

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	08/28/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 10/3/2014

2. COMAR Codification

Title Subtitle Chapter Regulation

10 09 80 01-.12

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

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6. Check applicable items:

- New Regulations

- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: May 1, 2014.

- Repeal of Existing Regulations

- Recodification

- Incorporation by Reference of Documents Requiring DSD Approval

- Reproposal of Substantively Different Text:

: Md. R
(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

- Yes - No

8. Incorporation by Reference

- Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

- OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

- Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by David Lapp, Assistant Attorney General, (telephone #410-767-5292) on August 12, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Joshua M. Sharfstein, M.D.

Title

Secretary

Telephone No.

410-767-6500

Date

August 28, 2014

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.80 Community-Based Substance [Abuse] Use Disorder Services

Authority: Health-General Article, §§8-204(c)(1) and 15-103(a)(1), Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulation .01, adopt new Regulations .02 , .04, and .07, amend and recodify Regulation .02 to be Regulation .03, Regulation .03 to be Regulations .05, Regulation .04 to be Regulation .06, Regulation .05 to be Regulation .08, and Regulation .07 to be Regulation .10, and recodify Regulation .06 to be Regulation .09, and Regulations .08 and .09 to be Regulations .11 and .12 under COMAR 10.09.80 Community-Based Substance Use Disorder Services.

Statement of Purpose

The purpose of this action is to amend the current chapter to include all covered community –based substance use disorder services under one chapter. The amendment clarifies the substance use disorder community-based services that are covered under the HealthChoice MCO self-referred process and covered by the Department on a fee-for-service basis.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street,

Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through November 3, 2014. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2015

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

There is no economic impact because these substance use disorder services were previously paid for as part of the capitated rate for HealthChoice managed care organizations (MCOs). These services are now carved-out of MCO capitated rates.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

There is no economic impact on small businesses because there is no change in payment for substance use disorder services delivered. Only the payor of the substance use disorder service will change.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 09 MEDICAL CARE PROGRAMS

10.09.80 Community-Based Substance [Abuse] Use Disorder Services

Authority: Health-General Article, §§8-204(c)(1) and 15-103(a)(1), Annotated Code of Maryland

10.09.80.01 (5/1/2014)

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

[(1) "Alcohol and Drug Abuse Administration" means the administration within the Department that establishes regulatory requirements which substance abuse providers are to maintain in order to become certified by the Office of Health Care Quality.]

(1) "*Administrative Service Organization (ASO)*" means the contractor procured by the State to provide the Department with administrative support services to operate the Maryland Public Behavioral Health System.

(2) (text unchanged)

[(3) "Certification" means the approval issued to a program by the Office of Health Care Quality.]

(4) "Community-based substance abuse program" means a program that provides services in community settings not regulated by the Health Services Cost Review Commission.

(5) "Comprehensive substance abuse assessment" means the process of gathering data about an individual's biopsychosocial problems to determine whether substance abuse treatment is needed and, if so, at what level of care.]

(3) "*Behavioral Health Administration*" means the administration within the Department that establishes regulatory requirements that behavioral health programs are to maintain in order to become certified or licensed by the Department.

(4) "*Community-based substance use disorder program*" means a program that provides services in community settings not regulated by the Health Services Cost Review Commission.

(5) "*Certification*" means the approval issued to a program by the Office of Health Care Quality.

(6) (text unchanged)

(7) "Discharge plan" means a written description of specific goals and objectives to assist the [recipient] participant upon leaving treatment.

(8) (text unchanged)

(9) "Individualized treatment plan" means a written plan of action that is developed and periodically updated and revised to address a [recipient's] participant's specific service needs.

(10)—(11) (text unchanged)

(12) "Office of Health Care Quality" means the office within the Department responsible for certification and inspection of programs for the [Alcohol and Drug Abuse] *Behavioral Health Administration*.

[(13) "Program" means the Maryland Medical Assistance Program.]

(14) "Progress note" means an objective documentation of the recipient's progress in relation to specific treatment goals and objectives.

(15) "Recipient" means an individual who is eligible for Program benefits.]

(13) "*Participant*" means an individual who is eligible for Program benefits.

(14) "*Program*" means the Maryland Medical Assistance Program.

