REQUEST FOR PROPOSALS

RFP # 2019-3

February 15, 2019

DUE FRIDAY, MARCH 1ST, 2019 BY 3:00 PM

Office Based Opioid Treatment

Questions regarding this RFP should be directed to:

Procurement Questions
Utah County Purchasing Agent – Robert Baxter
100 E. Center Street, #3600
Provo, Utah 84606
(801) 851-8233
robertb@utahcounty.gov

Proposal Content Questions
Richard Nance
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of Drug and Alcohol Prevention and Treatment
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Attachment – ASAM Public Policy Statement on Office-based
Opioid Agonist Treatment (OBOT)

SECTION 1 - INTRODUCTION

Purpose and Scope of RFP

The American Society of Addiction Medicine's definition of Opioid Based Opioid Treatment (OBOT): OBOT refers to models of opioid agonist treatment that seek to integrate the treatment of opioid addiction into the general medical and psychiatric care of the patient. The foundation of OBOT is the conceptualization of opioid addiction as a chronic medical condition with similarity to many other chronic conditions. An important feature of OBOT is that it allows primary care physicians to provide addiction treatment services in their usual clinical settings, thus expanding the availability of care.

Funding for this procurement comes from the federal State Opioid Response Grant funds (SOR) awarded to the State of Utah and passed through to local substance abuse authority programs. OBOT services provided through SOR are to be delivered through a hub-and-spoke model, where the hub is a physician's office, and the spokes are hospital emergency departments, police agencies, and jails in conjunction with peer counselors who make the initial contact with the patient at the spoke site, then continue to facilitate ongoing case management services for patients started in OBOT. Utah County already has an existing hub-and-spoke model for some inmates of the Utah County Jail.

Utah County Department of Drug and Alcohol Prevention and Treatment (ADDAPT) contracts with a full-time medical director whose office is in Provo and who is the hub for the hub-and-spoke model at the Jail. The purpose of this RFP is to select additional licensed physician treatment Providers that can provide **OBOT** services for adults residing in north and south areas of Utah County. It is the intention of ADDAPT to select one or more CONTRACTOR(s) to provide

.

Level of Care: **Office Based Opioid Treatment**
CONTRACTORs to be Selected: **1-2**
Maximum Funds Available: ..... **$150,000** (based on a 12-month fiscal year)

Proposal Due Date

It is recognized that few agencies and individual practitioners currently exist locally that are capable of handling the volume of clients funded each year by COUNTY. As a result, COUNTY reserves the right to solicit for additional responses in the event an inadequate number of proposals are received or accepted for consideration.

Proposals must be *delivered* and *receipt verified* by Utah County's Purchasing Agent **on or before 3:00 pm**. on **Friday, March 1** at the following location:

Utah County Purchasing Agent – Robert Baxter
100 E. Center Street, #3600
Provo, Utah 84606
(801) 851-8233

Or via email to robertb@utahcounty.gov

Contract Period and Effective Date
The initial term of any contractual agreement resulting from this RFP shall commence **March 15, 2019** and shall terminate on **December 31, 2019.** County shall have the option of renewing such contractual agreement for two (2) additional renewals periods of one year each.

Reimbursement Rates
COUNTY expects applicants to propose a fee-for-service reimbursement rate for the population to be served based on their treatment capacity and maximum funds available.

Notification
All applicants will be officially notified of the results of their proposals by email or telephone no later than **March 7, 2019**. Applicants should not call prior to this time to inquire into the status of their proposals.

Proposal Submission and Format

- The proposal should be submitted electronically via email in the form of a letter, complete with original signature(s) in either Adobe .pdf format or Microsoft Word format.
- The signature on the proposal must be that of the person(s) authorized to agree to all terms and conditions of this RFP.
- The Proposal should be formatted on standard 8 ½" X 11" pagination in portrait orientation that can be printed and photocopied and contain no more than the specified number of pages.
- Single spacing should be used.
- Standard black type, 12 CPI or larger fonts (i.e., Courier, Times New Roman). No handwritten responses or color copies should be submitted.
- No less than one-inch margins all around.
- Single-sided pages only.
- ***Proposals exceeding the specified number of pages may be excluded without further consideration. Attachments do not count toward the page limit.***

Disposition of Proposals
Any costs incurred in the preparation and submission of proposals or amendments pursuant to this RFP are the responsibility of the Offeror and will not be reimbursed. In addition, all materials submitted become the property of the Utah County and will not be returned.

