the provider organization submits a self study of the core rules (10A NCAC 27G .0201-.0204) verifying that they have met all the requirements therein. (The provider is not required to submit this if nationally accredited, licensed with DFS or has had a compliance review from NC Council of Community Programs within the past three years.) The documents created in adherence with the core rules should be utilized as evidence of provider compliance where noted in the check sheet and instructions.

The following set of instructions is to serve as general guidelines to facilitate the review of providers for endorsement. Service definition, core rules (as noted above), staff definitions (10A NCAC 27G .104) and other DHHS communications (e.g. Service Records Manual, Communication Bulletins, Implementation Updates and other publications) should be used to support the reviewer's determination of compliance. In addition, the Business Entity Type Reference document (attached) assists to clarify the requirements for different business entities such as corporations, partnerships and limited liability corporations and partnerships.

Provider Requirements

In this section, the provider is reviewed to ascertain that requirements are met in order for services to be provided. The provision of services is addressed later in this endorsement process.

a.(1). Review identified documents for evidence that provider meets DMH/DD/SAS and/or DMA standards as related to administration responsibilities, financial oversight, clinical services and quality improvement. These standards include, but are not limited to, policies and procedures (contents of which are mandated in 10A NCAC 27G .0201 – Governing Body Policies) and the key documents required by law for the formation of the business entity. (Refer to attachment titled Business Entity Type.) If the provider organization has met these criteria during the initial review for endorsement, this information does not need to be reviewed again. However, you must verify that there has been no change in the organization's business status and no change within the organization that might effect its operation.

a. (2). The policy and procedure manual should contain language indicating intent to have national accreditation within three years of their enrolment with DMA. Review DMA enrollment document to verify provider's date of enrollment. Once the provider has been enrolled with DMA for a period of three years, a certification of national accreditation or some other evidence supporting the provider organization's achievement of national accreditation must be produced and validated.

a.(3). Review documentation that demonstrates provider is a legal U.S. business entity. Documentation should indicate the business entity is currently registered with the local municipality **or** the office of the NC Secretary of State, that the information registered with the local municipality **or** the Secretary of State is current, and that there are no dissolution, revocation or revenue suspension findings currently attached to the provider entity. Also review

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corporate documentation demonstrating registration to operate a business in NC. Information for corporate entities may be verified on the web site for the Secretary of State. (Refer to key documents section of attachment titled Business Entity Type.)

Staffing Requirements

In this section, the reviewer is primarily concerned with the hiring practices of the provider and ensuring that all employees in place are equipped with the education, training and experience to work with the population served in the capacity and at the level of intervention for which they were hired. The review of the provision of services is more thoroughly examined in the “Program/Clinical Requirements” section of the endorsement review.

a. Policy and procedure manuals, program descriptions, and job descriptions specify the intent that the staff will meet the requirements specified in NCAC 27G.3603. Individuals administering medication are required to be a pharmacist, registered nurse, licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs (Note: In the vast majority of cases, this individual will be an LPN or RN). Individuals providing counseling must be licensed, certified, or registered with the NC Substance Abuse Professional Practice Board. If the individual is registered, there should be a current supervision contract documenting that this individual is receiving the approved supervision allowing them to practice.

Review employment application, resume, license, certification, or other documentation for evidence that individuals administering medication hold a valid license as a registered nurse, licensed practicing nurse, pharmacist, or other health professional authorized to administer or dispense opioid drugs (Note: in the vast majority of cases this individual will be an LPN or RN). Review documentation for evidence that persons providing counseling services are registered, certified, or licensed by the North Carolina Substance Abuse Professional Practice Board.

b. Policy and procedure manuals, program descriptions, and job descriptions specify the intent that the program will have a licensed physician in the position of medical director and that the program will be under the medical supervision of this individual. Review employment application, resume, license, certification, or other documentation for evidence that the program has a licensed physician in the role of medical director and that the program will be under the medical supervision of this individual.

c. Policy and procedure manuals, program descriptions, and/or job descriptions that specify the intent that there will be one full-time counselor for every fifty consumers in the opioid treatment program. Review employment application, resume, license, certification, or other documentation for evidence that the opioid treatment program has employed one full-time counselor for every fifty consumers enrolled in the program.

Service Type/Setting

The elements in this section pertain to the provider’s having an understanding that Opioid treatment is a periodic service for adults who require medication assisted treatment to achieve and sustain recovery. This service emphasizes abstinence from opiates as well as a abstinence or

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reduction in use and abuse of substances, fewer negative consequences of substance abuse, development of social support network and necessary lifestyle changes; educational skills, vocational skills leading to work activity, social and interpersonal skills, improved family functioning, the understanding of addictive disease, and the continued commitment to a recovery and maintenance program.

a. and b. Policy and procedure manuals, program descriptions, and/or medical records for documentation that specifies the intent that all consumers admitted to opioid treatment will document at least one year of opioid drug addiction. Review consumer medical records for documentation that all consumers admitted to opioid treatment have had at least one year of opioid drug addiction documented in the medical record.

