

Rules Advisory Committee Notification

Date: August 5, 2022

Contact: Brean Arnold, brean.n.arnold@dhsosha.state.or.us

The Health Systems Division has scheduled the following Rules Advisory Committee (RAC):

- **Program:** Chapter 410 Division 120 Medicaid General Rules, Clinical trial coverage changes
- **Meeting description:** Discuss proposed rule changes in OAR 410-120-1160
- **Meeting date and time:** 09/09/2022, 10:00a.m. to 12:00p.m.
- **Meeting location:** Virtual
- **Call-in number and participant code:** Meeting link and information will be sent to confirmed RAC members
- **Seeking RAC members?** Yes, please email Brean by close of business Friday August 26, 2022.

At the RAC, members will provide input that will help us develop the Notice of Proposed Rulemaking, including any fiscal impact and racial equity impact of the proposed rule changes.

Please share this information with others who may be affected by, and interested in providing input about, the proposed rule changes.

Proposed changes for Rules Advisory Committee discussion

To view the current rules, go to

<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1708>.

Rule(s)	Description of proposed changes
OAR 410-120-1160	The Consolidated Appropriations Act for 2021 amended the Medicaid statute to add routine patient costs for items and services furnished in connection with a qualifying clinical trial. This proposed rule aligns state OAR with Federal law.

Rules Advisory Committee contact information

If you are likely to be affected by the changes described above, you can ask to join us as a RAC member. To do this, contact the Program Manager for these rules:

- **Program Manager:** Brean Arnold, General Rules, HSD
- **Phone:** 503-569-0328
- **E-mail:** Brean.N.Arnold@dhsosha.state.or.us
- **Deadline** to request RAC membership is close of business Friday August 26, 2022.

If you are not chosen to join the RAC, you are welcome to submit public comment during the Public Comment Period for this rule, which begins upon filing of the Notice of Proposed Rulemaking.

Thank you in advance for your participation and continued interest.

About Rules Advisory Committees

Rules Advisory Committee meetings are held in accordance with [Oregon Revised Statute 183.333](#) (Policy statement; public involvement in development of policy and drafting of rules).

The RAC will hold at least one meeting to discuss the proposed revisions, the fiscal impact statement, and equity impact statement for the Notice of Proposed Rulemaking that the Division will file for these changes.

410-120-1160

Medical Assistance Benefits and Provider Rules

(1) Providers enrolled with and seeking reimbursement for services through the [Health Systems Division of Medical Assistance Programs](#) (Division) are responsible for compliance with current federal and state laws and regulations governing Medicaid services and reimbursement, including familiarity with periodic law and rule changes. The Division's administrative rules are posted on the Oregon Health Authority (Authority) website for the Division and its medical assistance programs. It is the provider's responsibility to become familiar with and abide by these rules.

(2) The following services are covered to the extent included in the Division client's benefit package of health care services, when medically or dentally appropriate and within the limitations established by the Division and set forth in the Oregon Administrative Rules (OARs) for each category of [Health Medical Services](#):

(a) Acupuncture services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);

(b) Administrative examinations as described in the Administrative Examinations and Billing Services program provider rules (OAR chapter 410, division 150);

(c) Substance Use Disorder treatment services:

(A) The Division covers substance use disorder (SUD) inpatient treatment services for medically managed intensive inpatient detoxification when provided in an acute care hospital and when hospitalization is considered medically appropriate. The Division covers medically monitored detoxification and clinically managed detoxification provided in a free standing detoxification center or an appropriately licensed SUDs residential treatment facility when considered medically appropriate;

(B) The Division covers non-hospital SUD treatment and recovery services on a residential or outpatient basis. For information to access these services, contact the client's PHP or CCO if enrolled, the community mental health program (CMHP), an outpatient substance use disorder treatment provider, the residential treatment program, or the Addictions and Mental Health Division (AMH);

(C) The Division does not cover residential level of care provided in an inpatient hospital setting for substance use disorder treatment and recovery;

(d) Ambulatory surgical center services as described in the Medical-Surgical Services program provider rules (OAR 410, division 130);

(e) Anesthesia services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);

(f) Audiology services as described in the Speech-Language Pathology, Audiology and Hearing Aid Services program provider rules (OAR chapter 410, division 129);

(g) Chiropractic services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);

[\(h\) Clinical trials as described in these General Rules:](#)

[\(a\) Coverage includes routine patient costs for a beneficiary participating in a qualifying clinical trial ~~or~~ any item or service provided to the individual under the qualifying clinical trial, including](#)

any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the items or services to the beneficiary are covered in the recipient's benefit package;

(b) "Qualifying clinical trial" is defined as a clinical trial in any clinical phase of development that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition as described in section 1905(gg)(2)(A) of the Act;

(c) A qualifying clinical trial is a study or investigation that is approved, conducted, or supported (including by funding through in-kind contributions) by one or more of the following:

(A) The National Institutes of Health (NIH);

(B) The Centers for Disease Control and Prevention (CDC);

(C) The Agency for Health Care Research and Quality (AHRQ);

(D) The Centers for Medicare & Medicaid Services (CMS);

(E) A cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs;

(F) A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants;

(G) A clinical trial, approved or funded by any of the following entities, that has been reviewed and approved through a system of peer review that the Secretary determines comparable to the system of peer review of studies and investigations used by the NIH, and that assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:

(i) The Department of Energy;

(ii) The Department of Veterans Affairs;

(iii) The Department of Defense;

(H) A clinical trial that is one conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act; or

(I) A clinical trial that is a drug trial exempt from being required to have one of the exemptions in the prior bullet.