Utah County Procurement Rules and Regulations
All applicable procurement rules contained in Utah County's Procurement Rules and Regulations apply to this RFP. Utah County procurement rules and regulations can be found online at:
http://www.utahcounty.gov/dept/clerkaud/procurementrulesregulations.asp

Additional Terms and Conditions
All additional terms and conditions included in a contractual agreement between CONTRACTOR and

COUNTY must be agreed to in full. Copies of applicable federal, state, and county laws, statutes, and administrative rules are available for inspection and copy in COUNTY's administrative office.

Minimum Bidder Qualifications

- Located in Utah County or an adjacent County if the level of care specified is not available within the geographic boundaries of Utah County.
- Maintaining an office for the practice of addiction medicine located in a city in Utah County other than Provo and Orem
- Eligible to be (or current) Medicaid provider or plans to become a Medicaid provider by March 15, 2019
- Licensed by Utah State Division of Occupational and Professional Licensing as a physician.
- Qualified by training, experience, and certification to administer medications for the treatment of opiate use disorders, such as buprenorphine and related products and formulations, naltrexone and related products and formulations, and naloxone.
- Qualified by training experience, and certification to prescribe and administer a broad range of medications for the treatment of mental health disorders.
- Certified by the American Board of Addiction Medicine or American Board of Psychiatry and Neurology and also a Member of the American Association of Addiction Psychiatry.
- Have privileges at one or more medical surgical hospitals within a 15-mile radius of the provider's office excluding Provo and Orem

Additional Qualifications that might be taken into consideration

- Belongs to one or more commercial insurance provider panels
- Eligible to be (or current) Medicare provider
- Is able to provide drug testing services or specimen collection for processing of drug tests by another laboratory.

SECTION 2 - Definitions and Terms

ASAM/ABAM – Means American Society of Addiction Medicine or American Board of Addiction Medicine.

Contractor - Agency or treatment provider that applies for, offers, or submits a proposal through this RFP process.

Individual Psychotherapy/Medication Management (individual mental health therapy)" means face to face interventions with an individual client with the focus on eliminating the client's substance abuse, and/or reducing or eliminating maladaptive or hazardous behaviors, increasing social functioning and restoring the client to the highest possible level of functioning. The treatment must be based on measurable treatment goals identified in the client's individual plan of care or treatment plan and must be delivered by a person with the appropriate licensure as defined by Utah Department of Professional Licensure.

Group Psychotherapy/Medication Management (Group Mental Health Therapy) on eliminating the clients' substance abuse, and/or reducing or eliminating maladaptive or hazardous behaviors, increasing social functioning and restoring the client to the highest possible level of functioning. The treatment must be based on measurable treatment goals identified in the client's individual plan of care or treatment plan and must be delivered by a person with the appropriate licensure as defined by Utah Department of Professional Licensure. Groups should not exceed 10 individuals unless a co-therapist is present.

Medication Assisted Treatment means assessment, diagnosis, treatment planning, medication prescription, medication administration, induction, and ongoing monitoring of treatment effectiveness of prescribed medications for SUD or co-occurring mental health disorders.

OBOT means office based medication assisted treatment for patients suffering from opiate use disorders.

Provider means an agency or treatment provider that applies for, offers, or submits a proposal through this RFP process.

Recovery Management – means a non-ASAM level of care provided by outpatient treatment providers to clients who no longer meet ASAM criteria for outpatient substance abuse treatment; who have substantially completed an episode of substance abuse treatment; and who will benefit from continued contact with treatment staff for the long-term maintenance of treatment gains.

Support Group – means a meeting of members who provide help and companionship to one another. Support groups are comprised of others who have been through the issue at hand. For example, Alcoholics Anonymous is made up of recovering or recovered alcoholics.

Treatment Plan - means an individualized written plan of care developed by an individual licensed as a mental health professional, psychologist, or physician under the Utah Mental Health Professional Practice Act. The initial treatment plan must be completed within 72 hours for residential placements and within three (3) face- to-face sessions for all other placements after the assessment and must be prescribed by a person with the appropriate licensure as defined by Utah Department of Professional Licensure.

Urine Drug Testing - Collection and Testing means collection and/or processing of a urine drug test. A urine specimen must be collected from a client under **direct observation** by CONTRACTOR staff. Any urine drug test performed according to this Contract must contain at a minimum, results for the following substances of abuse: Opiates, cannabinoids, cocaine metabolites, amphetamines/methamphetamine, and benzodiazepines.