(15) "*Progress note*" means an objective documentation of the recipient's progress in relation to specific treatment goals and objectives.

(16) (text unchanged)

(17) "Substance [abuse] *use disorder*" means a maladaptive pattern of substance use leading to clinically significant impairment or distress and manifested by recurrent and significant adverse consequences related to the repeated use of substances.

(18) (text unchanged)

.02 License Requirements.

A. A community-based substance use disorder provider shall be certified by the Department in accordance with COMAR 10.47.01.

B. An opioid maintenance therapy provider shall:

(1) Be certified by the Department in accordance with COMAR 10.47.01; and

(2) Maintain approval by the Drug Enforcement Administration.

[.02].03 Conditions for [Program] Provider Participation.

A. [A] Provider shall be community-based substance [abuse] *use disorder* [program] programs [shall] that meet [and comply with all requirements] all conditions for participation set forth in COMAR 10.09.36.03.

B. A community-based substance [abuse] *use disorder* [program] provider shall:

[(1) Receive certification by the Office of Health Care Quality in accordance with COMAR 10.47.01; and

(2) Meet the requirements established by the Alcohol and Drug Abuse Administration as described in COMAR 10.47.01.]

(1) Maintain verification of licenses and credentials of all professionals employed by or under contract with the provider in their respective personnel files; and

(2) Have clearly defined, written, patient care policies.

C. A provider of substance use disorder services shall maintain adequate documentation of each face-to-face contact with each participant, which, at a minimum, shall include:

- (1) Date of service;
- (2) Start time and end time;
- (3) Summary of interventions provided; and
- (4) An official e-Signature, or a legible signature, along with the printed or typed name of the individual providing care, with the appropriate title.

D. An opioid maintenance therapy provider shall comply with federal regulation 42 CFR §8.

.04 Eligibility and Referral

A. A participant may self refer or be referred to substance use disorder treatment by a:

- (1) Provider;
- (2) Family member; or
- (3) Caregiver.

B. The ASO shall have a toll free telephone line to accept referrals and help participants find an appropriate substance use disorder provider.

C. The ASO shall authorize medically necessary services according to guidelines established by the Department and in accordance with Regulation .03 of this chapter.

D. Substance Use Disorder Services.

(1) Substance use disorder services are services for which the participants' diagnosis and treatment provider meet the criteria specified in COMAR 10.09.70 and this chapter..

(2) The ASO shall reimburse substance use disorder providers.

[.03] .05 Covered Services.

[A.] The Program covers the following [medically necessary community-based substance abuse services when rendered to a recipient by a qualified program as described in Regulation .02 of this regulation]:

- [(1) Comprehensive substance abuse assessment as described in §B of this regulation;
- (2) Level I Group and Individual Substance Abuse Counseling Services as described in §C of this regulation;
- (3) Level II Intensive Outpatient Services as described in §D of this regulation; and
- (4) Methadone services as described in COMAR 10.09.08.04.]

[B.] A. Comprehensive substance [abuse] *use disorder* assessment [as referenced in §A of this regulation], which at a minimum shall:

- (1) (text unchanged)
- (2) Include:
 - (a) An assessment of the following areas:
 - (i) (text unchanged)
 - (ii) Substance [abuse] *use disorder* treatment history;
 - (b) (text unchanged)
 - (c) Recommendation for the appropriate level of substance [abuse] *use disorder* treatment [.]

[(1)] B. Level I group and individual substance [Abuse] *use disorder counseling* [Services as referenced in §A of this regulation provide services for recipients who require services for less than 9 hours weekly for adults and 6 hours weekly for adolescents.] that shall include:

(1) Services for participants who require less than 9 hours weekly for adults and 6 hours weekly for adolescents; and

[(2) Recipients who are appropriate for this level of treatment shall:

(a) At a minimum meet eligibility criteria, using guidelines such as the American Society of Addiction Medicine Patient Placement Criteria for Level I, or other guidelines approved by the Program; and

(b) Have a physical and emotional status that allows them to function in their usual environment.]

