

DEPARTMENT OF HEALTH & SOCIAL SERVICES



PROPOSED CHANGES TO REGULATIONS

OPIOID TREATMENT PROGRAM REQUIREMENTS

- 7 AAC 33. METHADONE PROGRAMS;
- 7 AAC 70. BEHAVIORAL HEALTH SERVICES;
- 7 AAC 135. MEDICAID COVERAGE; BEHAVIORAL HEALTH SERVICES;
- 7 AAC 160. MEDICAID PROGRAM; GENERAL PROVISIONS.



PUBLIC REVIEW DRAFT
October 6, 2016

COMMENT PERIOD ENDS: November 28, 2016

Please see the public notice for details about how to comment on these proposed changes.

Notes to reader:

1. Except as discussed in note 2, new text that amends an existing regulation is **bolded and underlined**.
2. If the lead-in line above the text of each section of the regulations states that a new section, subsection, paragraph, or subparagraph is being added, or that an existing section, subsection, paragraph, or subparagraph is being repealed and readopted (replaced), *the new or replaced text is not bolded or underlined*.
3. [ALL-CAPS TEXT WITHIN BRACKETS] indicates text that is to be deleted.
4. When the word “including” is used, Alaska Statutes provide that it means “including, but not limited to.”
5. Only the text that is being changed within a section of the current regulations is included in this draft. Refer to the text of that whole section, published in the current Alaska Administrative Code, to determine how a proposed change relates within the context of the whole section and the whole chapter.

Title 7 Health and Social Services.**Chapter 33. Methadone Programs.**

7 AAC 33 is repealed:

7 AAC 33. Methadone Programs. Repealed.

7 AAC 33.005. State approval required for methadone programs. Repealed. (Eff. 10/10/74, Register 51; am 6/2/94, Register 130; am 6/24/2004, Register 170; repealed ____/____/____, Register ____)

7 AAC 33.015. Preparation of treatment plans. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.025. Evaluation of programs. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.035. Identification and confidentiality. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.045. Organization and fiscal responsibility. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

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7 AAC 33.055. Methadone staff requirements. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.065. Criteria for patient selection. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.075. Program rules and patient instructions. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.085. Methadone dosage levels. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.095. Take-home medication procedures. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.105. Requirements for methadone preparation, record keeping, and security of stocks. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.115. Procedures for confined patients. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.125. Urinalysis procedures. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.135. Patient record requirements. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.140. Records; reports to the department. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.142. Records; closure of methadone program. Repealed. (Eff. 10/10/74, Register 51; repealed ____/____/____, Register ____)

7 AAC 33.145. Treatment termination procedures. Repealed. (Eff. 10/10/74, Register 51; repealed __/__/__, Register ____)

7 AAC 33.155. General provisions. Repealed. (Eff. 10/10/74, Register 51; am 6/24/2004, Register 170; repealed __/__/__, Register ____)

7 AAC 33.165. Definitions. Repealed. (Eff. 10/10/74, Register 51; repealed __/__/__, Register ____)

Chapter 70. Behavioral Health Services.

7 AAC 70.010(a)(1)(B) is amended to read:

(B) a substance use treatment provider receiving money from the department under AS 47.30.475 **or AS 47.37.045;**

7 AAC 70.010(a)(2) is amended to read:

(2) a substance use treatment provider that is subject to the requirements of AS 47.37, but does not receive money under AS 47.37, including **an opioid use disorder treatment program or** a substance use treatment provider that provides treatment to individuals referred by an alcohol safety action program; in this paragraph, "treatment" does not include services designed solely to provide support, advocacy, education, referral, or other assistance navigating the behavioral health services available to the recipient; and
(Eff. 10/1/2011, Register 199; am __/__/__, Register ____)

Authority:	AS 47.05.010	AS 47.30.477	AS 47.30.570
	AS 47.30.470	AS 47.30.530	AS 47.37.140
	AS 47.30.475	AS 47.30.540	

7 AAC 70.030(a)(1)(A) is amended to read:

7 AAC 70.030. Department approval of a provider of behavioral health services

(a) The department will approve an organization to provide behavioral health services in this state only if that organization

(1) meets the requirements for

(A) a behavioral health services provider under 7 AAC 70.100 that is providing one or more of the following:

(i) behavioral health clinic services;

(ii) behavioral health rehabilitation services;

(iii) **withdrawal management** [DETOXIFICATION] services;

(iv) residential substance use **disorder** treatment services in accordance with 7 AAC 70.120; [OR]