SECTION 3 - PURPOSE & GENERAL INFORMATION

Target Population and Eligibility

Criteria for determining a client's eligibility for Utah County funding include, but are not limited to the following:

1. Adults 18 years of age and older; and
2. Current residence is in Utah County; *and*
3. Primary diagnosis is Opioid Dependence and other substance use/abuse related disorder.

Core Treatment Modalities

Applicants must include the following minimum core treatment modalities in each level of care:

1. Group Therapy/Medication Management;
2. Individual Therapy/Medication Management;
3. Medication Assisted Treatment for opiate use disorders/other substance use disorders/mental health conditions
3. Aftercare/Recovery Management.

Treatment Related Services/Activities

Additional services/activities that must be included in each level of care:

1. Case Coordination/Staffing;

2. Community Support Group Involvement;
3. Drug Testing;
4. Treatment Planning and Review;
5. Discharge and Transitional Service Planning;
6. Outcome monitoring;
7. Reporting required data to appropriate State, Federal, and County agencies as directed.

Location and Accessibility

All CONTRACTOR facilities to be used in the provision of the services covered under this contract must be located within Utah County. ADDAPT will give more consideration to applications that can demonstrate reasonable access to UTA transportation (bus and train) routes. CONTRACTOR must submit evidence of accessibility of such facilities by indicating physical addresses of all facilities, and route numbers of public transportation serving provider's office.

CONTRACTOR Reimbursement

Funds will be distributed to the CONTRACTOR on a fee-for-service basis. COUNTY is responsible for determining client eligibility, assessing financial obligation and collecting all monthly fees from the client. CONTRACTOR will receive full payment per established rates following a review and approval of CONTRACTOR'S billing statements. Reimbursement will not be made if a client has not been properly authorized by COUNTY prior to services being rendered. In the event that the CONTRACTOR has received payment from COUNTY for services which are subsequently paid by a third-party, such payments will be identified by CONTRACTOR during the following billing period and deducted from the total reimbursement request or reimbursed to COUNTY.

COUNTY will pay Medicaid for COUNTY portion of Medicaid match for all COUNTY referred clients.

CONTRACTOR agrees to make available to the COUNTY all financial, administrative, utilization and clinical records, concerning services provided to clients pursuant to this CONTRACT and in accordance with all applicable county, state, federal and professional laws, regulations or guidelines. The CONTRACTOR shall allow independent, County, State, and Federal auditors and/or program reviewers to have access to its records, including all financial records, for audit review and inspection upon request. The CONTRACTOR shall not do anything to limit or interfere with COUNTY's access rights, except as expressly provided by law. The CONTRACTOR and the COUNTY acknowledge, however, that entities other than the COUNTY may also have access rights to the records, especially if those entities provided part of the funding for the programs or services covered by this Contract.

At any time during the duration of contracts associated with this RFP or subsequent agreements, COUNTY reserves the right to determine a client's length of stay in treatment service and/or increase, decrease or withdraw funding for any client referred by COUNTY to the CONTRACTOR. Periodically, COUNTY conducts utilization analysis, which determines number of clients to be served by CONTRACTOR at a given time.

In the event it is determined that changes in the method(s) of delivering treatment services to adult clients are in the best interest of the client or COUNTY, COUNTY reserves the right to increase or decrease funding amounts for services referenced in this RFP.

Reimbursement Rates

Reimbursement for approved services is based on service fees per agreement between CONTRACTOR and COUNTY.

CONTRACTOR Billing Restrictions
Under a contract resulting from this RFP, COUNTY accepts full financial liability for clients referred for treatment by COUNTY. CONTRACTOR agrees not to bill nor charge COUNTY funded clients directly for any services rendered which are directly or indirectly related to his/her substance abuse treatment, unless otherwise authorized by COUNTY.

Funding Limitations
The maximum amount authorized by this contract shall be reduced or the contract terminated if required by Federal/State law, County Ordinance, regulation, or action or if there is significant underutilization of funds, provided the CONTRACTOR shall be reimbursed for all services performed in accordance with this contract prior to date of reduction or termination. If funds are reduced, there will be a comparable reduction in amount of services to be given by the CONTRACTOR.

Proposal Evaluation and Award Determination

Proposal Selection Process
Proposals selected by the review committee for funding are only "recommended" selections. The Board of County Commissioners shall award the contract to one of the top three ranked offerors, or may elect to reject all proposals.

Utah County will attempt to notify all applicants as to the disposition of their proposal in writing by **March 7, 2019** unless otherwise notified.

RFP Selection Options
COUNTY reserves the right to reject any and all proposals or to withdraw this offer at any time. Awards will be made to applicants based on the pre-determined evaluation criteria contained in this RFP and in the best interest of COUNTY as set forth in this RFP.

