COVID-19 and Opioid Treatment

Guidance for the Field

The following information is meant to support opioid treatment programs (OTPs) relating to the corona virus (COVID-19) situation in Ohio. Our focus right now is implementing OhioMHAS’ emergency management plans and shoring up relationships that are increasingly important during this pandemic. These relationships are with our federal partners, other states, and local government entities. Our efforts at planning are aimed at supporting community providers and boards in meeting the needs of families, adults, and communities. We urge you to look at your own organizational and community planning and to connect with your local health departments to ensure that you are connected to information and strategies to support the Ohioans that you serve. As you consider your own business continuity plans, here are some helpful questions to guide your planning.

If you have additional questions, please email them to OTP_COVID19@mha.ohio.gov. We will update this document as needed and post updated versions on our OhioMHAS webpage.

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Reducing COVID-19 Transmission

How do we reduce transmission in our program facility?

- The Centers for Disease Control and Prevention has provided interim infection prevention and control recommendations in health care settings.
- Anyone with a respiratory illness (e.g., cough, runny nose) should be given a mask before entering the space.
- Provide hand sanitizer at the front desk and at each dosing window.
- Clean all surfaces and knobs several times each day with EPA-approved sanitizers.
- Provide educational pamphlets to patients and staff on how patients can respond to COVID-19.

Can we dose someone in a separate room if they present with a fever or cough?

Yes. Please develop procedures for OTP staff to take patients who present at the OTP with respiratory illness symptoms such as fever and cough to a location other than the general dispensary and/or lobby, to dose patients in closed rooms as needed. OTP staff should use interim infection prevention and control recommendations in health care settings published by the Centers for Disease Control and Prevention.

What guidance is there from Ohio and SAMHSA to provide patients with take-home dosing during this public health emergency?
For individual patient cases, please continue to submit exceptions through the SAMHSA [OTP extranet website](https://www.samhsa.gov). Consider communication outreach to patients through phone calls, emails, and signage onsite to let them know if they become sick to contact the OTP before coming onsite, so take-home approval can be prepared in advance for dispensing.

For large-scale, agency-wide policies to provide take-homes to large numbers of individuals, please submit a blanket exception request for your OTP through the SAMHSA OTP extranet website. For any blanket exception requests, OTP medical directors must also include details about agencies policies and procedures, including but not limited to, changes in urine drug screen frequency, changes in counseling frequency, rationale for changing phase requirements for each phase of treatment, and plans for handling patients in crisis and/or relapse situations. Any large-scale exception request must not be for more than a two-week period. Renewal of large-scale exception requests must be resubmitted shortly before the expiration of the current approved exception request. OTP medical directors must explicitly state detailed rationale for providing a renewal for these requests.

As per the State Opioid Treatment Authority of Ohio, here are the following courses of action approved by SAMHSA which an Ohio OTP may consider applying for via the SAMHSA OTP extranet website at this time relating to the Coronavirus public health threat in Ohio. Patients receiving any exemption must have naloxone personally furnished (not just prescribed) by your organization, or be able to show you, in person, that they have a naloxone unit that is not currently expired. Patients receiving take homes through this exception process must engage in one to two telehealth sessions per week with their OTP (e.g., through a mobile or landline device, not necessarily one that is video capable).

a. Blanket take home medication exceptions for patients with lab confirmed COVID-19 disease: As described above, patients with symptoms of a respiratory viral illness, with or without confirmation via COVID-19 viral testing, present an immediate risk to the rest of the population. Patients may receive up to two weeks of medication at the prescriber’s discretion. Patients who have fully recovered from COVID-19 are not eligible for additional exceptions, pending any research saying the patient can become re-infected.

b. For patients endorsing symptoms of a respiratory infection and cough and fever: They will be isolated and evaluated by a medical provider who will make a determination as to the safe number of take-home doses, taking into consideration the patient’s stability in treatment and ability to safely store and protect medication, not to exceed 14 days of medication.

c. Patients with significant medical comorbidities, particularly those patients over the age of 60, such as co-morbid chronic and severe pulmonary, cardiac, renal or liver disease, or immunosuppression, can be eligible for take-homes up to 7 to 14 days, at the discretion of a medical prescriber.