(v) **opioid use disorder treatment services; or**

7 AAC 70.030(a)(1)(B) is amended to read:

(B) a substance use treatment provider under 7 AAC 70.130 **and under 7 AAC 70.125**; and

7 AAC 70.030(e) is amended to read:

(e) The department will issue a provisional approval under (d) of this section for **up to** [A FIXED PERIOD OF] two years from the date the department issued the provisional approval, [.] **except for an opioid use disorder treatment services provider that shall only receive a provisional approval for a maximum of one year.**

(Eff. 10/1/2011, Register 199; am_____/_____/_____, Register____)

Authority: AS 47.05.010 AS 47.30.477 AS 47.30.570

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AS 47.30.470

AS 47.30.530

AS 47.37.140

AS 47.30.475

AS 47.30.540

7 AAC 70.050. Recipient eligibility for state-financed behavioral health services

7 AAC 70.50(2)(A) is amended to read:

(2) has

(A) a maladaptive pattern of substance use, including use of a narcotic drug that may require opioid use disorder treatment services; or

7 AAC 70.100. Qualifications of a community behavioral health services provider receiving money from the department

7 AAC 70.100(a) is amended by adding a new subsection to read:

(12) if providing residential substance use treatment services, must meet the additional requirements of 7 AAC 70.120; and

(14) if providing opioid use disorder treatment services, must meet the additional requirements in 7 AAC 70.125;

(Eff. 10/1/2011, Register 199; am 6/16/2016, Register 218; am_____/_____/_____, Register_____)

Authority: AS 47.05.010

AS 47.30.477

AS 47.30.570

AS 47.30.470

AS 47.30.530

AS 47.37.140

AS 47.30.475

AS 47.30.540

7 AAC 70 is amended by adding a new section to read:

7 AAC 70.125. Additional requirements for providing opioid use disorder treatment services.

(a) To be approved by the department to provide opioid use disorder treatment services, a community behavioral health services provider described in 7 AAC 70.010(a)(1)(B) or a substance abuse treatment provider described in 7 AAC 70.010(a)(2) must

(1) comply with all the requirements of 42 CFR, Part 8 adopted by reference in 7 AAC 70.910;

(2) be accredited or working toward accreditation in accordance with 7 AAC 150

(3) be certified by the Substance Abuse and Mental Health Services Administration;

(4) be registered with the Drug Enforcement Administration;

(5) meet the standards, if applicable, for drug room licensure outlined in 12 AAC 52.800 – 12 AAC 52.850;

(6) provide a comprehensive range of medical and behavioral health clinic and rehabilitative services that address addiction and addictive behavior;

(7) cooperate with the Department of Corrections to assist with opiate withdrawal or maintenance treatment of a recipient in custody;

(8) cooperate with the attending physician and hospital staff to continue opioid treatment services upon hospitalization of a recipient; and

(9) adhere to the Substance Abuse and Mental Health Services Administration, *Federal Guidelines for Opioid Treatment Programs*, adopted by reference in 7 AAC 70.910.

(b) All opioid treatment services including behavioral health clinic and rehabilitation services must be medically necessary and clinically appropriate in accordance with the

(1) The ASAM Criteria, Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, adopted by reference in 7 AAC 70.910;

(2) Diagnostic and Statistical Manual of Mental Disorders, adopted by reference in 7 AAC 70.910; and

(3) International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) adopted by reference in 7 AAC 70.910.

(c) Withdrawal of services may not occur in less than 21 days. Providers shall have written withdrawal procedures for a recipient's involuntary termination of treatment services that must be explained to the recipient before imposition of the procedures.

(d) Services must be available to assure the continuity of care of each recipient. Hours of operation shall consider and accommodate recipient schedules, including but not limited to such needs as transportation, school, homemaking, employment, and child care.

(1) Services shall be made available at least six (6) days per week, 52 weeks per year, with the exception of closures on state and federal holidays as identified by the State of Alaska Department of Administration and the U.S. Office of Personnel Management. Providers shall inform the department of its published hours of operation, including scheduled closures such as holidays.

(2) Providers shall offer medication dispensing each weekday (Monday through Friday), with at least three (3) hours scheduled outside of the regular 9:00 a.m. – 5:00 p.m. business day.

(3) Medication dispensing shall be scheduled for a period of at least two (2) hours on Saturdays, if open just six days a week, and at least two hours on Sundays, if open seven days a week.

(e) In the event of an emergency leading to temporary closure of a program, an up-to-date plan for emergency administration of medications should be maintained that:

(1) Provides for the capability to respond to emergencies on a 24-hour basis; and

(2) Identifies an alternative dosing location that is secured in advance which complies with registration requirements of the federal Drug Enforcement Administration.