The selection committee will make a recommendation to Utah County's Purchasing Agent and the Board of County Commissioners to:

1. *reject* any or all applicants and provide the services in-house;
2. *reject* any or all applicants and **re-open** the RFP;
3. *award* one or more applicant(s) a contract but **re-open** the RFP;
4. *award* an adequate number of applicants contracts and **close** the RFP;

In the event the RFP is re-opened, applicants whose proposals were rejected may resubmit a new/revised proposal within the established dates.

Proposal Review
The review of the proposals will be conducted by an ad hoc committee composed of selected members of the community at large, representatives from related professions, and Utah County staff. This committee will examine the overall thoroughness of the proposals based on the pre-established criteria contained in this RFP. All information requested in this RFP will be used by the review committee in making their decisions.

Each proposal will be scored according to its content utilizing specific criteria in the following areas:

35% Location and Client Accessibility
20% Provider licensure/certification/hospital privileges
10% Provider capacity
25% Costs
10% Treatment Related Service capabilities
100% TOTAL

Incomplete proposals may be rejected without full consideration.

SECTION 4 - PROPOSAL CONTENT

Proposals must be concise and in outline/bullet format whenever possible. Attachments should only contain the information requested in the Proposal Content section of the RFP. **Do not** include resumes or letters of support. Unsolicited information will be removed from an applicant's proposal prior to being forwarded to the review committee. Unsolicited information will not be considered in the proposal review process.

Responses may be shorter than the maximum length specified if adequately covered.

Proposal *(4 pages maximum)*

The proposal should be submitted in letter form addressed to the County's procurement officer at the address specified above. Submission may be made via email to robertb@utahcounty.gov including scanned copies of all attachments. The proposal should contain all of the following information:

- RFP Title
- Name of agency and person(s) authorized to represent the offeror in any negotiations and signing of contract(s).
- Legal authority for offerors to operate in the State of Utah by March 15, 2019 (reference attached copies of corporation registration, Business Licenses, etc.)
- Address, phone number, and e-mail address (if available) of business location *and* facility where services will be delivered (if separate).
- Name and address of corporate officers, partners and/or board members where applicable.
- Medicaid PROVIDER number or a statement that the offeror will enroll as a Medicaid PROVIDER **by March 15, 2019** and thereafter maintain Medicaid PROVIDER status throughout the period of the contract.
- Statement that applicant or applicant's staff physician is licensed by Utah State Division of Occupational and Professional Licensing as a physician.
- Federal Tax number and tax status (for profit, non-profit).
- Statement of assurance that the Applicant's proposal meets all the requirements of the RFP.
- Description of the offerors capacity to provide OBOT services to patients of County including the number of hours per week available to dedicate to the resulting contract, and the number of patients offeror may be able to treat within the available hours. Please describe your practice of medication assisted treatment for patients with opiate use disorders.

Additional Agency Documents

True copies of the items should be submitted in this order as *Attachment A*:

1. Completed fee scale proposal (form included)
2. Utah State DOPL provider license
3. Medicaid Provider certification and NPI number
4. Substance Abuse and Mental Health Administration Drug Addiction Treatment Act of 2000 (DATA 2000) waiver as an approved buprenorphine prescriber.
5. DEA registration including evidence of registration to prescribe DEA Schedule II – V medications.
6. Evidence of hospital privileges
7. Copy of Liability Insurance
8. Copy of Medical Malpractice Insurance
9. Any other documents requested in subsequent sections of this RFP.

SECTION 5 - PROPOSAL FINANCIAL CONTENT

FEE SCHEDULE

HCPC / CPT	Fee Type	Provider Proposed Fee	CPT Billing Type	Description
90838	Fee	$	75 - 80 min.	S.A. Ind. Psychotherapy Med. Eval. & Management
90853	Unit	$	per 15 min.	S.A. Group Therapy (per ct)
90847	Fee	$	per encounter	Counseling with family member or significant other of patient
90832	Fee	$	16-37 min	Individual psychotherapy in conjunction with E/M encounter (30 min)
90834	Fee	$	38-52 min	Individual psychotherapy in conjunction with E/M encounter (45 min)
90837	Fee	$	53+ min	Individual psychotherapy in conjunction with E/M encounter (>45 min)
99201	Fee	$	per encounter	Office Visit E & M May not require a Physician
99202	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:PF E:PF D:SF
99203	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:EP E:EP D:LC
99204	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:DT E:DT D:MC
99205	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:CM E:CM D:HC
99211	Fee	$	per encounter	Office Visit E & M May not require a Physician 10 min
99212	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:PF E:PF D:SF 15 min
99213	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:EP E:EP D:LC 25 min
99214	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:DT E:DT D:MC 40 min
99215	Fee	$	per encounter	Office Outpatient Visit Establish 2/3 H:CM E:CM D:HC
99347	Fee	$	per encounter	Home Services E/M Codes - established patient (Physician)
99348	Fee	$	25 min.	Home Services E/M Codes - established patient (Physician)
96732	Fee	$	per mg	Therapeutic, prophylactic, or diagnostic injection (specify drug) subcutaneous or intramuscular
H0033	Fee	$		Oral Medication Administration (Suboxone)