(d) Items and Services not included in clinical trial:

(A) Routine patient costs do not include any investigational item or service that is the subject of the qualifying clinical trial but is not included in the recipient's OHP benefit package;

(B) Routine patient cost does not include any item or service that is provided to the beneficiary solely to satisfy data collection and analysis for the qualifying clinical trial that is not used in the direct clinical management of the beneficiary and is not otherwise in the recipients OHP benefit package.

(h) Dental services as described in the Dental Services program provider rules (OAR chapter 410, division 123);

(i) Early and periodic screening, diagnosis, and treatment services (EPSDT) are covered for individuals under 21 years of age as set forth in the individual program provider rules. The Division may authorize services in excess of limitations established in the OARs when it is medically appropriate to treat a condition that is identified as the result of an EPSDT screening;

- (j) Family planning services as described in the Medical-Surgical Services program provider rules (OAR chapter 410, division 130);
- (k) Federally qualified health centers and rural health clinics as described in the Federally Qualified Health Centers and Rural Health Clinics program provider rules (OAR chapter 410, division 147);
- (l) Home and community-based waiver services as described in the Authority and the Department's OARs of Child Welfare (CW), Self-Sufficiency Program (SSP), Addictions and Mental Health Division (AMH), and Aging and People with Disabilities Division (APD);
- (m) Home enteral/parenteral nutrition and IV services as described in the Home Enteral/Parenteral Nutrition and IV Services program rules (OAR chapter 410, division 148) and related Durable Medical Equipment, Prosthetics, Orthotics and Supplies program rules (OAR chapter 410, division 122) and Pharmaceutical Services program rules (OAR chapter 410, division 121);
- (n) Home health services as described in the Home Health Services program rules (OAR chapter 410, division 127);
- (o) Hospice services as described in the Hospice Services program rules (OAR chapter 410, division 142);
- (p) Indian health services or tribal facility as described in The Indian Health Care Improvement Act and its amendments (Public Law 102-573), and the Division's American Indian/Alaska Native program rules (OAR chapter 410, division 146);
- (q) Inpatient hospital services as described in the Hospital Services program rules (OAR chapter 410, division 125);
- (r) Laboratory services as described in the Hospital Services program rules (OAR chapter 410, division 125) and the Medical-Surgical Services program rules (OAR chapter 410, division 130);
- (s) Licensed direct-entry midwife services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);
- (t) Maternity case management as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);
- (u) Medical equipment and supplies as described in the Hospital Services program, Medical-Surgical Services program, DMEPOS program, Home Health Services program, Home Enteral/Parenteral Nutrition and IV Services program, and other rules;
- (v) When a client's benefit package includes mental health, the mental health services provided will be based on the Health Evidence Review Commission (HERC) Prioritized List of Health Services;
- (w) Naturopathic services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);
- (x) Nutritional counseling as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);
- (y) Occupational therapy as described in the Physical and Occupational Therapy Services program rules (OAR chapter 410, division 131);

- (z) Organ transplant services as described in the Transplant Services program rules (OAR chapter 410, division 124);
- (aa) Outpatient hospital services including clinic services, emergency department services, physical and occupational therapy services, and any other outpatient hospital services provided by and in a hospital as described in the Hospital Services program rules (OAR chapter 410, division 125);
- (bb) Physician, podiatrist, nurse practitioner and licensed physician assistant services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130);
- (cc) Physical therapy as described in the Physical and Occupational Therapy and the Hospital Services program rules (OAR chapter 410, division 131 and 125);
- (dd) Post-hospital extended care benefit as described in OAR chapter 410, division 120 and 141 and Aging and People with Disabilities (APD) program rules;
- (ee) Prescription drugs including home enteral and parenteral nutritional services and home intravenous services as described in the Pharmaceutical Services program (OAR chapter 410, division 121), the Home Enteral/Parenteral Nutrition and IV Services program (OAR chapter 410, division 148), and the Hospital Services program rules (OAR chapter 410, division 125);
- (ff) Preventive services as described in the Medical-Surgical Services program (OAR chapter 410, division 130), the Dental Services program rules (OAR chapter 410, division 123), and prevention guidelines associated with the Health Evidence Review Commission's Prioritized List of Health Services (OAR 410-141-0520);
- (gg) Private duty nursing as described in the Private Duty Nursing Services program rules (OAR chapter 410, division 132);
- (hh) Radiology and imaging services as described in the Medical-Surgical Services program rules (OAR chapter 410, division 130), the Hospital Services program rules (OAR chapter 410, division 125), and Dental Services program rules (OAR chapter 410, division 123);
- (ii) Rural health clinic services as described in the Federally Qualified Health Center and Rural Health Clinic Program rules (OAR chapter 410, division 147);
- (jj) School-based health services as described in the School-Based Health Services Program rules (OAR chapter 410, division 133);
- (kk) Speech and language therapy as described in the Speech-Language Pathology, Audiology and Hearing Aid Services program rules (OAR chapter 410, division 129) and Hospital Services program rules (OAR chapter 410, division 125);
- (LL) Transportation necessary to access a covered medical service or item as described in the Medical Transportation program rules (OAR chapter 410, division 136);
- (mm) Vision services as described in the Visual Services program rules (OAR chapter 410, division 140).
- (3) Other Authority or Department, divisions, units, or offices, including Vocational Rehabilitation, AMH, and APD may offer services to Medicaid eligible clients, that are not reimbursed by or available through the Division of Medical Assistance Programs.

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.025 & 414.065