



215 S Power Road, Suite 114 & 216 Mesa, Arizona 85206

> Phone: (480) 981-1022 Fax: (480) 981 1405

PATIENT HANDBOOK

CELEBRATING 30 YEARS 1988-2018



Updated: September 8, 2023

"Built on Faith, Powered by Spirit, and all done in Love" Mind Woodworff



Updated: September 8, 2023

WELCOME

Welcome to New Hope Behavioral Health Center, Inc. It is our goal to help you achieve your treatment expectations and goals. NHBHC staff encourages you to ask any questions you might have and to take full advantage of the services NHBHC is licensed to provide.

What is New Hope Behavioral Health Center, Inc.?

New Hope Behavioral Health Center, Inc. is a for profit, out-patient substance abuse treatment center that provides a full range of out-patient treatment services to residents of Maricopa, Pinal, Pima, and surrounding counties in Arizona. New Hope Behavioral Health Center, Inc. treated its first patient in 1988 and since that date, thousands of people have received some type of service from us.

What services does New Hope Behavioral Health Center provide?

New Hope Behavioral Health Center provides out-patient treatment services to adults, eighteen years of age or older; and their families who are welcome to help them on their journey, with opioid use disorders. Services vary in type and level of intensity depending on each person's individual needs.

Education and prevention services are also available.

MISSION STATEMENT

New Hope Behavioral Health Center, Inc. uses a unique philosophy that has opened a door and created an opportunity for "New Hope to be Born Again." We strive for success in the development of innovative solutions for a well-balanced, healthy, and diverse community suffering from drug abuse and addiction from high-school students to the retired executive.

VISION STATEMENT

New Hope Behavioral Health Center, Inc. is recognized by the faith-based community as the provider and employer of choice for behavioral health care services in the treatment of opioid addiction disorders.

VALUES STATEMENT

The Staff of New Hope Behavioral Health Center, Inc. is values committed to the following:

- Compassion
- Service Excellence
- Integrity
- Optimal Care
- Creativity
- Positive Workplace
- Fiscal Management
- Grace upon Grace



LOCATION

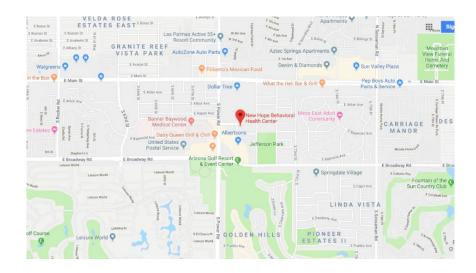
New Hope Behavioral Health Center, Inc. is located at:

215 S Power Road, Suite 114 & 216 Mesa, Arizona 85206 Phone: (480) 981-1022

Fax: (480) 981 1405

After-hours phone:

Medical: (480) 826-2646 Clinical: (480) 993-5919



Clinic Dosing Hours:

Monday, Tuesday, Thursday, Friday: 4:30 AM to 2:30 PM Wednesday: 4:30 AM to 11:30 AM and 12:30 PM to 2:30 PM Saturday: 6:30 AM to 8:30 AM Sunday and All Federal Holidays: CLOSED

Please call the clinic if you are having transportation issues prior to clinic closing



Updated: September 8, 2023

If you are experiencing a Mental Health Crisis, please contact the following number(s):

IN EMERGENCY SITUATIONS ALWAYS CALL 911

CRISIS HOTLINES

Maricopa County

• Maricopa County: Mercy Care 1-800-631-1314

Arizona Statewide Crisis Hotline:

Phone

1-844-534-4673 (HOPE)

Text

• 4HOPE (44673)

National 24-Hour Crisis Hotlines

Phone

- 988 Suicide & Crisis Lifeline: 988 (call or text)
- National Substance Use and Disorder Issues Referral and Treatment Hotline:
 1-800-662-HELP (4357)

Text

• Text the word "HOME" to <u>741741</u>

Teens

• Teen Life Line phone or text: 602-248-TEEN (8336)

Suicide and Crisis Hotlines by County and Tribal Nation

- Apache Country: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- Cochise County: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- Coconino County: Care 1st 1-877-756-4090
- **Gila County:** Mercy Care 1-800-631-1314
- Graham County: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- Greenlee County: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- La Paz County: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- Navajo County: Care1st 1-877-756-4090
- Maricopa County: Mercy Care 1-800-631-1314
- Mohave: Care 1st
 1-877-756-4090
- Pima County: Arizona Complete Health
 Complete Care Plan
 1-866-495-6735
- Pinal County: Mercy Care 1-866-495-6735



Veterans

Be Connected:

1-866-4AZ-VETS (429-8387)

Warm Lines

- Maricopa County / Central Arizona: 602-347-1100
- Arizona:
 - 888-404-5530
- Pima County: 844-733-9912
- Solari:
 - 602-347-1100
- Southern Arizona: 877-770-9912
- Tribal Nations: 855-728-860
- Families:
- <u>877-568-8468</u>

- Santa Cruz County: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- Yuma County: Arizona Complete Health - Complete Care Plan 1-866-495-6735
- Yavapai County: Care 1st 1-877-756-4090

Suicide and Crisis Hotlines by Tribal Nation

- Ak-Chin Indian Community: 1-800-259-3449
- Gila River Indian Community: 1-800-259-3449
- Salt River Pima Maricopa Indian Community: 1-855-331-6432
- Tohono O'odham Nation: 1-844-423-8759



CONFIDENTIALITY

All services and written information at New Hope Behavioral Health Center, Inc. are confidential as mandated by federal and state laws, as well as HIPAA regulations. Patient charts, or verbal disclosures, will **NOT** be released without the patient's written consent, except under the following circumstances:

- Information from charts requested through a valid subpoena naming a specific individual.
- Child abuse or elder abuse is identified or suspected.
- The patient is in a state of medical emergency that necessitates disclosure of information to medical personnel, including police if <u>suicide</u> is attempted or planned.
- If the patient threatens to harm someone, the intended victim and the police will be notified.