d. For select patients with only one take home (unearned) determined by the medical provider to be appropriate: These patients are eligible for a staggered take-home schedule, whereby half the OTP’s patients will present on Mondays, Wednesdays and Fridays, and the other half of OTP patients will present on Tuesday, Thursday, and Saturdays, with the remaining doses of the week provided as a take home would be appropriate. Patients should receive no more than two consecutive take homes at a time. This reduces the clinic’s daily census in half and has a tolerable risk profile. Patients are still evaluated frequently and do not receive more than 2 days of take-home medication at any one time, which often occurs during clinic-wide during long holiday weekends. Prescribers must be extremely careful with patients who have positive UDS for fentanyl or fentanyl analogues; additional take home exceptions are generally not recommended for these patients unless they meet the criteria of (a), (b), or (c).
e. Patients on buprenorphine: Ohio does not have any additional guidance for these patients because they are already permitted a 14-day supply of MAT during the first 90 days of treatment.

f. Unstable patients: Patients in any of the population categories above who are determined unstable or unsafe to manage take home doses should continue daily dosing in the clinic. Inability to safely take unsupervised medication due to a cognitive or psychiatric condition, or inability to keep a take-home dose of medication safe due to a chaotic living situation would be grounds for patients being deemed ineligible for this emergency take-home exemption. For these unstable patients who, for safety reasons, need to continue daily dosing, every precaution should be made to limit exposure from symptomatic patients and to medically fragile patients (No CSAT exemption required; follow the standard state OAC).

g. Patients not on a stable dose: Special considerations should be taken when patients are in the MAT induction phase or any phase in which they are increasing their methadone dose. Exceptions during this period should only occur if the patient meets the criteria of (a) or there are other unusual extenuating circumstances.

h. Stable patients with low risk of diversion, misuse or abuse of unsupervised dosing: Patients within this category are eligible for phase advancement according to the following schedule: Phase 1 (2 weekly take homes) and Phase 2 (3 weekly take homes) advanced to 6 weekly take homes. Phase 3 (4 weekly take homes) and Phase 4 (6 take homes) to 13 take homes.

i. Patients receiving an antagonist such as naltrexone: Patients should continue with naltrexone injections as long as PPE is available. If a patient receiving injections shows active signs or symptoms of COVID-19, the provider may exercise clinical judgement and forego the scheduled Vivitrol injection, prescribe oral naltrexone to be picked up at a pharmacy, and reschedule the Vivitrol injection for a minimum of 14 days later.

All patients must have a lockable take-home container and written instructions on protecting their medication from theft and exposure to children or animals. Staff should ensure that patient’s current lock box is of sufficient size to hold the additional take-homes. The clinic should remain open during regular business hours to field calls from patients who are receiving take homes. The efficacy and safety of this take-home strategy should be continually assessed. All medical exceptions should provide appropriate and complete documentation on medication safety and diversion risk.

Please feel free to send any supporting documentation to State Opioid Treatment Authority Rick Massatti in addition to your OTP’s submission on the SAMHSA OTP extranet website. While the SAMHSA extranet instructs OTPs not to submit COVID-19 specific exceptions to their website, many SOTAs are still using the website because that is the only good way that we have to track the extraordinary number of exceptions within the state. Email can be difficult to keep track of in the best of times, and the pandemic has made things chaotic. Please continue to submit all of your requests to the extranet. SAMHSA has given SOTAs the authority to fully approve the requests, so you do not have to wait for SAMHSA approval to proceed with fulfillment of a request.

**How can our patients quickly obtain naloxone to satisfy the requirements for take home exceptions? Would there be any restriction on patient eligibility?**

OhioMHAS is making funding available from the State Opioid Response (SOR) grant for purchase of naloxone to all OTPs, whether non-profit or for-profit. Currently, methadone patients are the only group who...
would qualify for the free naloxone because language within the exception guidance order only applies to them. OTPs may not charge patients for any of the free naloxone given through SOR dollars. If a patient does have insurance, then OTPs are requested to utilize naloxone through that funding source, rather than this funding source unless the patient is unable to pay any associated co-pays. In cases where methadone patients are at risk for not returning with naloxone in a timely fashion, OTPs should personally furnish naloxone from the inventory funded by SOR dollars. To request naloxone for your methadone patients, please contact Mindy Vance at Mindy.Vance@mha.ohio.gov. Naloxone supplies will be direct shipped to your organization. If patients are interested in obtaining naloxone on their own, outside of the clinic, then please direct them to http://stopoverdoses.ohio.gov to identify a source of naloxone within the county or to https://www.naloxoneforall.org/hro to order naloxone online.

Can we provide delivery of medication to our patients if they cannot leave their home, or a controlled treatment environment?

There is nothing under federal law that prohibits this from occurring, although resources to offer this level of service may vary by program. SAMHSA, the DEA, and the State of Ohio Board of Pharmacy have issued guidance documents for delivery of patient medications by an opioid treatment program. Please refer to the guidance from the Ohio Board of Pharmacy for more information and check it frequently for any updates.