80305	Fee	$		Observed Drug Screen
Admin	Unit	$	15 min.	Administrative duties and meeting attendance requested by Director or Deputy Directors

COUNTY will **not** reimburse a CONTRACTOR for the following services, unless agreed upon in writing by COUNTY, and there is written documentation of the conditions and/or limitations associated with the service(s):

1. Recreation therapy or activities;
2. Urinalysis / Drug Screens (supplies and lab tests) except as specified in contract;
3. Any non-substance use disorder or mental health related services***;***
4. Prescription and Over-the-Counter Medications;
5. Tobacco cessation classes or counseling;
6. Treatment for Gambling Addiction;
7. Treatment for Pornography Addiction;
8. Treatment for Domestic Violence;
9. Treatment for eating disorders; and,
10. DUI education.
11. Other services as may be deemed unnecessary, ineffective or beyond the intended scope of this procurement.

ASSURANCES

All proposals must contain a written assurance that, should Utah County offer a contract, the Contractor will agree to the following items:

Licensing: All applicable federal, state, and local licenses and Certifications must be acquired before the contract is entered into. Licenses must be maintained throughout the contract period.

Credible Electronic Health Record Reporting: Contractor will be required to use the Credible reporting system for documentation of all client care services. County will provide Credible Training at no charge to the contractor.

Computer Hardware and Software Requirements: The provider will maintain, at its own expense, minimum hardware, software, internet connectivity, Virus Protection Software, Email capability for the duration of the Contract.

CONTRACTOR represents and warrants that the information contained in Contractor's proposal, which may be incorporated by reference in subsequent contracts, is true and accurate.

CONTRACTOR agrees to notify COUNTY of any material change in the information on such application.

Attachment: ASAM Public Policy Statement on Office0based Opioid Agonist Treatment (OBOT)

ASAM
American Society of Addiction Medicine

Public Policy Statement on Office-based Opioid Agonist Treatment (OBOT)

BACKGROUND

Methadone maintenance treatment of opioid addiction was developed in 1965 and implemented in the United States as a form of opioid agonist treatment. In the 1970s, a system of federal regulation was imposed in response to reports of diversion of methadone into illicit channels. In 1993, the US government gave approval to LAAM as a second maintenance medication, and, in 2002, buprenorphine, a partial agonist with an improved safety profile, was approved for limited office use by specially qualified physicians. [See ASAM Public Policy Statements: Methadone Treatment, rev. 1991, and Buprenorphine for Opiate Dependence and Withdrawal, rev. 2002.]

When methadone maintenance, administered in licensed and accredited Opioid Treatment Programs (OTPs), is integrated with a comprehensive treatment service including individual and group psychotherapies and ancillary services such as occupational counseling, it has an efficacy and safety profile that has been solidly and repeatedly established in the clinical outcomes literature since 1965. Several distinguished bodies and consensus panels (e.g., NIH Consensus Statement 1997) have summarized this evidence and called for more access to this modality. Additionally, there is a growing European and North American literature supporting the efficacy and safety of office-based treatment with buprenorphine and methadone. Heroin addiction and addiction to prescription opioid analgesics are growing problems in the US, and the need for increased availability of effective treatment is clear.

Methadone maintenance treatment has been a significantly underutilized treatment modality in the US. Opioid agonist treatment programs reach only about 1/4th of the estimated 800,000 regular heroin users. In 2003, there were no Opioid Treatment Programs at all in five US states, and, in several other states, individual counties bar this treatment modality.

Treatment is underutilized at a time when the need for it is increasing: there is an increased availability of unusually pure and cheap heroin that can be profoundly addicting in intranasal and smokeable forms; heroin use is growing particularly rapidly among the young; and, there is a rising incidence of addiction to prescription opioid analgesics.