Please be aware that the clinical staff may receive information about you volunteered by an outside source; however, information *will not* be shared with that source unless you have signed a release specifically naming said person. This includes parents or others who may provide financial assistance for you.

Additional information regarding confidentiality issues may be obtained from the Administrator/Director or Custodian of Records by calling (480) 981-1022.

DUTY TO REPORT

New Hope Behavioral Health Center, Inc. is an out-patient Medication Assisted Treatment (MAT) program licensed by Federal and State regulatory agencies, and as such, we must continually meet standards to continue treatment services to our patients. New Hope Behavioral Health Center, Inc. also meets and maintains international treatment standards established by our accrediting agency

Among many of the rules and regulations, we are responsible for is "A Duty to Report."

The staff of New Hope is required, by law, to report to the appropriate authorities

Any suspected or alleged

- Abuse of a child or an adult*
- Neglect of a child
- Exploitation of a child or an adult

*Note: Abuse of child is to include, but not limited to, continued illicit use of drugs or alcohol while pregnant.

This notification to authorities is done immediately, without hesitation.



Copies of Record

You may request a copy of your records at any time for a fee for the cost of time, materials, equipment and personnel in producing such records. This fee will be determined by the Administrator of New Hope Behavioral Health Center who is also the "Custodian of Records". Please note that progress notes and assessments will not be released to a non-professional entity (family members, friends, etc.).

Insurance Company Requirements

At this time, NHBHC is contracted with AHCCCS (Arizona Health Cost Care Containment System) or any other contracted RBHA/TRBHA. We are also contracted with TriWest and some private insurance companies (you can call the billing department to find out who we contract with). You, as a patient, with other insurance may request an itemized bill to submit directly to your individual insurance company for reimbursement. An itemized bill presented to the patient does not guarantee that your insurance company will cover (pay) for services rendered at this clinic.

With regards to payment of services received at NHBHC require the clinic to submit services in a numeric code format identifying the services received and the diagnosis supporting services rendered. An insurance company may require supporting documentation in order to consider these charges for payment of services rendered. It is the responsibility of NHBHC to provide requested information to the insurance agency to determine necessity. By enrolling at NHBHC for services and signing the intake paperwork required for treatment, NHBHC is permitted to bill for services rendered to you during your enrollment in the clinic. It is the responsibility of you, the patient, to know your policy provisions and to comply with your insurance requirements. Should your insurance become inactive, you, the patient, will become a private pay patient and all charges during your inactive period will be your responsibility. Some insurance plans have copay or deductible requirements that are the responsibility of the patient. These charges are not waived and will be added to your bill for patient payment.

Private pay patients should expect to pay \$90 upon intake and \$60 weekly thereafter.

What rights do I have to receive services?

Services for treatment at New Hope Behavioral Health Center, Inc. are available without regard to age (unless a minor under 18 years of age), sex, gender identity, sexual orientation, race, creed, color, ancestry, national origin, disability, familial status, or marital status. Individuals who are enrolled in the AHCCCS (Arizona Health Care Cost Containment System) may be assigned to a different service provider. Everyone has the right to request or refuse treatment to the extent provided by the law. The right to treatment is not absolute, and under some circumstances it may be in the best interest of the patient and the agency if the patient is referred elsewhere. A complete copy of New Hope Behavioral Health Center, Inc.'s policy regarding Patient Rights is posted in all waiting room areas and is printed in this handbook.



PATIENT RESPONSIBILITIES

IMPORTANT

While receiving treatment services at New Hope Behavioral Health Center, Inc., patients are responsible for:

- Providing information necessary to complete an appropriate clinical, medical, and financial assessment to ensure proper treatment. This includes, but is not limited to:
 - Valid photo ID
 - Working phone number with a functioning voicemail
 - Information for an emergency contact
 - Insurance information (and insurance card)
- It is the policy of NHBHC that ALL patients attend at least one counseling session per month. These sessions must be one-on-one, at least 15 minutes in length, and preferably with the patient's assigned counselor; however, any counselor on-staff and available at the time will suffice. Group counseling sessions do not meet this requirement.
- Giving NHBHC ample notice if they plan to travel more than 200 miles from NHBHC and may require courtesy/guest dosing at another MAT clinic.
- Complying with coordination of care with other health care professionals that handle any/all care outside of NHBHC.
 - It is expected that patients are transparent about their methadone treatment with other health care providers, as this can have an impact on care delivery and safety of the patient.
- Working with the staff to develop an individual treatment plan and follow the agreed upon course of action. Treatment plans will be reviewed with the patient every 90 days for the first year, and then as needed, but at least annually, thereafter.
- Understanding that NHBHC does **NOT** provide pain management/chronic pain relief services. If this is the primary goal of the patient, NHBHC will deny him/her admission and refer them to medical services elsewhere.
- Complying with medical reviews on a yearly basis for justification of continued treatment which may include but is not limited to:
 - TB Testing
 - o RPR (blood test for Syphilis)
 - o Vitals
 - Urine analysis
 - Physical assessment
- Complying with state and federal policies regarding urinary analysis tests. Patients should expect to complete a urinary analysis test at least 8 times per year.
- Signing releases (when indicated) and other paperwork, contracts, and consents for the continuation of care.
- If eligible for take-home medication:
 - Complying with NHBHC's Diversion Control Plan, which requires Monthly Diversion Checks. These Diversion Checks are to assure accountability for patient take- home medication. They are random and you must comply with this requirement.
 - A patient must have a personal portable lock box (in working/locking condition) in order to be given take-home privileges as to store their take-home medication(s). One lock box per patient (user). Lock boxes cannot be shared.



