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Policy Title:	Opioid Dependence Treatment Program
Department:	Family Medicine – Pharmacotherapy
Effective Date:	
Approved By:	_____ **TITLE:**
Last Date Reviewed:	

I. Purpose

Opioid dependence is a chronic medical condition for which patients need ongoing treatment and support. As primary care providers, MAHEC providers are able to help patients access the treatment they need for opioid dependence within their medical home. The MAHEC Opioid Dependence Treatment Program (ODTP) was created in 2015 to provide patients with access to treatment of substance use disorder within their primary care home.

II. Scope

This policy & procedure applies to MAHEC patients who have a diagnosis of opioid dependency, request treatment for their substance use disorder through MAHEC's ODTP, and meet the eligibility criteria as described in this policy.

III. Responsibility

The ODTP Faculty Physician Lead (Blake Fagan), ODTP Director (Courtenay Wilson), ODTP APP (Carriedelle Fusco), ODTP Coordinator (TBD), and ODTP scheduler (Monica Gonzalez) are responsible for this procedure. Other ODTP team members include: Faculty physicians with their DATA 2000 waivers, PGY3 residents, behavioral medicine faculty, pharmacy faculty, medical assistants, and schedulers.

IV. Definitions

SOWS-Subjecive opiate withdrawal scale

Monotherapy Formulation-buprenorphine without naloxone, Subutex®

V. General

1. Patient Eligibility

- Established MAHEC patient, compliant with provider's plan of care for a minimum of three visits including initial ODTP intake visit.
- 18 years old or older.
- Meets the criteria for opioid dependence based on DSM V.
- Taking no more than 16mg/d of buprenorphine. If taking >16mg/d, must be willing to attempt to decrease to 16mg/d.
- No concurrent abuse of other medications or illicit substances or willing to discontinue use.
- Consents to required screens at initial consultation visit including but not limited to urine drug screen, alcohol screen, check of NCCSRS report.
- Signs Patient Consent and Patient Agreement.
- In good financial standing with MAHEC.

Conditions That Would Preclude a Patient as a Candidate for MAHEC's ODTP:

- Codependence on high doses of benzodiazepine or alcohol.
- Untreated mental health illness.
- Poor response to numerous previous well conducted attempts of buprenorphine treatments.
- Significant medical complications (especially end stage pulmonary diseases).
- Inability to follow treatment requirements.
- Physician discretion.

2. Initial Consultation Visit

All potential patients must have an initial consultation visit with the ODTP APP and/or ODTP Coordinator to determine if the patient meets the eligibility criteria. **No buprenorphine prescriptions will be given at the initial consultation visit.**

Components of the Initial Consultation visit:

- Education on opioid dependence and buprenorphine/naloxone treatment.
- Overview of the ODTP structure and expectations.
- Sign Patient Agreement and Consent for Treatment.
- Intake history.
- Urine drug screening (Dominion for initial ODTP visit).

- LFT's, hepatitis panel, HIV, Cr, urine hcg (females only).
- Review of North Carolina Controlled Substance Reporting System report.
- Consent to speak and obtain records from current & prior providers.

3. **Determination of Eligibility**

Based on the Initial Consultation Visit, the ODTP Director will determine if the patient meets eligibility criteria for the MAHEC ODTP clinic.

If accepted into the program, FM Scheduling department will be notified by the ODTP Coordinator to contact the patient to schedule the first visit with their assigned buprenorphine prescriber.

If not accepted into the program, the ODTP APP, ODTP Coordinator, or patient's assigned Primary Care Provider (PCP) will call the patient to explain why they were determined ineligible for enrollment in the program at this time.

4. First Visit with PCP

During the first visit, the PCP will assist the patient in developing goals for care, including duration of treatment, referrals to other support services, i.e. behavioral medicine, pharmacy, care management, etc.

5. Follow-up visits

To continue in the program, the patient must adhere to the treatment plan as outlined by the PCP.

If the assigned physician is not available, the patient is responsible for ensuring the ODTP visit is scheduled with the ODTP group. **No other physician may write for buprenorphine.** Refills will only be prescribed at clinic visits.