DEFINITIONS:

1. Opioid Treatment Programs (OTPs):

Licensed and accredited opioid agonist treatment programs, often called methadone maintenance treatment (MMT) programs, are currently authorized to dispense methadone, LAAM, and buprenorphine in highly structured protocols defined by Federal and State law and

regulation.[1] By regulation, patients must earn take-home medication privileges by demonstrating, via urinalysis or other drug testing, that they are free of illicit drugs, and by demonstrating cooperation with other treatment requirements. Research has shown that the best outcomes are found when medication (methadone) is combined with psychosocial treatments. Over time, many patients graduate to less structured services, with medications dispensed in weekly to (at most) monthly take-home quantities. The frequency and intensity of psychosocial services should vary according the phase of care, determined by patient progress and needs.

2. Office-Based Opioid Agonist Treatment (OBOT):

OBOT refers to models of opioid agonist treatment that seek to integrate the treatment of opioid addiction into the general medical and psychiatric care of the patient**.** The foundation of OBOT is the conceptualization of opioid addiction as a chronic medical condition with similarity to many other chronic conditions. An important feature of OBOT is that it allows primary care physicians to provide addiction treatment services in their usual clinical settings, thus expanding the availability of care.

OBOT can refer to treatment with methadone (a Schedule II medication) or with buprenorphine (a Schedule III medication). At present, only two medications (both formulations of sublingual buprenorphine) meet the requirements of the authorizing law, the *Drug Abuse Treatment Act of 2000* (DATA 2000). DATA 2000 provides for a model of OBOT by authorizing Schedule III-V medications to be used by qualified physicians in their offices for the treatment of opioid dependence or opioid addiction if those medications have been approved for this indication and if the physician has "the capacity to refer the patients for appropriate counseling and other appropriate ancillary services**."**

Several different models of OBOT have been tested in the US and in other countries. In a US model of OBOT usually called *Medical Maintenance*, there is a close affiliation between the office practice and the OTP that refers stable patients and continues to offer ancillary psychosocial treatment services as needed. In this model, exemptions must be requested by OTPs, and OBOT physicians must be affiliated with a sponsoring OTP.

European and Canadian models of agonist care are significantly less restrictive because they are not OTP clinic-based. Patients may be admitted and entirely managed in the physician's office with periodic visits, drug testing, and medication management. In the Canadian model, for example, agonist medications are dispensed as frequently as daily from a collaborating pharmacy, and, in addition to physician visits, patients participate in community-based psychosocial care. In such models physicians work relatively independently of OTPs.

3. Treatment Components, Structure and Intensity:

Examples of treatment *components* include counseling (individual and group), general medical care, psychiatric services, programs for family members, educational/vocational counseling, financial counseling, and legal services.

Treatment *structure* refers to elements such as the requirements a patient must meet in order to continue in treatment. Examples of such requirements are attendance compliance, no use of illicit drugs, and participation in psychosocial services.

[1] In 2003, the manufacturer of ORLAAM©, Roxane Pharmaceuticals, announced that it was ceasing production and distribution of the product and expected supplies to be depleted by February 2004. The remainder of this Public Policy Statement, therefore, refers only to methadone and buprenorphine.

Treatment *intensity* refers to the number of treatment components the patient utilizes (each of which can range from less to more rigorous) and the frequency with which the patient participates. For example, the frequency of counseling sessions can vary from one per day to one per month; the length of counseling session can range from ten minutes to one hour; the type of counseling can range from classroom sessions to those where the patient engages in an active role with the counselor.

Current US models of opioid agonist treatment rely on providing access to psychosocial services such as group therapy, patient education classes, relapse prevention services, mental health care, access to medical diagnostics and care, and randomized urine drug testing. Generally speaking, unstable patients in early treatment require both more structured treatment and greater intensity of such services than patients who are stable and have embraced a recovery-oriented lifestyle.

However, in areas where such services are not available, such as areas where there are no OTPs, pharmacological treatment alone with support of the treating clinician may still represent an important option for some patients.

Rationale for Expansion of Office-Based Opioid Treatment Programs:

Two formulations of buprenorphine are authorized by the Drug Abuse Treatment Act of 2000 (DATA 2000) for OBOT in the US. Methadone is approved for OBOT in Canada and several European countries, but not in the US. This situation means that whether a patient can be *routinely* treated in an office setting in the US is determined by the Schedule of the medication to be used and the approved indication, not by the clinical circumstances of the patient.