A working phone number is required and must be maintained throughout treatment with NHBHC to receive any take-home medication.

- Participating in a "DO NO HARM" environment that promotes wellness and detours unsafe and unhealthy practices.
- Treating other patients and staff in a respectful manner.
- NO Loitering, NO Littering, NO Destroying of public or private property. This may be grounds for immediate dismissal. This is a zero-tolerance policy. *
- Notifying a staff member, nurse, counselor of their intention to discontinue treatment services.
- Refraining from bringing alcohol, drugs, or weapons onto or into the agency's properties, smoking outside of designated areas. This is a zero-tolerance policy. *
- Arriving on time for appointments; or if unable to keep appointment, calling 24 hours in advance to cancel/reschedule.
- Providing medical staff with information regarding prescribed medications, over the counter (OTC)
 medication, and all herbal supplements or vitamin preparations the patient is taking throughout
 treatment.
- **For ALL Patients:** It is important to maintain updated Treatment Plans and Assessments with your intake facility. Without these, your services at New Hope Behavioral Health Center, Inc. will become your responsibility to pay.
- For ALL Patients: it is <u>YOUR</u> responsibility to notify New Hope Behavioral Health, Inc. about eligibility changes (newly enrolled/newly terminated/etc.—of any insurance provider). Timely payment of all copays, deductibles are required on a timely basis. When your coverage is terminated, you become a private (cash) pay patient and it is your responsibility to pay your bill timely. Unpaid balances will affect your phase status/eligibility in NHBHC program.

*Violation of Zero-Tolerance could lead to the immediate dismissal from the clinic and treatment services. * Zero-tolerance is defined as an activity that has the potential to lead to disrespectful, unsafe, or destructive outcomes.



PATIENT BENEFITS

When you come for your first appointment, you will be assessed by our intake team to determine if you meet eligibility requirements for MAT (medication assisted treatment) and the appropriateness for New Hope Behavioral Health Center, Inc. to meet your needs, based upon your presenting problem(s). These needs could include, but are not limited to, strengths, abilities, skills, interests, and preferences. The first appointment will help determine what treatment modality is most appropriate. Please understand that not all individuals with an opioid addiction are candidates for out-patient treatment and a referral may be suggested for more appropriate treatment intervention.

During the first 90 days of comprehensive maintenance treatment, a patient may receive a single dose of take-home medication for each day that the agency is closed for business, including Sundays and Federal/State holidays. NHBHC provides take-home medication services, for which patients become eligible for after 90 in comprehensive maintenance treatment. However, please note that take-home medication services are a privilege and **not a right**. NHBHC reserves the right to refuse any patient take-home medication privileges, as deemed necessary.

Take home privileges for suboxone (buprenorphine/naloxone) candidates are determined by the provider.

Adult therapy services include individual and group counseling. Counselors work from a solution-focused model that utilizes patients' strengths, teaches new skills, and promotes change in the patient's life. Group counseling is often the intervention of choice, as it has the potential to yield great personal change for the patient while contributing to their sense of belonging and providing social support and peer advice. Group counseling may be provided at New Hope Behavioral Health Center, Inc. when resources are available or by referral to outside resources.

COUNSELOR ASSIGNMENT

The counselor will meet with the patient to complete an assessment and jointly develop an individualized service plan that dictates the course of treatment. During the patient's time at NHBHC, any non-compliance of clinic policies, state, and/or federal mandates and the impact on their treatment will be addressed with a counselor.

Patients will be automatically assigned a counselor or clinician during the intake process or after admission, by review of the following information

- The patient's treatment goals and needs
- The most convenient times for you
- Language or other preferences

Patient input is also considered when assigning a counselor; patients have the right to request a change in counselor at any time. However, NHBHC reserves the right to refuse this request.

** Remember, the staff person who does your intake upon admission may not be assigned as your regular counselor or clinician. **



CULTURAL AND LINGUISTIC INFORMATION

It is the policy of New Hope Behavioral Health Center, Inc. to provide services that are culturally competent and that are provided in the patient's primary language whenever possible.

TREATMENT LENGTH

Time in treatment is individualized to meet the needs of the patient.

Transition and discharge from treatment is incorporated into the treatment plan and generally occurs following attainment of treatment goals established upon admission and/or fourteen (14) consecutive days absent from the clinic (AWOL). Failure to comply with the agreed upon treatment standards may result in an administrative discharge, as allowed by agency policy and signed contracts by the patient (you).