Telehealth

What does our OTP need to know about the use of telemedicine or telephonic services to provide medically necessary services for the continuity of care for OTP clients?

As per SAMHSA and the Ohio State Opioid Treatment Authority as of March 16th 2020, please see the following 3 scenarios where the use of telemedicine is appropriate in an OTP.

- **Scenario 1.** A known and already admitted OTP client who needs to have a dose evaluation consultation presents at an OTP and is symptomatic. No physical examination by prescriber is needed to perform a dose evaluation. HIPPA and 42 CFR compliant audio-visual Telemedicine or telephonic consults can be used to provide dose evaluations of clients to reduce risk of direct COVID-19 exposure to OTP prescribing staff.

- **Scenario 2.** A known and already admitted OTP client who needs to have a dose evaluation consultation presents at an OTP and they are non-symptomatic. No physical examination by prescriber is needed to perform a dose evaluation. HIPPA and 42 CFR compliant audio-visual Telemedicine or telephonic consults can be used to provide dose evaluation to reduce risk of direct COVID-19 exposure to OTP prescribing staff.

- **Scenario 3.** An OTP is experiencing staffing shortages from prescribing medical staff at the OTP needing to go into isolation or quarantine. OTP prescribing staff cannot attend the OTP physically due to isolation and/or quarantine, but they are not so symptomatic that these prescribing staff cannot still complete Scenario 1 and Scenario 2. HIPPA and 42 CFR compliant audio-visual Telemedicine or telephonic consults can be used by OTP prescribers to provide continuity of operations for the OTP.

These 3 scenarios may only occur when:

- There is a clear understanding from the OTP Medical Director that audio-visual telemedicine or telephonic services may not substitute for any service where a physical examination of the client is medically necessary, although it may be used to support the decision making of a physician when a
provider qualified to conduct physical examinations and make diagnoses is physically located with the patient.

- All OTP must adhere to 42 C.F.R. § 8.12(f)(2), which requires new clients at an OTP undergo a physical evaluation before admission to the OTP:

42 C.F.R. § 8.12(f)(2). “Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.”

What guidance is being provided for telehealth services to behavioral health organizations?

ODM and OhioMHAS are implementing these emergency rules to expand access to medical and behavioral health services using telehealth. This action is being taken to give health care providers maximum flexibility as they shift as many services as possible away from in-person visits. In addition to increasing access to care, these rules seek to also reduce pressure on Ohio hospitals. The goal of the emergency rule package is to dramatically increase regulatory flexibility so medical and behavioral health providers can offer health care services to Ohioans remotely, thereby increasing access to care, reducing pressure on our hospital systems, and reducing unnecessary patient traffic in waiting rooms during the COVID-19 emergency.

A MITS-BITS guidance document has been prepared to answer any questions you may have about the new telehealth policy for persons with Medicaid. The document has information and links to OhioMHAS and ODM rule changes concerning services available using telehealth, locations available for telehealth, telehealth delivery methods, and claims submission. Additional information on billing for telehealth should be thoroughly reviewed for organizations planning to take advantage of this new service. From the MITS-BITS dated March 20, 2020:

Prior to the implementation date for the system changes, providers may either hold claims until the system changes are implemented or submit claims for telehealth services using existing billing guidance. If providers choose to submit claims for telehealth service prior to implementation of the system changes, please note that it is very important for providers to continue to use the existing billing guidance. For example, providers should NOT add the GT modifier to services that are being added as new telehealth services under the emergency rules. If the GT modifier is added to the new services prior to the implementation date of the system changes claims may be denied. Additionally, until the system changes are made, providers should continue to use allowable place of service codes in existing billing guidance when submitting claims. Providers must maintain documentation of services delivered via telehealth prior to and after the system changes are made.

After the system changes are implemented, to the extent possible, providers should comply with the new billing guidance for telehealth services. Providers should maintain documentation to support any exceptions to the billing guidance necessary to maintain access to services to individuals during the emergency.

Providers should refer to the standard Behavioral Health Services and OTP billing guidance documents for any billing questions. Requirements for reporting service units have not changed and are still applicable for all services enabled to be billed under telehealth. For questions related to changes to OhioMHAS interactive videoconferencing policy as well as questions related to clinical and technical implementation of telehealth,
please e-mail COVID19BHTelehealth@mha.ohio.gov. Questions about the Medicaid coverage, billing, and reimbursement under the new policy can be submitted to BHEnroll@medicaid.ohio.gov.