[(3)] (2) [Before providing Level I services described in this section, the provider shall develop a] A written individualized treatment plan, with the participation of the [recipient] *participant* based on the comprehensive assessment [and placement recommendation as described in §A of this regulation. This plan shall] that shall:

(a)—(b) (text unchanged)

(c) Include:

- [(i) An assessment of the recipient's individual needs;
- (ii) Long-range and short-range treatment plan goals;
- (iii) Specific interventions for meeting the treatment plan goals;
- (iv) Target dates for completion of treatment plan goals;
- (v) Criteria for successful completion of treatment;
- (vi) Referrals to ancillary services, if needed; and
- (vii) Referral to recovery support services, if needed.]

(i) An assessment of the participant's eligibility, using guidelines such as the American Society of Addiction Medicine Patient Placement Criteria for Level I, or other guidelines approved by the Program;

(ii) The participant's individual needs;

- (iii) Long-range and short-range treatment plan goals;
- (iv) Specific interventions for meeting the treatment plan goals;
- (v) Target dates for completion of treatment plan goals;
- (vi) Criteria for successful completion of treatment;
- (vii) Referrals to ancillary services, if needed; and
- (viii) Referral to recovery support services, if needed;

[(4)] (3) [Each individual and group counseling session shall be documented] Documentation in the [recipient's] participant's record through written progress notes after each counseling session[.];

[(5)] Before discharge, the provider shall give the recipient a discharge plan which includes written recommendations to assist the recipient with continued recovery efforts, as well as appropriate referral services.]

(4) Family members, if necessary, as long as the participant is also present in a Level 1 group counseling session; and

(5) A discharge plan which includes written recommendations to assist the participant with continued recovery efforts, as well as appropriate referral services;

[D. Level II Intensive Outpatient Services.

(1) Level II Intensive Outpatient Services as referenced in §A of this regulation provides services for recipients who require 9 to 20 hours weekly for an adult and 6 to 20 hours weekly for an adolescent.

(2) Recipients who are appropriate for this level of treatment shall:

(a) At a minimum meet eligibility criteria, using guidelines such as the American Society of Addiction Medicine Patient Placement Criteria for Level II, or other guidelines approved by the Program; and

(b) Have a physical and emotional status that allows them to function in their usual environment;]

C. Level II.1 intensive outpatient services that shall include:

(1) Services for participants who require 9 to 20 hours weekly for an adult and 6 to 20 hours weekly for an adolescent;

[(3)] (2) [Before providing Level II Intensive Outpatient Services as described in this section, the provider shall develop a] A written individualized treatment plan, with the participation of the [recipient] participant based on the comprehensive assessment [and recipient placement recommendation as described in §A of this regulation. This plan shall:] that shall:

(a)—(b) (text unchanged)

(c) Include:

[(i)] The recipient's individual needs;

[(ii)] Long-range and short-range treatment plan goals;

[(iii)] Specific interventions for meeting the treatment plan goals which includes at least one group counseling session a week and at least one individual session every 2 weeks;

[(iv)] Target dates for completion of treatment plan goals;

[(v)] Criteria for successful completion of treatment;

[(vi)] Referrals to ancillary services, if needed; and

[(vii)] Referrals to recovery support services.]

[(i)] An assessment of the participant's eligibility, using guidelines such as the American Society of Addiction Medicine Patient Placement Criteria for Level II.1, or other guidelines approved by the Program;

[(ii)] The participant's individual needs;

[(iii)] Long-range and short-range treatment plan goals;

[(iv)] Specific interventions for meeting the treatment plan goals, which includes at least one group counseling session a week and at least one individual session every 2 weeks;

[(v)] Target dates for completion of treatment plan goals;

[(vi)] Criteria for successful completion of treatment;

[(vii)] Referrals to ancillary services, if needed; and

[(viii)] Referral to recovery support services, if needed;

[(4)] (3) [Although it is expected that each Level II.1 Intensive Outpatient] Service [will typically last 3 or more hours, it shall] that last at least 2 hours in order to be billed[.] although will typically last 3 or more hours;

[(5)] (4) A [recipient] participant progress note [shall be] added to the [recipient's] participant's record after each session[.]; and

[(6)] (5) [Before discharge, the provider shall give the recipient a] A discharge plan which includes written recommendations to assist the [recipient] participant with continued recovery efforts, as well as appropriate referral services[.];

D. Level II.5 partial hospitalization services that shall include:

(1) Services for participants who require 20 to 35 hours weekly of structured outpatient treatment;