The patient is required to bring the buprenorphine/naloxone tablets/films to each visit. A drug screen and pill count will be performed at each visit. If the patient does not bring the medication, it will be considered an abnormal medication count.

Random pill/film counts and drug screens may be performed. If the patient fails to come to the clinic within 24 hours of notification of pill/film count and/or drug screen, this will be considered an abnormal count and drug screen.

6. Group Medical ODTP Visits

Group medical ODTP visits will be offered in the fall of 2016. These will be on Thursday afternoons. These will be facilitated by the ODTP Coordinator and buprenorphine prescriptions will be written by one of the ODTP physicians. All new patients will be required to attend the group medical visit at least once per month unless the primary ODTP physician determines otherwise. Existing patients as of September 2016, will be informed of the new group ODTP visit and will be encouraged to attend these visits as well.

7. Referral to more intensive treatment program

The physician may refer the patient to a more intensive treatment program for the following reasons:

- Ongoing opioid use despite adequate buprenorphine/naloxone dosing (no cravings, withdrawal and adequate narcotic blockage).
- Two unexpected drug screens.
- Failure to comply with random drug screens or pill counts.
- Ongoing abuse of higher doses of benzodiazepines, stimulants, or barbiturates causing impairment, sedation, overdose, medical illness, or hazardous unsafe behaviors despite interventions by the ODTP Team.
- Abuse of alcohol causing sedation, impairment, or hazardous unsafe behaviors despite interventions by the ODTP Team.
- Cocaine: Continued use despite intensifying treatment with more frequent ODTP visits and monitoring.
- Failure to follow agreed upon policies and procedures.

VI. Extended Leave Policy

If an ODTP patient has to be out of the area for more than 30 days they may be eligible for buprenorphine refills without being seen by a provider. If an ODTP patient is in "good standing", no aberrant drug screens or CSRS reports, and their PCP feels they are stable enough to miss some visits they can be provided with up to 3 months worth of prescriptions.

If an ODTP patient is going to be out of the area for longer than 90 days they will need to find a buprenorphine prescriber in the area they are visiting. MAHEC Family Health will provide the prescriber they locate with medical records to assist in this transition and will take the care back over once the patient has returned to their home area.

VII. ODTP Team Meeting

The ODTP team meets on the fourth Tuesday of the month. The goals for this meeting are:

- To review patients for eligibility following their initial ODTP visit
- To ensure all active patients are meeting the requirements outlined in the Policies and Procedures.
- To address operational issues that may arise (EHR, scheduling, etc).
- To discuss clinical cases and share lessons learned.

VIII. Patients with Pain

1. Acute Pain

Patients who are being treated for addiction also may experience pain due to illness or injury. Pain in patients receiving buprenorphine treatment for opioid addiction should be treated initially with non-opioid analgesics when appropriate. Once daily dosing of buprenorphine often does not provide sufficiently sustained relief of pain. If buprenorphine is dosed once daily, the administration can be changed to divided doses while maintaining the same total daily dose.

Patients maintained on buprenorphine whose acute pain is not relieved by non-opioid medications or split daily dosing may require the use of short-acting opioid pain relievers. In such cases, the administration of buprenorphine generally should be discontinued. Higher doses of the opioid agonist may be required until the buprenorphine clears from they patient's system (24-36 hours). Non-combination opioid analgesics are generally preferred to avoid the risk of acetaminophen toxicity when combination products are used at the doses that are likely to be required for pain control in patients who have been maintained on buprenorphine. Analgesic dose requirements should be expected to decrease as buprenorphine clears the body.

When restarting buprenorphine, to prevent acutely precipitating withdrawal, administration generally should not begin until sufficient time has elapsed for the opioid pain medication to have cleared from the patient's system, as demonstrated by the onset of early withdrawal (see Induction Protocol below).