Program Requirements

The elements in this section are reviewed as they pertain to service delivery. It is important that consumers are served in accordance with the service definition according to individual needs.

a. Before an Opioid Treatment Program (OTP) can open for business, it must be licensed under 10A NCAC 27G.3600 (Outpatient Opioid Treatment). Review documentation to verify that the program is licensed as an Outpatient Opioid Treatment Program under 10A NCAC 27G.3600.

b. Before an Opioid Treatment Program can open for business, the program must be in compliance with the Substance Abuse and Mental Health Services Administration (SAMHSA) federal opioid treatment program regulations found in 42 CFR Chapter 1, Subchapter A, Part 8 (Certification of Opioid Treatment Programs), Subpart B (Certification and Treatment Standards) (8.11 - 8.15). The OTP must also be in compliance with the Drug Enforcement Administration (DEA) regulations and must be DEA and shall comply with all Drug Enforcement Administration regulations pertaining to Opioid Treatment Programs codified in 21 CFR, Food and Drugs (Part 1300 to end). Review documentation to verify that the OTP has been certified by SAMHSA to operate as an outpatient Opioid Treatment Program and has the required DEA controlled substance license.

c. Opioid Treatment Programs are required to be in compliance with the State Opioid Authority. In North Carolina, all of the State Opioid Authority requirements are contained in the DFS license as an Opioid Treatment Program, the SAMHSA certification to operate as an Opioid Treatment Program, the North Carolina controlled substance license, and the DEA controlled substance license. Therefore, if the OTP has each of these licenses or certifications, they are in compliance with the North Carolina State Opioid Authority.

d. Policy and procedure manuals and program descriptions should specify the intent that consumers must have ready access to evaluation and treatment services when warranted by the presence of symptoms indicating a co-occurring condition such as a mental health or medical illness. There should also be documentation of the OTP's intent to provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. Review consumer medical records for documentation that consumers have had ready access to evaluation

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and treatment services when warranted in that the program either provided or procured the following services:

- (1) individual, group or family therapy for each client;
- (2) educational counseling;
- (3) vocational counseling;
- (4) job development and placement;
- (5) money management;
- (6) nutrition education; and
- (7) referrals to supportive services including Alcoholics Anonymous, Narcotics Anonymous, legal counseling, vocational training and placement.

e. Policy and procedure manuals and program descriptions should specify the intent that consumers will have a minimum of two counseling sessions per month during the first year of treatment and a minimum of one counseling session per month thereafter. There will also be documentation of biochemical assays (drug tests) performed at least monthly on a random basis to identify if recent drug use has occurred. Review consumer medical records for documentation that consumers have had a minimum of two counseling sessions per month during the first year of treatment and a minimum of one counseling session per month thereafter. There should be documentation of biochemical assays (drug tests) performed at least monthly on a random basis to identify if recent drug use has occurred.

f. Policy and procedure manuals and program descriptions should specify the OTP will operate 6 days a week 12 months a year. Review consumer medical records, dosing records, and/or other records to document that the OTP operated six days a week 12 months a year.

g. Policy and procedure manuals and program descriptions should specify that consumers receiving methadone will not have an initial dose exceeding 30mg and the total dose for the first day will not exceed 40mg. Review consumer medical records and/or dosing records for documentation that consumers receiving methadone were given an initial dose that did not exceed 30mg and their total dose for the first day did not exceed 40mg..

h. Policy and procedure manuals and program descriptions should specify policies and procedures that reflect the special needs of patients who are pregnant and that prenatal care and other gender specific services for pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers. Review consumer medical records and/or other records for documentation and that prenatal care and other gender specific services for pregnant patients were provided either by the OTP or by referral to appropriate healthcare providers.

i. Policy and procedure manuals and program descriptions should specify that the OTP will maintain procedures to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. OTP's must also document the intent to ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers. Review policies and procedures, program descriptions, medical records, and other records that document that the OTP has procedures to identify the theft or diversion of take-home

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medications. Inspect the containers for take-home medication to ensure that the OTP's name, address, and telephone number are on each container and that the container is childproof (designed to reduce the risk of accidental ingestion).

j. Policy and procedure manuals and program descriptions should specify that the OTP will maintain procedures to ensure that clients are not dually enrolled by means of direct contact or a list exchange with all Opioid Treatment Programs within at least a 75-mile radius of the admitting OTP. Review policies and procedures, program descriptions, medical records, and other records that document the OTP has contacted all other Opioid Treatment Programs within at least 75-mile radius to ensure that no consumer is enrolled at more than one OTP.

Documentation Requirements

Review in policy and procedure manuals and program descriptions for language demonstrating that documentation for opioid treatment services will have, at a minimum, a daily record of dosing including a record of all take home doses prepared. For each counseling session, there should be a full service note that includes: 1) the purpose of contact, 2) describes the provider's interventions, 3) includes the time spent performing the interventions 4) effectiveness of the intervention, and 5) the signature (degree/credentials or position) of the person providing the service. All other clinically significant contacts with the client must also be recorded in the medical record. The documentation should indicate that Incident Reports will be completed per requirements and that the OTP will complete NCTOPPS forms as required. Review consumer medical records and other records for the same.