If you have a co-occurring illness (physical and/or mental), ongoing treatment services may be required and/or recommended, which you or your counselor identified together at the beginning of your treatment at NHBHC. Failure to comply with the agreed upon treatment could and may compromise your success in your recovery and treatment with NHBHC. The same consequences hold true in this example as it does in the above paragraph. You, the patient, will always retain the right to stop or end your treatment services with New Hope Behavioral Health Center, Inc. or request to be transferred to another Medication Assisted Treatment (MAT) program (OTP).

FAMILIAL INVOLVEMENT

New Hope Behavioral Health Center, Inc. believes that support in the form of "family" (as identified by the patient) and significant others are extremely beneficial for the recovery from, and the prevention of, addiction disorders. The patient's support system will be encouraged to participate in treatment services if the patient chooses. The patient will meet with his/her counselor or clinician to determine who is to be included.

PATIENT FEEDBACK

New Hope Behavioral Health Center, Inc. invites you to provide feedback regarding the quality of care using patient satisfaction surveys. Also, in the patient waiting room, a suggestion box is provided for any feedback. You are welcome to be part of our patient advisory group.

STAFF CONDUCT

All staff is always expected to conduct themselves in a manner reflecting the highest professional and ethical standard. New Hope Behavioral Health Center, Inc. has established a policy and procedure addressing this topic. To review this article(s), please set a time (appointment) with the Administrator/Director by calling (480) 981-1022.



VEHICLE SAFETY

New Hope Behavioral Health Center, Inc. cannot be, and is not, responsible for damage to, or loss of non-company owned vehicles at any facility or function. It is the responsibility of the owner of the lost, stolen, or damaged vehicle. Parking at New Hope Behavioral Health Center, Inc.'s is available at the vehicle owner's risk.

ACCESSIBILITY

NHBHC is committed to having its clinic comply with all aspects of a formal accessibility plan, which includes Health, Safety, and Transportation Issues.

Since NHBHC started in 1988, the clinic has complied with all required standards – providing an accessible, healthy, and safe environment for the patients served and for staff members.

NHBHC is committed to providing an organization climate that accommodates the needs of all patients, families, and staff members. Central to this commitment is the removal of architectural, attitudinal, employment, and other barriers that may impede full access to NHBHC services and programs.

Notes	

PATIENT GRIEVANCE PROCEDURE

Patient grievance procedure is the formal mechanism for the resolution of a disagreement that may arise between patients and staff. It assures that any patient with a legitimate grievance is given the opportunity for redress. Step one need to be initiated within fourteen (14) days from the time of the incident.

It is the policy of NHBHC that all patients have access to a procedure for submitting any grievances, comments, and suggestions.

Procedure:

Step One – within fourteen (14) days of grievance. A meeting shall occur between the patient and the counselor. It shall be an informal presentation of the grievance with the counselor. If a grievance cannot be resolved, the patient may submit a grievance. If the decision to submit a grievance is reached by the patient, he/she will be given the form for Step Two, and will fill out the patient portion with, or without, the counselor's assistance (preferably this is to be completed during the meeting). If no grievance is submitted, the counselor is expected to note a complaint and the meeting in the patient's file under "Progress Notes".

Step Two – (See Form A-102 Patient Grievance Form) within five (5) days of Step One meeting. A formal grievance hearing needs to be held with the Clinical Director, counselor, and patient. The patient needs to sign a written notification that the matter was sustained, settled, or withdrawn and a copy will be given to the patient. If sustained, proceed to the next step.

Step Three – A patient will always retain the right to appeal a grievance action to the State Department of Health. NHBHC shall be prohibited from involuntary discharging, retaliating, or discriminating against any patient who submits a complaint, grievance, assists the AZDBHS or any other legal authority in a complaint related investigation for reason such submission or assistance.

Agency grievance policies and procedures shall be explained to the patient, parental guardian, or designated representative at the time of admission.

Understanding of the grievance policies and procedures shall be verified by the dated signature of the patient, parent, guardian, or designated representative. These steps are also posted in the patient waiting room for easy access by patients and their families.

When information is received, either orally or in writing, that the individual has Limited English Proficiency (LEP) or any other communication need, NHBHC must follow requirements outlined in Article 3, Cultural Competency and Diversity, regarding oral interpretation services, translation of written materials, and services for the deaf and hard of hearing:

- 1. For all individuals with LEP, the provider must make available oral interpretation services.
 - a. For individuals needing translation in the prevalent non-English language within the region, NHBHC shall provide a written translation in accordance with the requirements of Article 3, Cultural Competency and Diversity.
 - b. For individuals who need translation in a language that is not considered a prevalent non-English language within the region or who require alternative formats (such as TTY/TTD), NHBHC shall provide oral interpretation of written materials or make alternative communication formats available as indicated.



The addresses and telephone numbers of agencies needed for grievance are as follows:

Arizona Department of Health Services Bureau of Medical Facility Licensing

150 N. 18th Ave., Suite 410 Phoenix, AZ 85007-3242 (602) 364 – 2595

State Opioid Treatment Authorities
Arizona Health Care Cost Containment System

701 E Jefferson St., MD 6500 Phoenix, AZ 85034 (602) 364 – 2111

CARF International

6951 E. Southpoint Rd. Tucson, AZ 85756-9407, USA 888-281-6531 Phone (520) 318-1129 Fax

The Administrator of New Hope Behavioral Health Center, Inc. conducts annual reviews of all written complaints and or grievances to identify trends, areas for improvement, and actions to be taken by the organization.