The decision to provide OBOT should not have to be made on the choice of the opioid agonist medication to be used. The selection of an opioid agonist treatment program, like the selection of any modality of treatment, should be based upon a multidimensional assessment of the patient's severity of illness, matching intensity and structure of treatment (level of care), using objective criteria such as those found in ASAM's Patient Placement Criteria, Second Edition Revised (ASAM PPC-2R).

Some opioid-addicted patients can be treated effectively with buprenorphine; others will require methadone. Some, particularly those new to treatment, may require highly structured treatment programs involving on-site, observed administration and dispensing of medication such as is utilized in OTPs, combined with intensive psychosocial and adjunctive therapies. Other patients do well in less structured settings and with a lower level of psychosocial services. The needs of patients change as their time in treatment lengthens and as they accomplish treatment goals and life changes associated with recovery. One size does not fit all, and ASAM strongly supports the need for a full continuum of service, linked to psychosocial stability, results of urine drug tests, and other patient-progress criteria.

ASAM believes that the level of structure and intensity of services in treatment programs in which patient are initiated on opioid agonist treatment with methadone should be higher than in programs treating stable patients. ASAM believes that appropriate levels of structure and intensity of services can be maintained by OBOT programs as well as by OTPs. For example, OBOT programs can have observed administration of medication, and psychosocial recovery resources, and trained and qualified OBOT physicians, knowledgeable about treating opioid addiction.

ASAM's policy recommendations seek to simplify current procedures for providing

Medical Maintenance for stable patients, encourage increased use of federal regulatory exemptions to test other innovative strategies for expanding access to methadone, permit OBOT physicians to change from Schedule III opioid agonists to Schedule II opioid agonists when buprenorphine is not able to "hold" the patient, and support public and private insurance coverage for Office Based Opioid Treatments.

ASAM Policy Recommendations:

1. Clinical Guidelines:

Physicians who provide office-based opioid agonist treatment (OBOT) should take into consideration clinical guidelines related to that treatment. Such guidelines should reflect research findings, best practices, and the consensus of experts in the field of opioid addiction treatment.

***ASAM recommends* development of OBOT practice guidelines through collaboration among addiction medicine and addiction psychiatry organizations.**

2. Physician Training:

Specific training should be required for physicians to qualify for approval to provide office-based opioid treatment using opioid agonists. Clinical use of buprenorphine requires certification in addiction medicine or addiction psychiatry, or 8 hours of specialized training, and receipt of a unique DEA number. The different safety profile of methadone compared with buprenorphine calls for additional specific training for physicians to be authorized to provide office-based opioid treatment with this medication.

***ASAM recommends* that physicians in office-based settings who treat patients for opioid dependence or opioid addiction using Schedule II medication (methadone) should be required to have completed a one-time training, over a 2-year period, consisting of 16 hours of accredited Category 1 continuing medical education (CME) specific to opioid pharmacotherapy with methadone. The content should be specified in practice guidelines developed through collaboration among addiction medicine and addiction psychiatry organizations.**

No part of this requirement would be met by the training described in Drug Abuse Treatment Act of 2000 to qualify physicians to use the Schedule III-V medications approved for treatment of opioid dependence (sublingual buprenorphine).

3. Continuum of Care:

ASAM recognizes the place that Opioid Treatment Programs (OTPs) hold in the continuum of care by providing highly structured treatment environments. The clinical, social, and public health benefits of methadone maintenance administered in federally licensed and accredited Opioid Treatment Programs have been repeatedly demonstrated in clinical research studies and are irrefutable. In addition, recent studies of Medical Maintenance support feasibility and efficacy of transferring stable patients to office-based physician care.

ASAM recognizes that "graduating" stable patients who wish to transfer from OTPs to office-based maintenance may increase the severity and complexity of the remaining patient mix within OTPs. Nonetheless, it is consistent with usual standards of medical practice to provide the least restrictive environment appropriate to the nature and stage of a patient's illness.

ASAM recognizes that patients who prove unstable in office settings will require the level of structure and intensity of integrated services available in an OTP if a higher level of structure cannot be obtained in the OBOT setting. It is essential that

referrals occur in both directions, i.e., that patients have the capacity to be "stepped-up into OTP" as well as "stepped-down to OBOT" based on clinical criteria.

ASAM recognizes that patients who require a higher level of service intensity consume more resources and that higher levels of funding are needed to support appropriate treatment for such complex patients.. Without a proportional increase in funding to match the intensity of service, there might be a *de facto* disincentive for OTPs to refer stable patients to the next lower level in the continuum of care.

***ASAM recommends*:**

(a) That all OTPs have the capacity to "graduate" a patient to Medical Maintenance when that level of care is indicated.