Please ensure that staff review any credentialing board and State of Ohio Medical Board requirements before they engage in telehealth services.

**Initiating New Treatment**

**Are there thoughts an OTP should consider when deciding whether to start a new, not yet admitted opioid use disorder diagnosed individual onto buprenorphine or methadone during the COVID-19 public health emergency?**

With shared decision making between client and prescriber, in terms of what we are facing in our state with COVID-19, OTP prescribers need to decide with clients which would be the easiest medication to start on at this time, and often times that medication may be a buprenorphine containing product.

Buprenorphine containing products for new clients should be considered for use to the greatest extent possible, because of the following reasons:

- All OTPs in Ohio are allowed to administer and dispense buprenorphine containing products through the OTP.

- Under the current regulations (42 CFR § 8.12 (i)(3)), OTPs must adhere to a time in treatment schedule in dispensing methadone products to patients for unsupervised use (“take home supplies”). Effective January 7, 2013, as per SAMHSA the time in treatment requirements for patients receiving buprenorphine products no longer applied in an OTP setting. Accordingly, if an OTP program physician determines that the patient is suitable, the OTP could dispense a one-week supply of medication, or longer, to a newly admitted patient.

- If prescribed, buprenorphine products can be prescribed via a telemedicine prescription from the first visit for new, not yet admitted clients. Please remember that any prescribed medications fall under the prescriber’s DEA DATA Waiver, and records for prescribed medications must be stored separately from records of dispensed medications. Contact your local DEA office with any questions.

- If prescribed, can result in a prescription that can be sent to be filled at a local pharmacy, instead of an OTP.

- Clients can be moved from buprenorphine containing products to methadone once the COVID-19 public health threat recedes easier than a client who may need to be switched from methadone to buprenorphine.

- If staff at an OTP get ill or an OTP needs to close in an emergency, continuity of care is easier to coordinate for buprenorphine clients than methadone clients as they can easier be switched to a DATA 2000 waiver prescriber and/or retail or community pharmacy.

If you put a new client on methadone please remember that:

- OTP Medical Directors are limited by federal law for client safety reasons of limiting OTP methadone clients to an initial 30 mg for their first dose of methadone.

- If the person cannot be seen for their next dose evaluation due to unforeseen circumstances relating
to the COVID-19 public health threat, then the individual would be stuck at the relatively low 30 mg
dose for a period of time, which may not resolve their opioid withdrawal symptoms until they can
have their dose escalated.

• SAMHSA and the State Opioid Treatment Authority will not endorse any new client titrating
themselves upwardly from home for methadone.

General Operations

Where can I refer patients if they have a question about testing for COVID-19?

More information about testing is available at the Ohio Department of Health website. Additionally, the Ohio
Department of Health has established a call center to address questions from members of the public, who
can call 1-833-427-5634.

What warrants a shut-down of an OTP?

OTPs are considered essential public facilities under Ohio Revised and Administrative codes, and should
make plans to stay open in most emergency scenarios, and be able to induct new patients. Director Amy
Acton issued an order mandating all Ohioans to stay home or at their place of residence, effective 11:59 p.m.
March 23, except for essential activities, essential governmental functions, or to operate essential businesses
and operations. Due to their critical nature, Ohio’s opioid treatment programs will be allowed to stay open
through this executive order. For more information on the order please see the Department of Health’s
website. You must consult with your State Opioid Treatment Authority Rick Massatti before making decisions
about operations.

We have patients and employees who are extremely anxious about COVID-19. What can we tell them to
support them?

Hearing the frequent news about COVID-19 can certainly cause people to feel anxious and show signs
of stress, even if they are at low risk or don’t know anyone affected. These signs of stress are normal. The
Substance Abuse and Mental Health Services Administration document titled Coping with stress during
infectious disease outbreaks includes useful information and suggestions. You could adapt messaging from
this document for the people you serve, or print this document to have available.

There are also steps people should take to reduce their risk of getting and spreading any viral respiratory
infection. These include: wash your hands often with soap and water for at least 20 seconds, cover your
mouth and nose with your elbow when you cough or sneeze, and stay home and away from others if you are
sick.

Should we be worried about any medication shortages and/or disruption of a medication supply for
methadone and/or any buprenorphine containing products?

At this time, there has been no reported concern from any state or federal partner about potential
disruption in the medication supply for methadone and/or any buprenorphine containing product. The DEA
has advised all OTPs to monitor their website for more information concerning the national drug supply and
other issues. Please contact the State Opioid Treatment Authority if your program has any specific concerns.
What else should my OTP be doing to prepare for or respond to COVID-19?