For translation or alternative format requests, call (480-981-1022)
Para recibir éste formulario en español, llame al (480-981-1022)

Notes							



PATIENT RIGHTS

(Arizona Administrative Code (AAC) R9-10-1008) The patient has the following rights

- 1. To be treated with dignity, respect, and consideration.
- 2. Not to be discriminated against based on race, national origin, religion, gender, sexual orientation, age, disability, marital status, diagnosis, or source of payment.
- 3. A patient is not subjected to:
 - a. Abuse;
 - b. Neglect;
 - c. Exploitation;
 - d. Coercion;
 - e. Manipulation;
 - f. Sexual abuse;
 - g. Sexual assault;
 - h. Restraint or Seclusion (Except as allowed in R9-10-1012 (B))
- 4. To receive treatment that:
 - a. Supports and respects the patient's individuality, choices, strengths, and abilities.
 - b. Supports the patient's personal liberty and only restricts the patient's personal liberty according to a court order, by the patient's consent, or as permitted in these Patient Rights.
 - c. Is provided in the least restrictive environment that meets the patient's treatment needs.
- 5. Not to be prevented or impeded from exercising a patient's civil rights, unless the patient has been adjudicated incompetent or a court of competent jurisdiction has found that the patient is unable to exercise a specific right or category of rights.
- 6. To submit a grievance to agency staff members and complaints to outside entities and other individuals without restraint or retaliation.
- 7. To have grievances considered by NHBHC in a fair, timely, and impartial manner
- 8. To seek, speak to, and be assisted by legal counsel of the patient's choice, at the expense of the patient.
- 9. To receive assistance from a family member, designated representative, or other individual in understanding, protecting, or exercising a patient's rights
- 10. If enrolled by the Department, or a Regional Behavioral Health Authority (RBHA) as an individual who is seriously mentally ill (SMI), to receive assistance from human rights advocates provided by the Department or the Department's designee in understanding, protecting, or exercising a patient's rights.
- 11. To have the patient's information and record kept confidential and released only as permitted under R9-10-1009.
- 12. To privacy in treatment, including the right not to be fingerprinted,



photographed, or recorded without consent, except:

- a. For photographing for identification and administrative purposes, for a patient receiving treatment as provided by A.R.S. 36-507(1-2).
- b. For video recordings used for security purposes that are securely maintained and kept only on a temporary basis.
- 13. To review, upon written request, the patient's own personal record during the agency's hours of operation, or at a time agreed upon by the Clinical Director, except as described in R9-10-1009; A.R.S. § 36-507 (3).
- 14. To review the following at NHBHC or the AZDBHS:
 - a. This Chapter
 - b. The report of the most recent inspection of the premises conducted by the AZDBHS
 - c. A plan of correction in effect, as required by the AZDBHS
 - d. If the licensee has submitted a report of inspection by a nationally recognized accreditation agency in lieu of having an inspection conducted by the Department, the most recent report of inspection conducted by the nationally recognized accreditation agency.
- 15. To be informed of all fees that the patient is required to pay and of NHBHC's refund policies and procedures before receiving a behavioral health service, except for a behavioral health service provided to a patient experiencing a crisis.
- 16. To consent to treatment, unless treatment is ordered by a court of competent jurisdiction, after receiving a verbal explanation of the patient's condition and the proposed treatment, including the intended outcome, the nature of the proposed treatment, any procedures involved in the proposed treatment, any risks or side effects from the proposed treatment, and any alternatives to the proposed treatment.
- 17. To be offered or referred for the treatment specified in the patient's treatment plan.
- 18. To receive a referral to another agency in NHBHC is unable to provide a behavioral health service that the patient requests or that is indicated in the patient's treatment plan.
- 19. To refuse treatment or withdraw consent to treatment, unless such treatment is ordered by a court according to A.R.S Title 36, Chapter 5 or is necessary to save the patient's life or physical health or is provided according to A.R.S § 36-512.

Notes



Update: September 8, 2023

Special-Risk Patients

Methadone should be given with caution, and the initial dose reduced, in certain patients such as the elderly and debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy, or urethral stricture. The usual precautions should be observed, and the possibility of respiratory depression requires added vigilance.

Information for Patients

- Patients should be cautioned that Methadose, like all opioids, may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving or operating machinery.
- Patients who are ambulatory should be cautioned that Methadose, like other opioids, may produce orthostatic hypotension.
- Patients should be cautioned that alcohol and other CNS depressants may produce an additive CNS depression when taken with this product and should be avoided.
- Patients should be instructed to seek medical attention immediately if they experience symptoms suggestive of arrhythmia (such as palpitations, dizziness, lightheadedness, or syncope) when taking Methadose.
- Patients initiating treatment with Methadose should be reassured that the dose of methadone will "hold" for longer periods of time as treatment progresses. NDA 17-116/S-021 Page 21.
- Patients should be instructed to keep Methadose in a secure place out of the reach of children and other household members. Accidental or deliberate ingestion by a child may cause respiratory depression that can result in death.
- Patients should be advised not to change the dose of Methadose without consulting their physician.
- Women of childbearing potential who become or are planning to become pregnant should be advised to consult their physicians regarding the effects of Methadose use during pregnancy.
- If a physically dependent patient abruptly discontinues use of Methadose, an opioid abstinence or
 withdrawal syndrome may develop. If cessation of therapy is indicated, it may be appropriate to taper
 the methadone dose, rather than abruptly discontinue it, due to the risk of precipitating withdrawal
 symptoms. Their physician can provide a dose schedule to accomplish a gradual discontinuation of the
 medication.
- Patients seeking to discontinue treatment with Methadose for opioid dependence should be apprised of the high risk of relapse to illicit drug use associated with discontinuation of methadone maintenance treatment.
- Patients should be advised that Methadose is a potential drug of abuse. They should protect it from theft, and it should never be taken by anyone other than the individual for whom it was prescribed.
- Breastfeeding:
 - Methadone use is usually compatible with breastfeeding. Pregnant mothers using methadone should be counseled about the benefits and risks of breastfeeding while using methadone. Counseling should include the following information:
 - The baby receives a small amount of methadone through breast milk.
 - The baby may experience methadone withdrawal if breastfeeding is discontinued suddenly.
 Patients discontinuing breastfeeding should develop a plan to wean with the baby's healthcare team.