2. Chronic Pain

Buprenorphine may provide analgesic benefit for patients with addiction and chronic pain. Split dosing is generally preferred to provide sustained pain relief. If the patient continues to experience pain with split daily dosing, methadone may be required, which must be provided in an OTP. MAHEC does not prescribe buprenorphine for pain in the absence of addiction. MAHEC does not prescribe methadone for pain when there is a picture of addiction as well.

IX. Induction Protocol

1. Identification of Patient

When a provider identifies a patient who is a potential candidate for induction onto buprenorphine, the provider will send a patient message to FM Initial ODTP clinic inbox for review. The ODTP Coordinator is responsible for managing this inbox. First, the ODTP Coordinator will determine if the patient meets the eligibility criteria. If so, then the ODTP

Coordinator, ODTP Director, and PCP will review the patient to determine if the induction should proceed. If the team agrees induction is in the patient's best interest, the ODTP Coordinator will notify the ODTP Scheduler to contact the patient to schedule the first visit with their assigned buprenorphine prescriber. If the team decide not to proceed with the induction, the ODTP Coordinator or PCP will notify the patient.

2. **Intake Visit**

The patient must complete an intake visit with the ODTP APP. The visit will include:

- Review of the induction protocol and the policies and procedures of MAHEC's ODTP.
- Education on buprenorphine including administration, dosing, potential side effects, and risks.
- Patient will be required to sign the consent for the induction and Patient Agreement.
- Patient will be given a prescription for two days' worth of buprenorphine/naloxone.

3. **Induction**

The goal of the induction is to find the minimum dose of buprenorphine at which the patient discontinues or markedly diminishes use of other opioids and experiences no withdrawal symptoms, minimal or no side effects, and no uncontrollable cravings for drugs of abuse.

There are three different induction protocols that will be used depending on the opioid of abuse. For all induction protocols, the process will be the same.

1) The patient will be scheduled with his/her assigned buprenorphine provider for at least two visits to begin the induction. The first visit must be on a Monday or Tuesday morning and the second visit must be the following day. The patient should also be scheduled for the group ODTP visit on Thursday afternoon the week of the induction.
2) The patient will bring the medication to clinic on the day of the induction.
3) The patient will remain in the exam room with the door open during the induction.
4) The medical assistant working with the physician will administer the SOWS as outlined in the protocol.

Protocol 1: **Conversion from short/immediate acting opioids**

Short Acting Opioids: Heroin; crushed Oxycontin; Immediate release formulations, including: Percocet, Vicoden, oxycodone, tramadol, etc.
Intermediate Acting Opioids: Oxycontin, other extended release formulations

Using TIP 40 induction protocol, Figure 4-1, proceed as follows:

Day 1:

1. Patient is instructed to take their last dose of opioid 12-24 hours before their induction visit. For intermediate acting opioids, period of abstinence should be 24 hours.
2. During the office visit the physician will assess the patient's status using the SOWS. The SOWS assessment will continue every 30 minutes until the SOWS is between 11-20 at which point the patient should be exhibiting early signs of opioid withdrawal (sweating, yawning, rhinorrhea, and lacrimation).
3. Once the SOWS is between 11-20, the physician will give the first dose of 2/0.5-4/1mg buprenorphine/naloxone. The patient will remain in the exam room and status will be monitored for two hours.
4. The MA will administer the SOWS two hours after the first dose and record the score on the flow sheet.
    a. If SOWS < 10, day one dose is established.
    b. If SOWS $\geq$ 10, repeat dose every two hours up to maximum 8/2mg for the first day.
        i. If SOWS remains $\geq$10 after the max dose of 8/2mg, consider managing withdrawal symptoms with clonidine, ondansetron, and/or NSAIDs.
    c. The total amount of buprenorphine administered in the first day should not exceed 8mg.