(2) A written individualized treatment plan, with the participation of the participant based on the comprehensive assessment that shall:

(a) Be updated every 7 days;

(b) Be reviewed and approved by a licensed physician or licensed practitioner of the healing arts, within the scope of his or her practice under State law; and

(c) *Include:*

(i) *An assessment of the participant's eligibility, using guidelines such as the American Society of Addiction Medicine Patient Placement Criteria for Level II.1, or other guidelines approved by the Program;*

(ii) *The participant's individual needs;*

(iii) *Long-range and short-range treatment plan goals;*

(iv) *Specific interventions for meeting the treatment plan goals, includes at least one group counseling session a week and at least one individual session every 2 weeks;*

(v) *Target dates for completion of treatment plan goals;*

(vi) *Criteria for successful completion of treatment;*

(vii) *Referrals to ancillary services, if needed; and*

(viii) *Referral to recovery support services, if needed;*

(3) *A participant progress note added to the participant's record after each session; and*

(4) *A discharge plan which includes written recommendations to assist the participant with continued recovery efforts, as well as appropriate referral services; and*

E. Opioid maintenance therapy service that shall include:

(1) *A Comprehensive substance use disorder assessment as described in §A of this regulation; and*

(2) *An individualized treatment plan as described in COMAR 10.47.01.04 that shall:*

(a) *Be completed and signed by the participant's substance use disorder counselor and the participant within 7 working days of the comprehensive assessment;*

(b) *Be updated every 90 days for the first year of treatment; and*

(c) *Include an individualized treatment plan updated every 180 days and signed by the substance use disorder counselor and participant after completion of continuous treatment and if the participant meets the requirements for unsupervised or take home use set forth in 42CFR §8.12(i);*

(3) *The following services:*

(a) *Pharmacological interventions, including methadone dosing, full and partial opiate agonist treatment medications to provide treatment support, and recovery to opioid-addicted participants;*

(b) *Substance use disorder and related counseling as recommended in the individualized treatment plan;*

(c) *Medical services, including, but not limited to, those required to be provided by the Program in accordance with COMAR 10.47.02.11; and*

(d) *Ordering and administering non-narcotic drug; and*

(4) *Arrangement for transportation of medication to inpatient treatment programs under the conditions outlined in COMAR 10.47.02.11.*

[.04] 06 Limitations.

A. The Program under this chapter does not cover the following:

(1) Community-based substance [abuse] *use disorder* services not specified in Regulation .0[3]4 of this chapter;

(2) Community-based substance [abuse] *use disorder* services not approved by a licensed physician or other licensed practitioner of the healing arts, within the scope of his or her practice under State law;

(3) *Services not medically necessary, including court-ordered assessments and services which are deemed to not be medically necessary;*

(4) *Investigational and experimental drugs and procedures;*

(5) *Services that are provided in a hospital inpatient or outpatient setting or in an intermediate care facility for behavioral health;*

(6) *Services beyond the provider's scope of practice; and*

(7) *Services that are separately billed but included as part of another service.*

B. Providers may not [bill] *be reimbursed by the Program for:*

(1) (text unchanged)

(2) More than one comprehensive substance [abuse] *use disorder* assessment for a [recipient] *participant* per provider per 12-month period unless the patient was discharged from treatment with that provider for more than 30 days;

(3) More than one Level I group counseling session per day per [recipient] *participant*;

(4) More than six Level I individual counseling units as measured in 15 minute increments per day per [recipient] *participant*;

(5) More than four sessions of *Level II.1 Intensive Outpatient* treatment per week;

(6) [Services rendered but not appropriately documented;] Level I group or individual counseling during the same week as a Level II.1 Intensive Outpatient treatment unless the participant has been discharged from or admitted to a new level of care:

(7) [Services rendered by mail, telephone, or otherwise not one-to-one, in person;] Overlapping episodes of Level II.1 Intensive Outpatient treatment and Level II.5 Partial Hospitalization;

(8) [Completion of forms or reports;] Opioid Maintenance Therapy during the same week as a Level I group counseling session, Level I individual counseling session, Level II.1 Intensive Outpatient treatment or Level II.5 Community-based Partial Hospitalization;

(9) [Broken or missed appointments; and] *Psychiatric day treatment program or an intensive outpatient mental health program on the same day as a Level II.1 Intensive Outpatient program or Level II.5 Community-based Partial Hospitalization program;*