- Use of other substances of abuse during breastfeeding will expose the baby to additional risks. Patients who use other substances of abuse should not breastfeed.
- When starting methadone for the first time or increasing the dose, breastfeeding patients should watch their babies closely for changes in behavior or breathing patterns.

METHADOSE™ ORAL CONCENTRATE

(Methadone hydrochloride oral concentrates USP)

https://www.mallinckrodt.com/products/generics/addiction-treatment-products/methadoseoral-concentrate-methadone-hydrochloride-oral-concentrate-usp-10-mgml-cii/

https://www.accessdata.fda.gov/drugsatfda docs/label/2008/017116s021lbl.pdf

INDICATIONS AND USAGE

- Detoxification treatment of opioid addiction (heroin or other morphine-like drugs).
- Maintenance treatment of opioid addiction (heroin or other morphine-like drugs), in conjunction with appropriate social and medical services.

<u>Limitations of Use</u> Methadone products used for the treatment of opioid addiction in detoxification or maintenance programs are subject to the conditions for distribution and use required under 21 CFR, Title 42, Sec 8.

IMPORTANT SAFETY INFORMATION

WARNING: LIFE-THREATENING RESPIRATORY DEPRESSION, RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS, LIFE-THREATENING QT PROLONGATION, ACCIDENTAL INGESTION, ABUSE POTENTIAL, INTERACTIONS WITH DRUGS AFFECTING CYTOCHROME P450 ISOENZYMES and TREATMENT FOR OPIOID ADDICTION

Life-Threatening Respiratory Depression

Respiratory depression, including fatal cases, have been reported during initiation and conversion of patients to methadone, and even when the drug has been used as recommended and not misused or abused. Proper dosing and titration are essential and METHADOSE should only be prescribed by healthcare professionals who are knowledgeable in the use of methadone for detoxification and maintenance treatment of opioid addiction. Monitor for respiratory depression, especially during initiation of METHADOSE or following a dose increase. The peak respiratory depressant effect of methadone occurs later, and persists longer than the peak pharmacologic effect, especially during the initial dosing period.

Risks From Concomitant Use with Benzodiazepines or Other CNS Depressants



Update: September 8, 2023

Concomitant use with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, is a risk factor for respiratory depression and death.

- Reserve concomitant prescribing of benzodiazepines or other CNS depressants in patients in methadone treatment to those for whom alternatives to benzodiazepines or other CNS depressants are inadequate.
- Follow patients for signs and symptoms of respiratory depression and sedation. If the patient
 is visibly sedated, evaluate the cause of sedation and consider delaying or omitting daily
 methadone dosing.

<u>Life-Threatening QT Prolongation</u>

QT interval prolongation and serious arrhythmia (torsades de pointes) have occurred during treatment with methadone. Most cases involve patients being treated for pain with large, multiple daily doses of methadone, although cases have been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction. Closely monitor patients with risk factors for development of prolonged QT interval, a history of cardiac conduction abnormalities, and those taking medications affecting cardiac conduction for changes in cardiac rhythm during initiation and titration of METHADOSE.

Accidental Ingestion

Accidental ingestion of METHADOSE, especially by children, can result in fatal overdose of methadone.

Misuse, Abuse, and Diversion of Opioids

METHADOSE contains methadone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit.

Interactions with Drugs Affecting Cytochrome P450 Isoenzymes

The concomitant use of METHADOSE with all cytochrome P450 3A4, 2B6, 2C19, 2C9 or 2D6 inhibitors may result in an increase in methadone plasma concentrations, which could cause potentially fatal respiratory depression. In addition, discontinuation of concomitantly used cytochrome P450 3A4, 2B6, 2C19, or 2C9 inducers may also result in an increase in methadone plasma concentration. Follow patients closely for respiratory depression and sedation and consider dosage reduction with any changes of concomitant medications that can result in an increase in methadone levels.

Conditions for Distribution and Use of Methadone Products for the Treatment of Opioid Addiction



For detoxification and maintenance of opioid dependence, methadone should be administered in accordance with the treatment standards cited in 42 CFR Section 8, including limitations on unsupervised administration.

CONTRAINDICATIONS

METHADOSE is contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity (e.g., anaphylaxis) to methadone or any other ingredient in METHADOSE.