Day 2:

1. The MA will administer the SOWS and record the score in the flow sheet.
    a. If SOWS < 10, give the total dose administered in day one.
    b. If SOWS $\geq$ 10, give dose equal to the total amount of buprenorphine/naloxone administered on day one plus an additional 4/1mg.
    c. The patient will remain in the exam room and status monitored for two hours.
2. The MA will administer the SOWS two hours after the first dose.
    a. If SOWS < 10, day two dose is established.
    b. If SOWS $\geq$ 10, give dose an additional 4/1mg buprenorphine/naloxone. Repeat as needed every two hours until max dose of 16/4mg.
        i. If SOWS remains $\geq$10 after the max dose of 16/4mg, consider managing withdrawal symptoms with clonidine, ondansetron, and/or NSAIDs.
    d. The total amount of buprenorphine administered in the second day should not exceed 16mg.

Group Visit Day (Thursday, Day 3 or 4 of induction):

1. The MA will administer the SOWS and record the score in the flow sheet.
    a. If SOWS < 10, daily dose of buprenorphine/naloxone is established.
    b. If SOWS $\geq$ 10, give dose equal to the total amount of buprenorphine/naloxone administered on previous day plus an additional 4/1mg.
    c. The patient will remain in the exam room and status monitored for two hours.
2. The MA will administer the SOWS two hours after the first dose.
    a. If SOWS < 10, daily dose of buprenorphine/naloxone is established.
    b. If SOWS $\geq$ 10, give dose an additional 4/1mg buprenorphine/naloxone. Repeat as needed every two hours until max dose of 24/6mg.
        i. If SOWS remains $\geq$10 after the max dose of 24/6mg, consider managing withdrawal symptoms with clonidine, ondansetron, and/or NSAIDs.
    e. The total amount of buprenorphine administered should not exceed 24mg.

Week 2 and Beyond

1. Once the patient's daily dose of buprenorphine/naloxone is established, the patient should be seen weekly for 4 weeks and then monthly thereafter. These visits will preferably be conducted at the ODTP group visit. However, the patient may schedule individually with his/her physician at the physician's discretion.
2. If the patient has reached the maximum dose of buprenorphine/naloxone (24/6mg) and continues to have illicit opioid use, withdrawal symptoms, or compulsions to use, then the physician should increase intensity of nonpharmacological interventions, consider referral to OTP or other more intense level of treatment.

Protocol 2: Abstinence

Patients who are not physically dependent on opioids but who have a known history of opioid addiction, have failed other treatment modalities, and have a demonstrated need to cease the use of opioids, may be candidates for buprenorphine treatment. Other patients in this category would be those recently released from a controlled environment who have a known history of opioid addiction and a high potential for relapse.

These patients will not have withdrawal when they present since they are not currently opioid-dependent; thus, the SOWS does not guide dosing.

Day 1

1. The physician will administer 2/0.5mg of buprenorphine/naloxone.
2. The patient will remain in the exam room and status will be monitored for at least 2 hours.

Day 2

1. If patient has no illicit opioid use or compulsion to use, then daily dose of buprenorphine/naloxone is established.
2. If patient does have illicit opioid use or compulsion to use, the physician will administer 4/1mg of buprenorphine/naloxone.
    a. The patient will remain in the exam room and status will be monitored for at least 2 hours.

Group Visit Day (Thursday, Day 3 or 4 of induction):

1. If patient has no illicit opioid use or compulsion to use, then daily dose of buprenorphine/naloxone is established.
2. If patient does have illicit opioid use or compulsion to use, the physician will administer 6/1.5mg of buprenorphine/naloxone.
    a. The patient will remain in the exam room and status will be monitored for at least 2 hours.

Week 2 and Beyond

1. The patient should return to clinic every 2-3 days until the daily dose of buprenorphine/naloxone is established as evidenced by a lack of illicit opioid use or compulsion to use. The dose may be increased at an interval of 2/0.5mg daily to a maximum dose of 24/6mg.
2. Once the patient's daily dose of buprenorphine/naloxone is established, the patient should be seen weekly for 4 weeks and then monthly thereafter. These visits will preferably be conducted at the ODTP group visit. However, the patient may schedule individually with his/her physician at the physician's discretion.
3. If the patient has reached the maximum dose of buprenorphine/naloxone (24/6mg) and continues to have illicit opioid use, withdrawal symptoms, or compulsions to use, then the physician should increase intensity of nonpharmacological interventions, consider referral to OTP or other more intense level of treatment.

