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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

DMAP 37-2019

CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILED

09/05/2019 9:18 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: CCO Drug Utilization Review (DUR) requirements under the SUPPORT for Patients and Communities Act

EFFECTIVE DATE: 10/01/2019 THROUGH 12/31/2019

AGENCY APPROVED DATE: 08/28/2019

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Filed By:
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NEED FOR THE RULE(S):

The Division needs to amend this rule to comply with federal law to define certain minimum statewide Drug Utilization Review (DUR) standards for opioids in Administrative Rule and must require CCOs to meet or exceed those standards.

JUSTIFICATION OF TEMPORARY FILING:

The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and recipients of Medicaid benefits. These rules need to be adopted promptly so that the Authority may comply with federal law.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act viewable at: <https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf>

Center for Medicaid and CHIP Services – Informational Bulletin released August 5, 2019 to states on the implementation of new Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also referred to as the SUPPORT for Patients and Communities Act or the SUPPORT Act, viewable at: <https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf>

AMEND: 410-141-3070

RULE TITLE: Preferred Drug List Requirements

RULE SUMMARY: In order to comply with Section 1004 on Medicaid Drug Utilization Review (DUR) of the SUPPORT Act, OHA must define certain minimum statewide DUR standards for opioids in Administrative Rule and must require CCOs to meet or exceed those standards.

RULE TEXT:

- (1) Prescription drugs are a covered service based on the funded Condition/Treatment Pairs. MCEs shall pay for prescription drugs except:
- (a) As otherwise provided, mental health drugs that are in Standard Therapeutic Class 7 (ataractics-tranquilizers) or Standard Therapeutic Class 11 (psychostimulants-antidepressants) (based on the National Drug Code (NDC) as submitted by the manufacturer to First Data Bank);
 - (b) Depakote, Lamictal, and their generic equivalents and those drugs that the Authority specifically carved out from capitation according to sections (13), (14), and (15) of this rule;
 - (c) For drugs covered under Medicare Part D when the client is fully dual eligible.
- (2) MCEs may use the statewide Practitioner-Managed Prescription Drug Plan under ORS 414.330 to 414.337.
- (3) MCEs may use a restrictive drug list if it allows access to other drug products not on the drug list through prior authorization (PA).
- (4) MCEs shall publish up-to-date, accurate, and complete lists of all covered drugs on their preferred drug lists, including any tiering structures, that have been adopted and any restrictions on the way certain drugs may be obtained.
- (5) As specified in 45 CFR 156.122, the preferred drug list must:
- (a) Exist in a manner easily accessible to members and potential members, state and federal government, and the public;
 - (b) Be accessible on the plan's public website in a machine-readable format through a clearly identifiable web link or tab without requiring an individual access account or policy number;
 - (c) Be made available in paper form if requested by a member; and
 - (d) If the issuer has more than one plan, the member shall be easily able to discern which of the preferred drug lists applies to which plan.
- (6) The preferred drug list shall:
- (a) Include Federal Drug Administration (FDA) approved drug products for each therapeutic class sufficient to ensure the availability of covered drugs with minimal prior approval intervention by the provider of pharmaceutical services;
 - (b) Include at least one item in each therapeutic class of over-the-counter medications; and
 - (c) Be revised periodically to assure compliance with this requirement.
- (7) MCEs shall cover at least one form of contraception within each of the eighteen methods identified by the FDA. As set forth in OAR 410-141-3320, the member may refer themselves directly to family planning services without getting a referral from a PCP or other participating provider.
- (8) MCEs shall provide their participating providers and their pharmacy subcontractor with:
- (a) Their drug list and information about how to make non-drug listed requests;
 - (b) Updates made to their drug list within 30 days of a change that may include but are not limited to:
 - (A) Addition of a new drug;
 - (B) Removal of a previously listed drug; and
 - (C) Generic substitution.
- (9) Prior authorization for prescription drug requests shall be addressed by the MCEs as described in OAR 410-141-3225.
- (10) MCEs shall authorize the provision of a drug requested by the Primary Care Provider or referring provider if the prescriber certifies medical necessity for the drug such as:
- (a) The equivalent of the drug listed has been ineffective in treatment; or
 - (b) The drug listed causes or is reasonably expected to cause adverse or harmful reactions to the member.
- (11) Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act are excluded. Payment is governed by OAR 410-121-0150.
- (12) MCEs may not authorize payment for any Drug Efficacy Study Implementation (DESI) Less Than Effective (LTE) drugs that have reached the FDA Notice of Opportunity for Hearing (NOOH) stage, as specified in OAR 410-121-0420 (DESI)(LTE) Drug List. DESI LTE drugs are identified by the Covered Outpatient Drug (COD) Status equal to 05 or 06 in the list available at:

<https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e>

(13) An MCE may seek to add drugs to the list contained in section (1) of this rule by submitting a request to the Authority no later than March 1 of any contract year. The request must contain all the following information:

(a) The drug name;

(b) The FDA approved indications that identify the drug may be used to treat a severe mental health condition; and

(c) The reason the Authority should consider this drug for carve out.

(14) If an MCE requests that a drug not be paid within the global budget, the Authority shall exclude the drug from the global budget for the following January contract cycle if the Authority determines that the drug has an approved FDA indication for the treatment of a severe mental health condition such as major depressive, bi-polar, or schizophrenic disorders.

(15) The Authority shall pay for a drug that is not included in the global budget pursuant to the Pharmaceutical Services program rules (chapter 410, division 121). An MCE may not reimburse providers for carved-out drugs.

(16) MCEs shall submit quarterly utilization data within 45 days after the end of the quarter pursuant to 42 CFR 438.3.

(17) MCEs are encouraged to provide payment only for outpatient and physician administered drugs produced by manufacturers that have valid rebate agreements in place with the CMS as part of the Medicaid Drug Rebate Program. MCEs may continue to have some flexibility in maintaining preferred drug lists regardless of whether the manufacturers of those drugs participate in the Medicaid Drug Rebate Program.

(18) MCEs shall utilize a pharmacy and therapeutics (P&T) committee and a Drug Use Review (DUR) program. The committees may work in tandem or independent of the other, if all committee requirements for both committee types are met. A P&T committee must maintain written documentation of the rationale for all decisions regarding the drug list development and revisions. The committee shall follow the membership and meeting standards specified in 45 CFR 156.122(3)(i) and (ii). Meetings shall be held at least quarterly. MCEs shall provide a detailed description of its P&T committee including its DUR functions on an annual basis. The report shall be in the form and manner required by the OHP. The data requested by the Authority shall be calculated to meet federal reporting obligations.

(19) The committee in its DUR capacity shall assure prescriptions are appropriate, medically appropriate, and not likely to result in adverse medical results. The committee must be designed to educate prescribers and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. The committee shall include prospective DUR, retrospective DUR, and educational programs as each is defined and described by 42 CFR 456, subpart K and Section 1902(o) of the Social Security Act [42 U.S.C. 1396a(o)].

STATUTORY/OTHER AUTHORITY: ORS 413.042, 414.615, 414.625, 414.635, 414.651

STATUTES/OTHER IMPLEMENTED: ORS 414.610–414.685