(b) That OBOT physicians, affiliated or independent, and OTPs establish a collaborative relationship that permits patients to be referred back and forth between programs, providing differing models and intensities of treatment, according to clinical needs.

(c) That reimbursement levels be more closely linked to the level of care provided: more intensive, more complex and time-consuming services should be reimbursed at higher rates.

4. Expansions of Office-Based Agonist Treatment:

(a) Medication Changes from Schedule III to Schedule II:

Currently, buprenorphine is the only agent approved for prescription by qualified physicians in office-based management of opioid dependence or opioid addiction. Although each qualified physician (or group practice) is currently limited to 30 patients, OBOT with buprenorphine does represent an expansion of treatment availability.

Not all patients who begin opioid agonist treatment on buprenorphine in an OBOT setting under DATA 2000 provisions can be satisfactorily managed on buprenorphine, and some will require a transfer to methadone. ASAM supports allowing trained and qualified physicians to change the agonist medication from buprenorphine to methadone when indicated.

***ASAM recommends* that, as a further expansion of office-based agonist maintenance treatment, federal law and regulation be revised to authorize use of Schedule II medication (methadone) by appropriately trained and qualified physicians for patients who were started on buprenorphine under DATA 2000 when a change in medication is clinically indicated.**

(b) Medical Maintenance Simplification:

Current federal regulations provide for exemptions for Medical Maintenance to be available only through OTPs. ASAM believes that knowledgeable and trained physicians can provide Medical Maintenance treatment without having a contractual or agent relationship with an OTP.

ASAM recommends that federal law and regulations be revised to

(1) Endorse Medical Maintenance as an advanced, but routine, component of OTPs.

(2) Eliminate the need for OTPs to apply for a regulatory exemption for Medical Maintenance.

(3) Make waivers available to qualified physicians to provide Medical Maintenance Treatment independent of an OTP.

5. Insurance Coverage:

Opioid addiction and opioid dependence are medical illnesses defined in DSM-IV and ICD-10. High proportions of patients with heroin addiction have co-occurring disorders such as HIV, hepatitis B and C, soft tissue infections, and psychiatric disorders. Early and combined treatments will provide cost offsets against later, more expensive, medical services.

ASAM recommends **public and private medical insurance coverage for treatment of opioid addiction or opioid dependence in both office-based settings and in Opioid Treatment Programs.**

ASAM recommends **that public and private insurers provide adequate reimbursement for both the pharmacotherapeutic and psychosocial components of addiction treatment because each is an essential element in recovery that reduces long-term medical costs.**

6. Demonstration Projects & Regulatory Exemptions:

Innovative projects evaluating a variety of treatment delivery strategies are needed in order to allow meaningful and measured expansions of access to treatment. Such projects can be especially important in medically underserved areas, in rural areas and other parts of the country that currently do not have access to OTPs.

Transfer of stabilized OTP patients to Medical Maintenance in office-based settings was initially available to physicians via an Investigational New Drug (IND) application only. In 2000, this was made available, via application to CSAT, through the OTP program-wide exemption provisions of 21 CFR §291.505(d)(11). As of December 2002, five exemptions had been authorized; three publications from these sites reported feasibility, reasonable retention rates, comparable outcomes to OTPs, and a high level of physician and patient satisfaction. ASAM believes that Medical Maintenance has been adequately tested and should now be endorsed as a routine service component of OTP programs (and no longer require application for exemption).

It is also important to evaluate the feasibility and efficacy of direct admissions to OBOT methadone maintenance programs as is done in France and Canada. There are data from such studies conducted in other countries; studies should evaluate analogous treatment models under conditions in the US.

ASAM recommends that federal regulations provide for exemptions to study models other than Medical Maintenance, especially models that incorporate elements of structure appropriate to support patients new to treatment. Future regulatory exemptions should focus on other methods of expanding access to methadone. There is a great need to test European and other models that expand access to opioid agonist medications. For example, rural and underserved areas may not have OTPs within reasonable driving distances, and models of OBOT opioid agonist treatment need to be tested in such locales.

ASAM recommends **that SAMHSA/CSAT develop rules and procedures for granting regulatory exemptions for demonstration projects designed to evaluate the safety and efficacy of direct admissions to OBOT using methadone and innovative models of treatment delivery, especially in currently underserved areas.**

ASAM recommends **additional federal funding and technical support for demonstration projects in community settings.**

ASAM recommends **federal funding to implement and evaluate these models.**

Approved by the ASAM Board of Directors July 2004

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