7 AAC 70.130(1) is amended by adding a new subsection to read:

(D) 7 AAC 70.125, if providing opioid use disorder treatment services;

(Eff. 10/1/2011, Register 199; am ____/____/2016, Register ____)

Authority:	AS 47.05.010	AS 47.30.477	AS 47.30.570
	AS 47.30.470	AS 47.30.530	AS 47.37.140
	AS 47.30.475	AS 47.30.540	

7 AAC 70.910. Requirements adopted by reference

7 AAC 70.910 is amended to read:

The following documents referenced in this chapter are adopted by reference:

(1) *American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition, June 2013 (DSM-5), as amended from time to time;

(2) *American Society of Addiction Medicine, ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions*, Third Edition, 2013;

(3) the *Revised Clinical Institute Withdrawal Assessment for Alcohol Scale (CIWA-Ar)*, originally published in the *British Journal of Addiction* (1989), Volume 84;

(4) the *Clinical Opiate Withdrawal Scale (COWS)*, originally published in the *Journal of Psychoactive Drugs*, Volume 35, Number 2, April-June 2003.

(5) *International Classification of Diseases - 10th Revision, Clinical Modification (ICD-10-CM)*, 2016 revision, as amended from time to time;

(6) *Zero to Three: National Center for Infants, Toddlers, and Families, Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood: Revised Edition (DC:0-3R), revised as of 2005.*

(7) **42 CFR, Part 8, certification of opioid treatment programs, revised as of October 1, 2013;**

(8) **Substance Abuse and Mental Health Services Administration, *Federal Guidelines for Opioid Treatment Programs*. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP.**

Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.

(Eff. 10/1/2011, Register 199; am 6/16/2016, Register 218; am ____/____/2016, Register ____)

Authority:	AS 47.05.010	AS 47.30.475	AS 47.30.540
	AS 47.05.012	AS 47.30.477	AS 47.30.570
	AS 47.30.470	AS 47.30.530	AS 47.37.140

Chapter 135. Medicaid Coverage; Behavioral Health Services.

Sec 10. Scope of Medicaid behavioral health services.

7 AAC 135.010. Scope of Medicaid behavioral health services

7 AAC 135.010(c)(12) is amended to read:

(c) The department will pay for the following behavioral health rehabilitation services in accordance with this chapter if the service is provided by a member of the provider's staff who is performing that service as a regular duty within the scope of that staff member's knowledge, experience, and education:

(12) behavioral health treatment plan review for a recipient in **an opioid use disorder** [A METHADONE] treatment program;

(Eff. 10/1/2011, Register 199; am ____/____/2016, Register ____)

Authority: AS 47.05.010

AS 47.07.030

7 AAC 135.040. Service authorization and limitation

7 AAC 135.040(c)(9) is amended to read:

(c) A community behavioral health services provider may provide the following behavioral health rehabilitation services without specific authorization by the department:

(9) one medical evaluation of a recipient in an opioid [A METHADONE] treatment program per admission for that **opioid use disorder** [METHADONE] treatment program, including

(A) consultation and referral;

(B) verification of **one year of** addiction; and

(C) establishing **dosage for** methadone **or other agonist or partial-agonist** [DOSAGE];

7 AAC 135.040(c)(14) is amended to read:

(14) behavioral health treatment plan review for a recipient in **an opioid use disorder** [A METHADONE] treatment program, limited to one review per admission; (Eff. 10/1/2011, Register 199; am 6/16/2016, Register 218; am ____/____/2016, Register ____)

Authority: AS 47.05.010

AS 47.07.030

Chapter 160. Medicaid Program; General Provisions.

Sec 990. Definitions.

7 AAC 160.990(b)(96) is repealed and readopted to read:

(96) “opioid **use disorder** treatment program” means an individual or entity that administers or

dispenses a narcotic drug to a narcotic addict for withdrawal or maintenance treatment, and provides to individuals when appropriate or necessary a comprehensive range of medical and behavioral health clinic and rehabilitative services, and is approved by the department and the U.S. Food and Drug Administration, and is registered with the U.S. Drug Enforcement Administration;

Authority: AS 47.05.010 AS 47.07.040 AS 47.07.055

(Eff. 2/1/2010, Register 193; am 7/7/2010, Register 195; am 1/1/2011, Register 196; am 10/1/2011, Register 199; am 4/1/2012, Register 201; am 7/1/2013, Register 206; am 5/18/2014, Register 210; am 6/16/2016, Register 218; am ____/____/2016, Register ____)