This application form regarding the Arizona Opioid Treatment Program (OTP) Exemption Request and Record of Justification under 42 CFR 8.11(H), shall be completed in its entirety and signed as specified below. Information submitted on the application is subject to verification. A completed application shall be submitted for each Authorized Healthcare Professional Recognized by the State of Arizona for which you are applying.

PROGRAM OTP NO:

PROGRAM NAME:

PROGRAM ADDRESS:

TELEPHONE: **FAX:** **E-MAIL (PROGRAM SPONSOR):**

NAME & TITLE OF PROGRAM SPONSOR:

NAME & TITLE OF PROGRAM MEDICAL DIRECTOR:

SAMHSA CERTIFICATION NUMBER AND EXPIRATION DATE:

RECENT ACCREDITATION SURVEY DATE:

Exemptions Requested:
Based on SAMHSA's authority under 42 C.F.R. 8.11 (h), the OTP program sponsor requests the following exemption(s) from the requirements of 42 C.F.R. 8.12 in order for mid-level practitioners to perform the functions specifically designated below at the above listed OTP (please check all that apply).

☐ 8.12 (e) Patient admission criteria
Ensuring that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drugs are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment (a function of a program physician).

Waiving, when clinically appropriate, the requirement of a 1-year history of addiction under 42 C.F.R. §

☐ 8.12(e) (1), for patients released from penal institutions (within 6 months after release), for pregnant patients, and for previously treated patients (up to 2 years after discharge). (A function of a program physician.)

Certifying pregnancy for purposes of the above bullet point (a function of a program physician.)

Assessing patients with two or more unsuccessful detoxification episodes within a 12-month period for other forms of treatment (a function of a program physician).

☐ 8.12(h) Medication administration, dispensing, and use.
Documenting in a patient's record that 40 milligrams did not suppress opioid abstinence symptoms when providing an initial dose of methadone in excess of 30 milligrams or 40 milligrams in the first day (a function of a program physician).

Making dosing and administration decisions (a function of a program physician that is "familiar with the most up-to-date product labeling.")

☐ 8.12 (i) Unsupervised or "take-home" use
Making OTP decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in 42 C.F.R. § 8.12(i)(1) (a function of the medical director).

Considering the take-home criteria listed in 42 C.F.R. 8.12(i)(2) when determining which patients may be permitted unsupervised use (a function of the medical director).

AUTHORIZED HEALTHCARE PROFESSIONALS RECOGNIZED BY THE STATE

☐ Physician Assistants

☐ Nurse Practitioners

☐ Other Mid-level providers; Please Specify_____

DEA Mid-Level Practitioners: https://www.deadiversion.usdoj.gov/drugreg/practioners/index.html

- Additional Restrictions by ARS:
  https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

Justification for Request

☐ Health Care Reform – Medicaid Expansion
Comments:

☐ Opioid Epidemic
Comments:

☐ Work Force Shortage
Comments:

☐ Behavioral Health Integration
Comments:
Other Comments:

OTHER CONSIDERATIONS:
What percent increase in patients could be served with this OTP program exemption?
Comments:

What is the OTP on-site work schedule for the OTP medical director and the mid-level practitioner?
Comments:

Provide the name, (a copy of) Drug Enforcement Administration DEA registration number, (a copy of) state license number for each mid-level practitioner subject to this exemption request. Attach a copy of each mid-level practitioner's Curriculum Vitae (CV).
Comments:

REGULATIONS IN SUPPORT/COMMENTS FOR REQUEST**

☐ State Specific Rules for Authorized Healthcare Professionals (Is this Mid-level provider authorized by the state to provide the requested services?)
Comments:

☐ Describe state oversight, licensing, accreditation, and monitoring activities that ensure the healthcare professionals providing medical services requested in this program exemption are licensed and providing services within their scope of practice.
Comments:

☐ SAMHSA-CSAT Accreditation Guidelines
Comments:

☐ Patient Health and Safety

☐ Other
Comments:

Include (a copy) of documentation regarding the following:

- Medical Director's and Mid-Level Practitioner's current DEA Registration, State License, CV, and Medication Assisted Treatment (MAT) Training (if the Medical Director has a waiver DEA registration, then the waiver DEA registration number would be indicated and also noted on CV if no DEA X number, a copy of MAT certification training is required;

- How Mid-Level Practitioners and physicians collaborate on patient care; Provide policy and procedures on how physicians provide supervision for patient care;

Documentation Comments:

Other Comments:

SUBMITTED BY

NAME OF SPONSOR	SIGNATURE OF SPONSOR	DATE
		/ /

NAME OF MEDICAL DIRECTOR	SIGNATURE OF MEDICAL DIRECTOR	DATE
		/ /

STATE RESPONSE TO REQUEST	STATE OPIOID TREATMENT AUTHORITY	DATE
		/ /

☐ Approved
☐ Denied

Comments:

FEDERAL RESPONSE TO REQUEST	CENTER FOR SUBSTANCE ABUSE TREATMENT	DATE
		/ /

☐ Approved
☐ Denied

Comments:

DATE OF APPROVAL: / / **EXEMPTION EXPIRATION DATE:** / / ***

**42 CFR 8.11(h) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and 42 CFR 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

***The OTP's policies and procedures documenting mid-level practitioner practices and oversight must be provided as an attachment to this application.

********A continuing exemption request must be filed simultaneously with submission of a SMA-162 for SAMHSA OTP recertification.

Refer to the following link for the state opioid treatment authority contact information: http://dpt2.samhsa.gov/regulations/smalist.aspx

SUBMIT FORM:

ARIZONA STATE OPIOID TREATMENT AUTHORITY

grantsmanagement@azahcccs.gov
Arizona Health Care Cost Containment System
701 E. Jefferson St., MD 6500, Phoenix, Arizona 85034