WARNINGS AND PRECAUTIONS

- METHADOSE and METHADOSE Sugar-Free are for oral administration only. The preparation must not be injected. METHADOSE and METHADOSE Sugar-Free, if dispensed, should be packaged in childresistant containers and kept out of reach of children to prevent accidental ingestion.
- Serious, life-threatening, or fatal respiratory depression has been reported with the use of methadone, even when used as recommended. Patients with chronic pulmonary disease, elderly, cachectic, or debilitated patients may be at increased risk. Monitor closely, especially during initiation and titration.
- Concomitant use of methadone and benzodiazepines or other CNS depressants increases the risk of adverse reactions including overdose and death. As a routine part of orientation to methadone treatment, educate patients about the risks of concomitant use of benzodiazepines, sedatives, opioid analgesics, or alcohol.
- Cases of QT interval prolongation and serious arrhythmia (torsades de pointes) have been observed during treatment with methadone. These cases appear to be more commonly associated with, but not limited to, higher dose treatment (>200 mg/day). Most cases involve patients being treated for pain with large, multiple daily doses of methadone, although cases have been reported in patients receiving doses commonly used for maintenance treatment of opioid addiction. Monitor patients with risk factors for development of prolonged QT interval, a history of cardiac conduction abnormalities, and those taking medications affecting cardiac conduction.
- Accidental ingestion of even one dose of METHADOSE, especially by children, can result in respiratory depression and death due to an overdose.
- METHADOSE contains methadone, an opioid agonist and a Schedule II controlled substance. Methadone can be abused in a manner similar to other opioid agonists, legal or illicit.
- Neonatal opioid withdrawal syndrome (NOWS) is an expected and treatable outcome of prolonged use of opioids during pregnancy. Observe newborns for signs of NOWS and manage; accordingly, NOWS may be life threatening if not recognized and treated in neonates.
- Concomitant use of METHADOSE with CYP3A4, CYP2B6, CYP2C19, CYP2C9, or CYP2D6 inhibitors, may
 increase plasma concentrations of methadone and use with CYP3A4, CYP2B6, CYP2C19, or CYP2C9
 inducers or discontinuation of CYP3A4, CYP2B6, CYP2C19, CYP2C9, or CYP2D6 inhibitors in patients
 treated with METHADOSE may decrease methadone plasma concentrations.



- Cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of METHADOSE with serotonergic drugs. Discontinue METHADOSE if serotonin syndrome is suspected.
- Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. If adrenal insufficiency is diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid until adrenal function recovers.
- Methadone may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. Monitor during initiation and/or titration of methadone.
- Use in patients with increased intracranial pressure, brain tumors, head injury, or impaired consciousness may reduce respiratory drive, and the resultant CO₂ retention can further increase intracranial pressure. Use of methadone should be avoided in patients with impaired consciousness or coma.
- METHADOSE is contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus. The methadone in METHADOSE may cause spasm of the sphincter of Oddi.
- Methadone may increase frequency of seizures in patients with seizure disorders and increase the
 risks of seizures occurring in other clinical settings associated with seizures. Monitor patients with a
 history of seizure disorders for worsened seizure control.
- Avoid use of METHADOSE with mixed agonist/antagonists or partial agonist analgesics due to risk of
 precipitation of withdrawal symptoms. When discontinuing METHADOSE, gradually taper the
 dosage.
- METHADOSE may impair the ability to perform potentially hazardous activities such as driving or
 operating heavy machinery. Advise patients not to perform such tasks until they know how they will
 react to the medication.
- False positive urine drug screens for methadone have been reported for several drugs including diphenhydramine, doxylamine, clomipramine, chlorpromazine, thioridazine, quetiapine, and verapamil.

ADVERSE REACTIONS

The most frequently observed adverse reactions included lightheadedness, dizziness, sedation, nausea, vomiting, and sweating. This is not a complete list of potential adverse events associated with methadone. Please see Full Prescribing Information for a complete list.



For opioid dependence: SUBOXONE (buprenorphine and naloxone) Sublingual Film[®] (CIII)

https://www.suboxone.com/

INDICATION

SUBOXONE (buprenorphine and naloxone) Sublingual Film[®] (CIII) is a prescription medicine used to treat opioid addiction in adults and is part of a complete treatment program that also includes counseling and behavioral therapy.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about SUBOXONE Sublingual Film?

Keep SUBOXONE Sublingual Film in a secure place out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes SUBOXONE Sublingual Film, get emergency help or call 911 right away. Tell your healthcare provider if you are living in a household where there are small children.

SUBOXONE Sublingual Film contains an opioid medicine called buprenorphine that can cause serious and life-threatening breathing problems, especially if you take or use certain other medicines or drugs.

Talk to your healthcare provider about naloxone, a medicine available to patients for emergency treatment of an opioid overdose, including accidental use of SUBOXONE Sublingual Film by a child. If naloxone is given, you must call 911 or get emergency medical help right away to treat an overdose or accidental use of an opioid.

SUBOXONE Sublingual Film can cause serious and life-threatening breathing problems. Get emergency help right away if you:

feel faint



- feel dizzy
- are confused
- feel sleepy or uncoordinated
- have blurred vision
- have slurred speech
- are breathing slower than normal
- cannot think well or clearly

Do not take SUBOXONE Sublingual Film with certain medicines. Taking SUBOXONE Sublingual Film with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

Do not inject ("shoot-up") SUBOXONE Sublingual Film. Injecting SUBOXONE Sublingual Film may cause life-threatening infections and other serious health problems. Injecting SUBOXONE Sublingual Film may cause sudden serious withdrawal symptoms such as pain, cramps, vomiting, diarrhea, anxiety, sleep problems, and cravings.