Protocol 3: Conversion from methadone

Patient must be on methadone dose of 30mg or less per day for a minimum of one week before initiating buprenorphine induction treatment. Patients should not receive buprenorphine until at least 24 hours after the last dose of methadone.

During the initial consultation visit, the ODTP Coordinator will receive signed consent to communicate with the patient's Opioid Treatment Program (OTP). The ODTP Coordinator will then contact the patient's OTP to determine the methadone dosage levels and time of last dose.

Using TIP 40 induction protocol, Figure 4-1, proceed as follows:

Day 1

1. Patient is instructed to take their last dose of methadone 24-36 hours before their induction visit.
2. During the office visit the physician will assess the patient's status using the SOWS. The SOWS assessment will continue every 30 minutes until the SOWS is between 11-20 at which point the patient should be exhibiting early signs of opioid withdrawal (sweating, yawning, rhinorrhea, and lacrimation).
3. Once the SOWS is between 11-20, the physician will give the first dose of buprenorphine 2mg. The patient will remain in the exam room and status will be monitored for two hours.
4. The MA will administer the SOWS two hours after the first dose and record the score on the flow sheet.
    a. If SOWS < 10, day one dose is established.
    b. If SOWS $\geq$ 10, repeat dose every two hours up to maximum 8mg for the first day.
        i. If SOWS remains $\geq$10 after the max dose of 8mg, consider managing withdrawal symptoms with clonidine, ondansetron, and/or NSAIDs.
    c. The total amount of buprenorphine administered in the first day should not exceed 8mg.

Day 2

1. On Day 2, the buprenorphine monotherapy should be switched to buprenorphine/naloxone.
2. The MA will administer the SOWS and record the score in the flow sheet.
    a. If SOWS < 10, give the total dose administered in day one.
    b. If SOWS $\geq$ 10, give dose equal to the total amount of buprenorphine administered on day one plus an additional 4/1mg.
    c. The patient will remain in the exam room and status monitored for two hours.
3. The MA will administer the SOWS two hours after the first dose.
    a. If SOWS < 10, day two dose is established.
    b. If SOWS $\geq$ 10, give dose an additional 4/1mg buprenorphine/naloxone. Repeat as needed every two hours until max dose of 16/4mg.
        i. If SOWS remains $\geq$10 after the max dose of 16/4mg, consider managing withdrawal symptoms with clonidine, ondansetron, and/or NSAIDs.
    f. The total amount of buprenorphine administered in the second day should not exceed 16mg.

Group Visit Day (Thursday, Day 3 or 4 of induction):

3. The MA will administer the SOWS and record the score in the flow sheet.
    a. If SOWS < 10, daily dose of buprenorphine/naloxone is established.
    b. If SOWS $\geq$ 10, give dose equal to the total amount of buprenorphine/naloxone administered on previous day plus an additional 4/1mg.
    c. The patient will remain in the exam room and status monitored for two hours.
4. The MA will administer the SOWS two hours after the first dose.
    a. If SOWS < 10, daily dose of buprenorphine/naloxone is established.
    b. If SOWS $\geq$ 10, give dose an additional 4/1mg buprenorphine/naloxone. Repeat as needed every two hours until max dose of 24/6mg.
        i. If SOWS remains $\geq$10 after the max dose of 24/6mg, consider managing withdrawal symptoms with clonidine, ondansetron, and/or NSAIDs.
    g. The total amount of buprenorphine administered should not exceed 24mg.

Week 2 and Beyond

4. Once the patient's daily dose of buprenorphine/naloxone is established, the patient should be seen weekly for 4 weeks and then monthly thereafter. These visits will preferably be conducted at the ODTP group visit. However, the patient may schedule individually with his/her physician at the physician's discretion.
5. If the patient has reached the maximum dose of buprenorphine/naloxone (24/6mg) and continues to have illicit opioid use, withdrawal symptoms, or compulsions to use, then the physician should increase intensity of nonpharmacological interventions, consider referral to OTP or other more intense level of treatment.