- Ensure you have up-to-date emergency contacts for your employees and your patients. You are recommended to update the cell phone number and carrier of your patients weekly because this population’s cell phone numbers change frequently. Just make it a standard part of the dosing process and medication pickup process, and patients will come to expect it.

- Ensure your program leadership has the contact information of the State Opioid Treatment Authority Rick Massatti:
  - Email: OTP_COVID19@mha.ohio.gov
  - Cell phone: 614-302-9513

- Ensure that all organization contact information including medical director, program sponsor and any other key staff is updated on the SAMHSA extranet website and within the Lighthouse central registry.

- Allow all patients with earned take-homes to utilize these take homes. While it can be an incentive to draw patients to attend counseling appointments, please take this opportunity to reduce patient appearance at the clinic as much as possible by giving them their maximum number of take-home doses at the prescriber’s discretion. When possible, please include the “earned time” at other federally licensed opioid treatment programs, providing there is clear and consistent documentation that the patient has met the requirements of that program (e.g., counseling attendance and negative UDS for all substances outside of the patient’s treatment plan, including marijuana).

- Develop procedures for OTP staff to take patients who present at the OTP with respiratory illness symptoms such as fever and coughing to a location other than the general dispensary and/or lobby to dose patients in closed rooms as needed.

- Develop protocols for provision of take-home medication if a patient presents with respiratory illness such as fever and coughing.

- Develop a communication strategy and protocol to notify patients who are diagnosed with or exposed to COVID-19, and/or patients who are experiencing respiratory illness symptoms such as fever and coughing, that whenever possible the patient should call ahead to notify OTP staff of their condition. This way OTP staff can have a chance prepare to meet them upon their arrival at an OTP with pre-prepared medications to be dispensed in a location away from the general lobby and/or dispensing areas.

- Develop a plan for possible alternative staffing/dosing scheduling in case you experience staffing shortages due to staff illness. Include criteria for staff members who may need to stay home when ill and/or return to the workforce when well.

- Consider limiting critical staff access to patients when possible. For example, some staff may meet with a patient through a glass window or through tele-communications devices within that same facility.

- OTPs are required to have enough medication inventory onsite for ten days’ worth of patient medication. This language is likely to be revised to 15 days or more (medication safe size permitting) in case neighboring OTPs close due to staffing shortages.
• Current guidelines recommend trying to maintain a six-foot distance between patients onsite in any primary care setting as best as possible. We realize in an OTP setting that this guidance may be difficult to achieve, but it should be attempted to the best of everyone's ability in an aspirational sense while considering the space and patient flow within your OTP's physical location. OTPs should consider expanding dosing hours to help space out service hours to help mitigate the potential for individual patients queuing in large numbers in waiting room and dosing areas. OTPs should also consider reserving special dosing times for high-risk populations like those who have medical comorbidities. While the effects of COVID-19 for pregnant women and the fetus are unknown, OTPs should consider using these special dosing times for this population as well. More information can be found about the impact of COVID-19 on women and children at the CDC website.

• OTPs should include in their respective disaster plans, details for continuity of patient care in the event of clinic closure. Examples may involve alternate dosing sites, memorandums of understanding between local OTPs agreeing to guest dose displaced patients, and availability of staff to verify dosing.

• OTPs should direct specific questions about operations under the circumstances related to COVID-19 or other such pathogens in the future to OhioMHAS. SAMHSA provides general guidance regarding OTP regulation and operation, but specific questions must be addressed by the SOTA. SAMHSA will not answer specific questions about program disaster plans or operation of programs.

• For additional guidance on developing and implementing disaster plans, please refer to TAP 34: Disaster Planning Handbook for Behavioral Health Treatment Programs.

• SAMHSA recognizes that social distancing and quarantine may come with concerns for individuals, families, and communities. SAMHSA hopes these Tips For Social Distancing, Quarantine, And Isolation During An Infectious Disease Outbreak are of use during this time.

**Keep Updated**

**How can my OTP be kept abreast of COVID-19 developments within the OTP setting?**

OhioMHAS will be holding bi-weekly webinars for OTPs to address any developments in COVID-19. Organizations should attend the webinars for updates and to present any barriers to and successes for patient care. At this time, it is difficult to add people to the OTP contact list, so you are recommended to forward the email from your management to any other applicable staff.

**Upcoming Webinar Dates**

• March 24th  https://attendee.gotowebinar.com/rt/3852574800035713035

• March 27th  https://attendee.gotowebinar.com/rt/2650045529806875147

• March 31st  https://attendee.gotowebinar.com/rt/7358921779059901195