Do not switch from SUBOXONE Sublingual Film to other medicines that contain buprenorphine without talking with your healthcare provider. The amount of buprenorphine in a dose of SUBOXONE Sublingual Film is not the same as in other medicines that contain buprenorphine. Your healthcare provider will prescribe a starting dose of SUBOXONE Sublingual Film that may be different than other buprenorphine containing medicines you may have been taking.

Do not stop taking SUBOXONE Sublingual Film suddenly. You could become sick and have withdrawal symptoms because your body has become used to the medicine (physical dependence). Physical dependence is not the same as drug addiction.

In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with SUBOXONE Sublingual Film.

Never give anyone else your SUBOXONE Sublingual Film. They could die from taking it. Selling or giving away SUBOXONE Sublingual Film is against the law.

Death has been reported in those who are not opioid dependent.

Who should not take SUBOXONE Sublingual Film?

Do not take SUBOXONE Sublingual Film if you are allergic to buprenorphine or



naloxone.

Do not take SUBOXONE Sublingual Film before the effects of other opioids (e.g., heroin, hydrocodone, methadone, morphine, oxycodone) have started to wear off as you may experience withdrawal symptoms.

Before taking SUBOXONE Sublingual Film, tell your healthcare provider about all of your medical conditions, including if you have:

- trouble breathing or lung problems
- a curve in your spine that affects your breathing
- Addison's disease
- an enlarged prostate gland (men)
- problems urinating
- liver, kidney, or gallbladder problems
- alcoholism
- a head injury or brain problem
- mental health problems
- adrenal gland or thyroid gland problems

Tell your healthcare provider if you are:

- pregnant or plan to become pregnant. Opioid-dependent women on buprenorphine maintenance therapy may require additional analgesia during labor. If you take SUBOXONE Sublingual Film while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- breastfeeding or plan to breastfeed. SUBOXONE Sublingual Film can pass into
 your breast milk and harm your baby. Talk to your healthcare provider about the
 best way to feed your baby if you take SUBOXONE Sublingual Film. Monitor your
 baby for increased drowsiness and breathing problems if you breastfeed during
 treatment with SUBOXONE Sublingual Film.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What should I avoid while taking SUBOXONE Sublingual Film?



- Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBOXONE Sublingual Film affects you. Buprenorphine can cause drowsiness and slow reaction times. SUBOXONE Sublingual Film can make you sleepy, dizzy, or lightheaded.
- You should not drink alcohol or take prescription or over-the-counter medicines that contain alcohol while taking SUBOXONE Sublingual Film, because this can lead to loss of consciousness or even death.

What are the possible side effects of SUBOXONE Sublingual Film?

SUBOXONE Sublingual Film can cause serious side effects, including:

- **Trouble breathing.** Taking SUBOXONE Sublingual Film with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants can cause breathing problems that can lead to coma and death.
- Sleepiness, dizziness, and problems with coordination.
- **Physical dependence or abuse.** SUBOXONE Sublingual Film can be abused in a manner similar to other opioids, legal or illicit.
- **Liver problems.** Call your healthcare provider right away if you notice any of these symptoms:
 - your skin or the white part of your eyes turning yellow (jaundice)
 - o dark or "tea-colored" urine
 - light colored stools (bowel movements)
 - loss of appetite
 - o pain, aching, or tenderness on the right side of your stomach area
 - o nausea
- Your healthcare provider should do blood tests to check your liver before you start taking and while you take SUBOXONE Sublingual Film.
- Allergic reaction. You may have a rash, hives, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.
- **Opioid withdrawal.** Call your healthcare provider right away if you get any of these symptoms:
 - shaking
 - sweating more than normal
 - feeling hot or cold more than normal
 - runny nose



- watery eyes
- goosebumps
- o diarrhea
- vomiting
- muscle aches
- **Decrease in blood pressure.** You may feel dizzy if you get up too fast from sitting or lying down.
- The most common side effects of SUBOXONE Sublingual Film include:
 - headache
 - o nausea
 - vomiting
 - constipation
 - o pain
 - increased sweating
 - decrease in sleep (insomnia)
- SUBOXONE Sublingual Film may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects. Call your healthcare provider for medical advice about side effects.

To report pregnancy or side effects associated with taking SUBOXONE Sublingual Film, please call <u>1-877-782-6966</u>. You are encouraged to report negative side effects of drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call <u>1-800-FDA-1088</u>.

Notes			



RESOURCES

New Hope Behavioral Health Center Billing Department:

Direct: 480-562-6642

Arizona Department of Health Services

150 North 18th Avenue Phoenix, Arizona 85007 General and Public Information:

(602) 542-1025

Arizona Health Care Cost Containment System (AHCCCS)

AHCCCS

801 E Jefferson St Phoenix, Arizona 85034

Behavioral Health Services

(602) 417-4000

Or

(800) 654-8713

Arizona Department of Economic Security

(855) 777-8590

Adult Protective Services

(877) 767-2385

Arizona Department of Child Safety

(602) 255-2500

Child Abuse Hotline

(888) SOS-CHILD (767-2445)

Community Resources:

https://211arizona.org/ By phone: 211

INSURANCE PROVIDER CONTACT INFORMATION:

These numbers can be found on the back of your insurance cards.



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Update: September 8, 2023





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