(10) *Community-based substance use disorder services on the same day that a participant received similar services as a hospital inpatient or outpatient;*

(11) *Services rendered but not appropriately documented;*

(12) *Services rendered by mail, telephone, or otherwise not one-to-one, in person;*

(13) *Completion of forms or reports;*

(14) *Broken or missed appointments; and*

[(10)] (15) *Travel to and from site of service.*

[C. The provider shall meet the requirement of §B(1) of this regulation by:

(1) *Charging the individual in full for service rendered;*

(2) *Using a sliding fee scale based on the individual's income;*

(3) *Waiving all or part of the fee for a specific individual; or*

(4) *Agreeing to accept what a third party pays as payment in full, whether or not the provider bills individuals who lack this coverage.]*

C. The Program will make no direct payment to participants.

D. The provider shall meet the requirement of §B(1) of this regulation by:

(1) *Charging other members of the public in full for service rendered;*

(2) *Using a sliding fee scale based on the other individual's income;*

(3) *Waiving all or part of the fee for a specific individual; or*

(4) *Billing the other insurance company and agreeing to accept what other third party pays as payment in full, whether or not the provider bills individuals who lack third party coverage.*

.07 Authorization Requirements.

A. For services outlined in Regulation .04 of this chapter, the community-based substance use disorder program shall notify the ASO and obtain authorization to provide substance use disorder services from ASO.

B. The ASO agent shall authorize services that are:

(1) *Medically necessary and*

(2) *Of a type, frequency, and duration that are consistent with expected results and cost-effectiveness.*

C. No payment shall be rendered for services that have not been authorized.

[.05] .08 Payment Procedures.

A.—C. (text unchanged)

D. Rates for the services outlined in this regulation shall be as follows:

(1) *Comprehensive substance [abuse] use disorder assessment — \$142;*

(2) *Level I group substance [abuse] use disorder counseling — \$39 per session;*

(3) *Level I individual substance [abuse] use disorder counseling — \$20 per 15-minute increment with a maximum of six 15-minute increments per day;*

(4) *Level II.1 Intensive outpatient treatment — \$125 per diem; [and]*

[(5) *Methadone maintenance — See COMAR 10.09.08.04.]*

(5) *Level II.5 Partial Hospitalization — \$130 per diem; and*

(6) *Opioid Maintenance Therapy— \$80 per participant per week.*

E. In order to bill an individual for Level II.1 intensive outpatient treatment as described in §D(4) of this regulation, the per diem session shall include a minimum of 2 hours, but more frequently be composed of 3-hour sessions. A maximum of 4 per diems may be billed per week.

F. In order to bill an individual for Level II.5 partial hospitalization, the per diem session shall include a minimum of 2 hours. Providers may bill a maximum of 7 per diems per week.

G. The Department shall pay participating opioid maintenance therapy programs as described in §D(6) of this regulation, per patient, per week provided the participant has received at least one face-to-face documented treatment service in the week for which the Program is billed.

H. Services not authorized consistent with COMAR 10.09.80.07C.

I. The Department shall authorize supplemental payment on Medicare claims only if:

(1) *The provider accepts Medicare assignments;*

(2) *Medicare makes direct payment to the provider;*

(3) *Medicare has determined that the services are medically necessary;*

(4) *The services are covered by the Program; and*

(5) *Initial billing is made directly to Medicare according to Medicare guidelines.*

J. The Department shall make payment on Medicare claims subject to the following provisions:

(1) *Deductible and coinsurance shall be paid in full for services designated as mental health services by Medicare; and*

(2) *The Program shall reimburse services not covered by Medicare, but considered medically necessary by the Program, according to the limitations of this chapter.*

[.06].09 (text unchanged)

[.07].10 Cause for Suspension or Removal and Imposition of Sanctions.

A.—D. (text unchanged)

E. The Department shall give to the provider reasonable written notice of the Department's intention to impose sanctions. In the notice, the Department shall:

(1) Establish the:

(a) Effective date of the proposed action; and

(b) Reasons for the proposed action; and

(2) Advise the provider of the right to appeal.

[.08].11—[.09].12 (text unchanged)

JOSHUA M. SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene