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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

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

FILED

02/28/2025 10:18 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Update and clarify process for revising CCO mental health drug carve-out list; HRSN housekeeping.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/21/2025 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S)

ORS 414.742 states that OHA "may not establish capitation rates or global budgets that include payment for mental health drugs." 410-141-3855 automatically carves out mental health drugs with a standard therapeutic class of 7 (ataractics-tranquilizers) or 11 (psychostimulants-antidepressants) from those prescription drugs coordinated care organizations (CCOs) are responsible for payment. However, a new drug approved by the FDA to treat schizophrenia, xanomeline/trospium (brand name, Cobenfy), was placed in class 99 (miscellaneous drugs) due to a different mechanism of action, and therefore isn't carved out. Additionally, drugs are being listed by their generic names so that any derivatives of the drugs (e.g., long-acting forms) are included as well. The process for adding drugs and removing them from the carve-out list is also being clarified.

The modifications to 410-141-3515 and 410-141-3835 are of a housekeeping nature affecting language related to health related social needs (HRSN) services. They correct rule references and remove language that is being added to 410-120-2020 through other rulemaking that would otherwise be duplicative.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

None

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The rule changes will not impact OHP benefits and have no expected impact on racial equity. The mental health drugs on the carve out list will be covered services for OHP, this just impacts whether OHA or CCOs will be responsible to pay for them. The HRSN rules changes are of a housekeeping nature only.

FISCAL AND ECONOMIC IMPACT:

OHA does not anticipate there will be a fiscal impact from these rule changes.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

1. None anticipated

2. (a) None anticipated

(b) None anticipated

(c) None anticipated

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

None

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

410-141-3515, 410-141-3835, 410-141-3855

AMEND: 410-141-3515

RULE SUMMARY: Correct an HRSN rule reference and remove language being added to 410-120-2020 in separate rulemaking.

CHANGES TO RULE:

410-141-3515

Network Adequacy

- (1) Managed Care Entities (MCEs) shall maintain and monitor a network of participating providers that is sufficient in number, provider type, and geographic distribution to ensure adequate service capacity and availability to provide available and timely access to medically appropriate and culturally responsive covered services to both current members and those the MCE anticipate shall become enrolled as members.¶¶
- (2) The MCE shall develop a provider network that enables members to access services within the standards defined in this rule.¶¶
- (3) The MCE shall meet access-to-care standards that allow for appropriate choice for members. Services and supports shall be as close as possible to where members reside and, to the extent necessary, offered in nontraditional settings that are accessible to families, diverse communities, and underserved populations.¶¶
- (4) MCEs shall meet quantitative network access standards defined in rule and contract.¶¶
- (5) MCEs shall ensure access to integrated and coordinated care as outlined in OAR 410-141-3860, which includes access to a primary care provider or primary care team that is responsible for coordination of care and transitions.¶¶
- (6) In developing its provider network, the MCEs shall anticipate access needs so that the members receive the right care at the right time and place, using a patient-centered, trauma informed approach. The provider network shall support members, especially those with behavioral health conditions, in the most appropriate and independent setting, including in their own home or independent supported living.¶¶
- (7) In assessing the capacity and adequacy of its provider network, MCEs shall consider, in conjunction with the quantitative standards set forth in this rule, the variety of provider and facility types with the demonstrated ability and expertise to render specific medically or dentally appropriate covered services within the scope of applicable licensing and credentialing. This includes, but is not limited to, the prescribing of Medication-Assisted Treatment

and more specialized oral health care services.¶¶

(8) All MCEs shall ensure 95 percent of members can access the following provider and facility types, further defined by the Authority in guidance made available on the CCO Contracts Forms webpage <https://www.oregon.gov/oha/HSD/OHP/Pages/CCO-Contract-Forms.aspx>, within acceptable travel time or distance standards set forth this rule:¶¶

(a) Tier one:¶¶

(A) Primary care providers serving adults and those serving pediatrics;¶¶

(B) Primary care dentists serving adults and those serving pediatrics;¶¶

(C) Mental health providers serving adults and those serving pediatrics;¶¶

(D) Substance use disorder providers serving adults and those serving pediatrics¶¶

(E) Pharmacy;¶¶

(F) Additional provider types when it promotes the objectives of the Authority or as required by legislation.¶¶

(b) Tier two:¶¶

(A) Obstetric and gynecological service providers;¶¶

(B) The following specialty providers, serving adults and those serving pediatrics;¶¶

(i) Cardiology;¶¶

(ii) Neurology;¶¶

(iii) Occupational Therapy;¶¶

(iv) Medical Oncology;¶¶

(v) Radiation Oncology;¶¶

(vi) Ophthalmology;¶¶

(vii) Optometry;¶¶

(viii) Physical Therapy;¶¶

(ix) Podiatry;¶¶

(x) Psychiatry;¶¶

(xi) Speech Language Pathology.¶¶

(C) Hospital;¶¶

(D) Durable medical equipment;¶¶

(E) Methadone Clinic;¶¶

(F) Additional provider types when it promotes the objectives of the Authority or as required by legislation.¶¶

(c) Tier three:¶¶

(A) The following specialty providers, serving adults and those serving pediatrics;¶¶

(i) Allergy & Immunology;¶¶

(ii) Dermatology;¶¶

(iii) Endocrinology;¶¶

(iv) Gastroenterology;¶¶

(v) Hematology;¶¶

(vi) Nephrology;¶¶

(vii) Otolaryngology;¶¶

(viii) Pulmonology;¶¶

(ix) Rheumatology;¶¶

(x) Urology.¶¶

(B) Post-hospital skilled nursing facilities;¶¶

(C) Additional provider types when it promotes the objectives of the Authority or as required by legislation.¶¶

(9) All MCE acceptable travel time and distance monitoring must assess the geographic distribution of providers relative to members and calculate driving time and distance from the member's physical address to the provider's location through the use of geocoding software or other mapping applications. The Authority shall provide tools and additional guidance specific to time and distance monitoring on the CCO Contracts Forms webpage <https://www.oregon.gov/oha/HSD/OHP/Pages/CCO-Contract-Forms.aspx>.¶¶

(a) A CCO service area may contain multiple geographic designations. When calculating travel time and distance, geographic designations shall not overlap and the following definitions of geographic designations shall apply:¶¶

(A) Large urban area: Conjoined urban areas with a total population of at least 1 million people or with a population density greater than 1,000 people per square mile.¶¶

(B) Urban area: An area with greater than 40,000 people within a 10 mile radius of a city center.¶¶

(C) Rural area: An area greater than 10 miles from the center of an urban area.¶¶

(D) County with extreme access considerations: County with a population density of 10 or fewer people per square mile.¶¶

(b) When calculating travel time and distance, MCEs shall use the following standards:¶¶

(A) Large Urban Area:¶¶

- (i) Tier one: 10 minutes or 5 miles;¶
- (ii) Tier two: 20 minutes or 10 miles;¶
- (iii) Tier three: 30 minutes or 15 miles.¶

(B) Urban Area:¶

- (i) Tier one: 25 minutes or 15 miles;¶
- (ii) Tier two: 30 minutes or 20 miles;¶
- (iii) Tier three: 45 minutes or 30 miles.¶

(C) Rural Area:¶

- (i) Tier one: 30 minutes or 20 miles;¶
- (ii) Tier two: 75 minutes or 60 miles;¶
- (iii) Tier three: 110 minutes or 90 miles.¶

(D) County with Extreme Access Considerations:¶

- (i) Tier one: 40 minutes or 30 miles;¶
- (ii) Tier two: 95 minutes or 85 miles;¶
- (iii) Tier three: 140 minutes or 125 miles.¶

(10) MCEs may request an exception to a standard set in (8) and (9) of this rule. MCEs may request multiple exceptions.¶

(a) Exception requests must be submitted in a format provided by the Authority and made available on the CCO Contract Forms webpage <https://www.oregon.gov/oha/HSD/OHP/Pages/CCO-Contract-Forms.aspx>.¶

(b) The Authority shall review and approve or deny exception requests based on criteria made available on the CCO Contracts Forms webpage. Approved exceptions must be reviewed at least annually.¶

(11) OHA may grant exceptions to the standards set in (8) and (9) of this rule when enrollment capacity is increased.¶

(12) MCEs shall have an access plan that establishes a protocol for monitoring and ensuring access, outlines how provider capacity is determined, and establishes procedures for monthly monitoring of capacity and access and for improving access and managing access in times of reduced participating provider capacity. The access plan and associated monitoring protocol shall address the following:¶

(a) Expected utilization of services based on anticipated member enrollment and health care needs of the member population;¶

(b) The number and types of providers required to furnish the contracted services based on the expected utilization of services referenced above and the number and types of providers actively providing services within the MCE's current provider network;¶

(c) How the MCE shall meet the accommodation and language needs of individuals with LEP as defined in OAR 410-141-3500 and people with disabilities in their service area in compliance with state and federal rules including but not limited to ORS 659A, Title VI of the Civil Rights Act of 1964, Section 1557 of the Affordable Care Act, the Americans with Disabilities Act, and Section 504 of the Rehabilitation Act of 1973;¶

(d) The availability of telemedicine within the MCE's contracted provider network.¶

(13) MCEs shall make the services it provides (including primary care, specialists, pharmacy, hospital, vision, ancillary, and behavioral health services or other services as necessary to achieve compliance with the requirements of 42 CFR 438, subpart K) as accessible to members for timeliness, amount, duration, and scope as those services are to other patients within the same service area. If the MCE is unable to provide those services through the use of participating providers qualified and specialized to treat a member's condition, it must arrange for the member to access care from non-participating providers as geographically close to the member as possible, including providers outside the service area.¶

(14) MCEs shall have policies and procedures and a monitoring system to ensure that members who are aged, blind, or disabled, or who have complex or high health care needs, multiple chronic conditions, or have behavioral health conditions, or who are children receiving Department or Oregon Youth Authority (OYA) services have access to primary care, oral care (when the MCE is responsible for oral care), behavioral health providers, and referral, and involve those members in accessing and managing appropriate preventive, health, remedial, and supportive care and services. MCEs shall monitor and have policies and procedures to ensure:¶

(a) Access to providers of pharmacy, hospital, vision, ancillary, and behavioral health services;¶

(b) Priority access for pregnant women and children ages birth through five (5) years to health services, developmental services, early intervention, targeted supportive services, oral and behavioral health treatment.¶

(15) MCEs shall have policies and procedures that ensure scheduling and rescheduling of member appointments are appropriate to the reasons for and urgency of the visit. The member shall be seen, treated, or referred within the following timeframes:¶

(a) Physical health:¶

(A) Emergency care: Immediately or referred to an emergency department depending on the member's condition;¶

(B) Urgent care: Within 72 hours or as indicated in initial screening and in accordance with OAR 410-141-3840;¶

(C) Well care: Within four (4) weeks, or as otherwise required by applicable care coordination rules, including OAR 410-141-3860 through 410-141-3870.¶

(b) Oral and Dental care for children and non-pregnant individuals:¶

(A) Dental Emergency services as defined in OAR 410-120-0000: Seen or treated within 24 hours;¶

(B) Urgent dental care: Within two (2) weeks;¶

(C) Routine oral care: Within eight (8) weeks, unless there is a documented special clinical reason that makes a period of longer than eight (8) weeks appropriate.¶

(c) Oral and Dental care for pregnant individuals:¶

(A) Dental Emergency services. Seen or treated within 24 hours;¶

(B) Urgent dental care, within one (1) week;¶

(C) Routine oral care: Within four (4) weeks, unless there is a documented special clinical reason that must make access longer than four (4) weeks appropriate.¶

(d) Behavioral health:¶

(A) Urgent behavioral health care for all populations: Within 24 hours;¶

(B) Specialty behavioral health care for priority populations:¶

(i) In accordance with the timeframes listed in this rule for assessment and entry, terms are defined in OAR 309-019-0105, with access prioritized per OAR 309-019-0135. If a timeframe cannot be met due to lack of capacity, the member must be placed on a waitlist and provided interim services within 72 hours of being put on a waitlist. Interim services must be comparable to the original services requested based on the level of care and may include referrals, methadone maintenance, HIV/AIDS testing, outpatient services for substance use disorder, risk reduction, residential services for substance use disorder, withdrawal management, and assessments or other services described in OAR 309-019-0135;¶

(ii) Pregnant women, veterans and their families, women with children, unpaid caregivers, families, and children ages birth through five years, individuals with HIV/AIDS or tuberculosis, individuals at the risk of first episode psychosis and the I/DD population: Immediate assessment and entry. If interim services are necessary due to capacity restrictions, treatment at appropriate level of care must commence within 120 days from placement on a waitlist;¶

(iii) IV drug users including heroin: Immediate assessment and entry. Admission for treatment in a residential level of care is required within fourteen (14) days of request, or, if interim services are necessary due to capacity restrictions, admission must commence within 120 days from placement on a waitlist;¶

(iv) Opioid use disorder: Assessment and entry within 72 hours;¶

(v) Medication assisted treatment: As quickly as possible, not to exceed 72 hours for assessment and entry;¶

(vi) Children with serious emotional disturbance as defined in OAR 410-141-3500: Any limits that the Authority may specify in the contract or in sub regulatory guidance.¶

(C) Routine behavioral health care for non-priority populations: Assessment within seven days of the request, with a second appointment occurring as clinically appropriate.¶

(16) HRSN Services. All MCEs or, as applicable, the Authority, must make a referral to an HRSN Service Provider that is capable of delivering the authorized HRSN Service(s) as expeditiously as a Member's circumstances requires. The time period for delivery of the HRSN Service must not exceed four (4) weeks, which is the same time frame for scheduling appointments for Well Care as set forth in this OAR. The HRSN Service(s) is considered "delivered" once the Member receives the HRSN Service that was authorized.¶

(a) The timelines identified in this rule are not required to be met in circumstances of impossibility related to HRSN Service Vendor availability, as determined by the Authority in its sole discretion.¶

(b) The timelines identified in of this rule are not applicable to Members who are receiving HRSN Outreach and Engagement Services only. Instead, HRSN Outreach and Engagement Services must be delivered within a reasonable period of time in light of the Member's availability.¶

(c) For Members who have not authorized the sharing their information with an HRSN Service Provider, the four (4) week timeline identified in section (11) of this rule, shall commence when the HRSN Authorized Member has delivered the referral to the referred HRSN Service Providers and the HRSN Service Provider has confirmed with the MCE or, as applicable, the Authority, receipt of the referral.¶

(d) MCEs and the Authority, are not responsible for preventing Imminent Eviction. MCEs and the Authority shall refer Members facing imminent eviction to local or state providers or programs that has the ability to address a Member's imminent eviction. MCEs and the Authority must still screen these Members for eligibility for other HRSN Services, including other HRSN Housing Supports, and if Authorized for the other HRSN Service, refer the HRSN Authorized Member to the applicable HRSN Service Providers.¶

(17) MCEs shall implement procedures for communicating with and providing care to members who have difficulty communicating due to a medical condition, who need accommodation due to a disability, or, as detailed in OAR chapter 950, division 050 for those who have Limited English Proficiency, prefer to communicate in a

language other than English or who communicates in signed language.¶¶

(a) The policies and procedures shall ensure the provision of Oregon certified or Oregon qualified interpreter services by phone or in person anywhere the member is attempting to access care or communicate with the MCE or its representatives;¶¶

(b) MCEs shall ensure the provision of certified or qualified interpreter services for all covered services to interpret for members with hearing impairment or in the primary language of non-English-speaking members;¶¶

(c) All interpreters must be linguistically appropriate and capable of communicating in both English and the member's primary language and be able to translate clinical information effectively. Interpreter services must enable the provider to understand the member's complaint, make a diagnosis, respond to the member's questions and concerns, and communicate instructions to the member;¶¶

(d) MCEs shall ensure the provision of services that are culturally appropriate as described in National CLAS Standards, demonstrating both awareness for and sensitivity to cultural differences and similarities and the effect on the member's care. MCEs shall ensure the provision of Oregon certified or Oregon qualified interpreters.¶¶

(e) MCEs shall comply with requirements of the Americans with Disabilities Act of 1990, as amended via the ADA Amendments Act of 2008, in providing access to covered services for all members and shall arrange for services to be provided by non-participating providers when necessary;¶¶

(f) MCEs shall collect and actively monitor data on language accessibility to ensure compliance with these language access requirements;¶¶

(g) MCEs shall report to the Authority such language access data and other language access related analyses in the form and manner set forth in this rule and as may otherwise be required in the MCE contract. The Authority shall provide supplemental instructions about the use of any required forms;¶¶

(A) Using the interpreter services self-assessment reporting template provided by the Authority, MCEs shall conduct an annual language access self-assessment and submit the completed language access self-assessment to the Authority on or before the third Monday of each January;¶¶

(B) MCEs shall collect and report language access and interpreter services to the Authority quarterly using the report form provided by the Authority. The quarterly due date for each Report is the first day of each calendar quarter, reporting data for the twelve (12) months ending one quarter before the due date.¶¶

(C) MCEs shall complete and submit to the Authority any other language access reporting that may be required in the MCE contract.¶¶

(187) MCEs shall collect and actively monitor data on provider-to-enrollee ratios, interpretation utilization by the MCE and the MCE's provider network, travel time and distance to providers, percentage of contracted providers accepting new members, wait times to appointment (including specific data for behavioral health wait times), and hours of operation. MCEs shall also collect and actively monitor data on call center performance and accessibility for both member services and NEMT brokerage services call centers.¶¶

(198) MCEs must submit a Delivery System Network (DSN) report annually to the Authority that includes access data and other access-related analyses in the form and manner required by the Authority, including but not limited to capacity reports on:¶¶

(a) Behavioral health access;¶¶

(b) Interpreter utilization by the MCE's provider network;¶¶

(c) Behavioral health provider network.¶¶

(2019) MCEs shall report the methodology for monitoring network adequacy to the Authority and the Authority-contracted External Quality Review Organization (EQRO).¶¶

(240) MCEs shall implement and require its providers to adhere to the following appointment and wait time requirements:¶¶

(a) A member may request to reschedule an appointment if the wait time for a scheduled appointment exceeds 30 minutes. If the member requests to reschedule, they shall not be penalized for failing to keep the appointment;¶¶

(b) MCEs shall implement written procedures and a monitoring system for timely follow-up with members when a participating provider has notified the MCE that the member failed to keep scheduled appointments. The procedures shall address:¶¶

(A) Timely rescheduling of missed appointments, as deemed medically appropriate;¶¶

(B) Documentation in the clinical record or non-clinical record of missed appointments;¶¶

(C) Recall or notification efforts; and¶¶

(D) Method of member follow-up.¶¶

(c) If failure to keep a scheduled appointment is a symptom of the member's diagnosis or disability or is due to lack of transportation to the MCE's participating provider office or clinic, or lack of interpreter services, MCEs shall provide outreach services and offer Care Coordination as medically appropriate to make a plan with the member to resolve barriers;¶¶

(d) Recognition of whether NEMT services were the cause of the member's missed appointment.¶¶

(221) MCEs shall assess the needs of their membership and make available supported employment and Assertive

Community Treatment services when members are referred and eligible:¶¶

(a) MCEs shall report the number of individuals who receive supported employment and assertive community treatment services, at a frequency to be determined by the Authority. When no appropriate provider is available, the MCE shall consult with the Authority and develop an approved plan to make supported employment and Assertive Community Treatment (ACT) services available;¶¶

(b) If ten (10) or more members in a MCE region have been referred, are eligible, and are appropriate for assertive community treatment, and have been on a waitlist to receive ACT for more than thirty (30) days, MCEs shall notify the Authority and take action to reduce the waitlist and serve those individuals by:¶¶

(A) Increasing team capacity to a size that is still consistent with fidelity standards; or¶¶

(B) Adding additional Assertive Community Treatment teams; or¶¶

(C) When no appropriate ACT provider is available, the MCE shall consult with the Authority and develop an approved plan to increase capacity and add additional teams.¶¶

(232) HRSN Service Provider Minimum Network Requirements.¶¶

(a) An MCE must offer HRSN Services in all service areas in which the MCE operates.¶¶

(b) The MCE must ensure that HRSN Services are delivered to Members within the timelines outlined in OAR 410-120-20020.

Statutory/Other Authority: ORS 413.042, 414.615, 414.625, 414.635, 414.651

Statutes/Other Implemented: ORS 414.610 - 414.685

AMEND: 410-141-3835

RULE SUMMARY: Corrected an HRSN rule reference and include additional HRSN rule references.

CHANGES TO RULE:

410-141-3835

MCE Service Authorization

- (1) Coverage of services is outlined by MCE contract and Oregon Health Plan (OHP) benefits coverage in OAR 410-120-1210 and OAR 410-120-1160.¶
- (2) A member may access urgent and emergency services 24 hours a day, seven (7) days a week without prior authorization.¶
- (3) The MCE may not require a member to obtain the approval of a primary care physician to gain access to behavioral assessment and evaluation services. A member may self-refer to assessment, evaluation, and behavioral health services from the Provider Network. Members may obtain primary care services in a behavioral health setting, and behavioral health services in a primary care setting without authorization.¶
- (4) A member may access the following outpatient behavioral health services from within the MCE's Provider Network, without Prior Authorization, including but not limited to:¶
 - (a) "Assertive Community Treatment" as defined in OAR 309-019-0105, "Enhanced Care Services" as defined in OAR 309-019-0105, "Enhanced Care Outreach Services" as defined in OAR 309-019-0105, "Wraparound" as defined in OAR 309-019-0105, "Behavior Supports, Crisis Care" as defined in OAR 309-019-0105, "Respite Care" as defined in OAR 309-019-0105, and "Intensive Outpatient Services and Supports" as defined in OAR 309-019-0165;¶
 - (b) Behavioral Health Peer Delivered Services as defined in OAR 309-019-0125 from within the MCE's Provider Network;¶
 - (c) Medication-Assisted Treatment for Substance Use Disorders as defined in OAR 309-019-0105, including opioid and opiate use disorders. Prior authorization may only be required:¶
 - (A) For a medication approved by the United States Food and Drug Administration after January 1, 2024; or¶
 - (B) For a brand name drug for medication-assisted treatment if a generic equivalent is available to substitute for the prescribed brand name drug. For the purposes of this rule, a different formulation of the medication is not a generic equivalent.¶
- (5) Contractors must permit out-of-network IHCPs to refer an MCE-enrolled American Indian/Alaska Native to a network provider for covered services as required by 42 CFR 438.14(b)(6).¶
- (6) The MCE shall ensure the services are furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid and as described in ORS chapter 414 and applicable administrative rules, based on the Prioritized List of Health Services and OAR 410-120-1160, 410-120-1210, and 410-141-3830.¶
- (7) MCEs may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary.¶
- (8) MCEs shall observe required timelines for standard authorizations, expedited authorizations, and specific OHP rule requirements for authorizations for services, including but not limited to residential treatment or substance use disorder treatment services and requirements for advance notice set forth in OAR 410-141-3885. MCEs shall observe required timely access to service timelines as indicated in OAR 410-141-3515.¶
- (9) MCEs may place appropriate limits on a service authorization for Covered Services based on Medical Necessity and Medical Appropriateness as defined in OAR 410-120-0000, or for utilization control provided that the MCE:¶
 - (a) Ensures the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished;¶
 - (b) Authorizes the services supporting individuals with ongoing or chronic conditions or those conditions requiring long-term services and supports in a manner that reflects the member's ongoing need for the services and supports;¶
 - (c) Provides family planning services in a manner that protects and enables the member's freedom to choose the method of family planning to be used consistent with 42 CFR § 441.20 and the member's free choice of provider consistent with 42 USC § 1396a(a)(23)(B) and 42 CFR § 431.51; and¶
 - (d) Ensures compensation to individuals or entities that conduct utilization management activities is not structured to provide incentives for the individual or entity to deny, limit, delay, or discontinue medically necessary services to any member.¶
- (10) MCEs may not use quality of life in general measures in establishing utilization controls (e.g., prior authorization) or otherwise making benefit determinations per OAR 410-120-1320.¶
- (11) Once a member is determined to be eligible for HRSN Services as outlined in OAR 410-120-2000, OAR 410-

120-2005, and OAR 410-120-2015, MCEs may place appropriate limits on a service authorization for HRSN Services or for utilization control provided the MCE:¶

(a) Ensures the HRSN Services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished; and¶

(b) Authorizes the HRSN Services supporting individuals with ongoing or chronic conditions or those conditions requiring long-term services and supports in a manner that reflects the member's ongoing need for the services and supports;¶

(c) Ensures compensation to individuals or entities that conduct utilization management activities is not structured to provide incentives for the individual or entity to deny, limit, delay, or discontinue the delivery of HRSN Services to any member who is eligible for those services under OAR 410-120-2000, OAR 410-120-2005, and OAR 410-120-2015.¶

(12) For authorization of services:¶

(a) Each MCE shall follow the following timeframes for authorization requests other than for drug services:¶

(A) For standard authorization requests for services not previously authorized, provide notice as expeditiously as the member's condition requires and no later than fourteen (14) days following receipt of the request for service with a possible extension of up to Fourteen (14) additional days if the following applies:¶

(i) The member, the member's representative, or provider requests an extension; or¶

(ii) The MCE justifies to the Authority upon request a need for additional information and how the extension is in the member's interest.¶

(B) For expedited authorization decisions:¶

(i) The MCE shall provide notice as expeditiously as the member's health condition requires and no later than 72 hours after receipt of the request for service, which period of time shall be determined by the time and date stamp on the receipt of the request;¶

(ii) The MCE may extend the 72 hour period up to fourteen (14) days if the member requests an extension or if the MCE justifies to the Authority upon request a need for additional information and how the extension is in the member's interest.¶

(b) Prior authorization requests for outpatient drugs, including a practitioner administered drug (PAD), shall be addressed by the MCEs as follows:¶

(A) Respond to requests for prior authorizations for outpatient drugs within 24 hours as described in 42 CFR 438.210(d)(3) and section 1927(d)(5) of the Social Security Act. An initial response shall include:¶

(i) A written, telephonic or electronic communication of approval of the drug as requested to the member, and prescribing practitioner, and when known to the MCE, the pharmacy; or¶

(ii) A written notice of adverse benefit determination of the drug to the member, and telephonic or electronic notice to the prescribing practitioner, and when known to the MCE, the pharmacy if the drug is denied or partially approved; or¶

(iii) A written, telephonic, or electronic request for additional documentation to the prescribing practitioner when the prior authorization request lacks the MCE's standard information collection tools such as prior authorization forms or other documentation necessary to render a decision; or¶

(iv) A written, telephonic, or electronic acknowledgment of receipt of the prior authorization request that gives an expected timeframe for a decision. An initial response indicating only acceptance of a request shall not delay a decision to approve or deny the drug within 72 hours.¶

(B) The 72 hour window for a coverage decision begins with the initial date and time stamp of a prior authorization request for a drug;¶

(C) If the response is a request for additional documentation, the MCE shall identify and notify the prescribing practitioner of the documentation required to make a coverage decision and comply within the following timeframes:¶

(i) Upon receiving the MCE's completed prior authorization forms and required documentation, the MCE shall issue a decision as expeditiously as the member's health requires, but no later than 72 hours from the date and time stamp of the initial request for prior authorization as follows:¶

(I) If the drug is approved as requested, the MCE shall notify the member in writing and prescribing practitioner, and when known to the MCE, the pharmacy, telephonically, or electronically; or¶

(II) If the drug is denied or partially approved, the MCE shall issue a written notice of adverse benefit determination to the member, and telephonic or electronic notice to the prescribing practitioner, and when known to the MCE, the pharmacy.¶

(ii) If the requested additional documentation is not received within 72 hours from the date and time stamp of the initial request for prior authorization, the MCE shall issue a written notice of adverse benefit determination to the member, and telephonic or electronic notice to the prescribing practitioner, and when known to the MCE, the pharmacy.¶

(D) The MCE shall provide approved services as expeditiously as the member's health condition requires;¶

- (E) If an emergency situation justifies the immediate medical need for the drug during this review process, an emergency supply of 72 hours or longer shall be made available until the MCE makes a coverage decision.¶
- (c) For members with special health care needs as determined through an assessment requiring a course of treatment or regular care monitoring, each MCE shall have a mechanism in place to allow members to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the member's condition and identified needs;¶
- (d) Any service authorization decision not reached within the timeframes specified in this rule shall constitute a denial and becomes an adverse benefit determination. A notice of adverse benefit determination shall be issued on the date the timeframe expires;¶
- (e) MCEs shall give the member written notice of any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested or when reducing a previously authorized service authorization. The notice shall meet the requirements of CFR 438.404 and OAR 410-141-3885;¶
- (f) The MCE and its subcontractors shall have and follow written policies and procedures to ensure consistent application of review criteria for service authorization requests including the following:¶
- (A) For medical, behavioral, or oral health Covered Services:¶
- (i) The MCE shall consult with the requesting provider for medical, behavioral, or oral health services when necessary;¶
- (I) Requesting all the appropriate information to support decision making as early in the review process as possible; and¶
- (II) Adding documentation in the authorization file on outreach methods and dates when additional information was requested from the requesting provider.¶
- (ii) Decisions shall be made by an individual who has clinical expertise in addressing the member's medical, behavioral, or oral health needs or in consultation with a health care professional with clinical expertise in treating the member's condition or disease. This applies to decisions to:¶
- (I) Deny a service authorization request;¶
- (II) Reduce a previously authorized service request; or¶
- (III) Authorize a service in an amount, duration, or scope that is less than requested.¶
- (B) For HRSN Services, the MCE shall comply with OAR 410-120-20020.¶
- (C) MCEs shall have written policies and procedures for processing prior authorization requests received from any provider. The policies and procedures shall specify timeframes for the following:¶
- (i) Date and time stamping prior authorization requests when received;¶
- (ii) Determining within a specific number of days from receipt whether a prior authorization request is valid or non-valid;¶
- (iii) The specific number of days allowed for follow-up on pended prior authorization requests to obtain additional information;¶
- (iv) The specific number of days following receipt of the additional information that an approval or denial shall be issued;¶
- (v) Providing services after office hours and on weekends that require prior authorization.¶
- (D) An MCE shall make a determination on at least 95 percent of valid prior authorization requests within two (2) working days of receipt of a prior authorization or reauthorization request related to:¶
- (i) Drugs;¶
- (ii) Alcohol;¶
- (iii) Drug services; or¶
- (iv) Care required while in a skilled nursing facility.¶
- (g) MCEs shall notify providers of an approval, a denial, or the need for further information for all other prior authorization requests within fourteen (14) days of receipt of the request as set forth in OAR 410-141-3885 unless otherwise specified in OHP program rules:¶
- (A) MCEs shall make three reasonable attempts using two methods to obtain the necessary information during the fourteen (14) day period;¶
- (B) If the MCE needs to extend the timeframe, the MCE shall give the member written notice of the reason for the extension;¶
- (C) The MCE shall make a determination as the member's health or mental health condition requires, but no later than the expiration of the extension.¶
- (13) Report to the Authority annually requests for prior authorization. The report shall include:¶
- (a) The number of requests received;¶
- (b) The number of requests that were initially denied and the reasons for the denials, including, but not limited to, lack of medical necessity or failure to provide additional clinical information requested by the insurer;¶
- (c) The number of requests that were initially approved; and¶

(d) The number of denials that were reversed by internal appeals or external reviews.

Statutory/Other Authority: ORS 413.042, ~~ORS 414.065~~, 414.651, 414.615, 414.625, 414.635

Statutes/Other Implemented: ORS 414.065, ~~ORS 414.610-414.685~~

AMEND: 410-141-3855

RULE SUMMARY: Add new drug to treat schizophrenia, xanomeline/trospium (brand name, Cobenfy), to the CCO mental health drug carve-out list and list other drugs by their generic names. Clarify process for adding drugs and removing them from the carve-out list.

CHANGES TO RULE:

410-141-3855

Pharmaceutical Services

(1) Prescription drugs are a covered service for conditions that are described in the funded region of the Prioritized List of Health Services, as described in OAR 410-141-3820. MCEs shall pay for covered 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~~FDA-approved formulations of valproic acid and its derivatives, lamotrigine, and xanomeline/trospium and those drugs that the Authority specifically carved out from capitation according to section (10) of this rule;¶

(c) Drugs covered under Medicare Part D when the member is fully dual eligible; and¶

(d) Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act, for which payment is governed by OAR 410-121-0150.¶

(2) MCEs may use the statewide Practitioner-Managed Prescription Drug Plan under ORS 414.330 to 414.337.¶

(3) MCEs may use a preferred drug list if it allows access to other drug products not on the drug list through prior authorization.¶

(4) As specified in 45 CFR 156.122 and 42 CFR 438.10, MCEs shall publish up-to-date, accurate, and complete preferred drug lists, including any tiering structures, that have been adopted and any coverage criteria or other restrictions on the way certain drugs may be obtained. MCEs shall ensure that:¶

(a) The preferred drug list is easily accessible to members and potential members, state and federal government, and the public;¶

(b) The preferred drug list is accessible on the MCE's public website in a machine-readable format through a clearly identifiable web link or tab without requiring a member to access account or policy number;¶

(c) Be made available in paper form if requested by a member; and¶

(d) If an MCE has more than one plan, members may be easily able to discern which preferred drug list applies to which plan.¶

(5) 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.¶

(6) MCEs shall cover at least one form of contraception within each of the 18 methods identified by the FDA. As set forth in OAR 410-141-3515, the member may refer themselves directly to family planning services without getting a referral from a PCP or other participating providers.¶

(7) Prior Authorization for prescription drug requests shall be addressed by the MCEs as described in OAR 410-141-3835.¶

(8) 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.¶

(9) 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 federal "Drug Products in the Medicaid Drug Rebate Program" list available at:

<https://data.medicaid.gov/>.¶

(10) 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), unless otherwise provided in this rule. An MCE may not reimburse providers for carved-out drugs.¶

(a) Adding drugs to the carve-out list.¶

(A) An MCE may seek to add drugs to the carve-out 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:¶

(Ai) The drug name;¶

(Bii) The FDA-approved indications that identify the drug may be used to treat a severe mental health condition, ~~along with any other FDA-approved indications;~~ and¶

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

~~(bB) If the Authority approves an MCE request for a drug not to be paid within the global budget, the Authority shall exclude the drug from the global budget for the following January contract cycle.¶~~

(i) Amend section (1) of this rule according to the process described in ORS 183.335(5) within sixty (60) days of the request to exclude the drug from the global budget 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;¶

(ii) Within 180 days of amending section (1) of this rule as described in subsection (i), adopt this same amendment to section (1) using the permanent rulemaking process described in ORS 183.335(1)-(4). ¶

(C) The Authority may add drugs to the carve-out list at any time using the rulemaking process described in ORS 183.333-183.335.¶

(b) Removing drugs from the carve-out list.¶

(A) An MCE may seek to remove drugs from the carve-out 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:¶

(i) The drug name;¶

(ii) The FDA approved indications for the drug; and¶

(iii) The reason the Authority should consider removing this drug from the list of carved out drugs.¶

(B) If the Authority approves an MCE request for a carved-out drug to be paid within the global budget, the Authority shall include the drug in the global budget for the following January contract cycle.¶

(C) The Authority may remove drugs from the carve-out list in conjunction with a January contract cycle using the rulemaking process described in ORS 183.333-183.335.¶

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

(12) 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.¶

(13) 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) 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;¶

(b) 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;¶

(c) 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)].¶

(14) As required by ORS 414.328, CCOs shall implement a synchronization policy for the dispensing of prescription drugs to members of the CCO. A "synchronization policy" means a procedure for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently.¶

(15) Enrolled providers are required to check the Prescription Drug Monitoring Program (PDMP) as defined in ORS 431A.655 before prescribing a schedule II controlled substance pursuant to 42 U.S.C 1396w-3a:¶

(a) Providers shall maintain documentation of the prescription drug history of the individual being treated; and¶

(b) In the case that an enrolled provider is not able to conduct the PDMP check, the providers shall maintain documentation of efforts, including reasons why the provider was unable to conduct the check;¶

(c) The PDMP check does not apply to clients in exempt populations:¶

- (A) Individuals receiving hospice care;¶
 - (B) Individuals receiving palliative care;¶
 - (C) Individuals receiving cancer treatment;¶
 - (D) Individuals with sickle cell disease;¶
 - (E) Residents of long-term care facilities described in) 42 U.S.C. 1396d, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy in accordance with 42 U.S.C. 1396w-3a(h)(2)(B); and¶
 - (F) Individuals admitted to an inpatient hospital facility. This exemption shall only apply to schedule II controlled substances provided or administered to the individual admitted to the inpatient hospital facility.¶
- (d) PDMP requirements are in accordance with OAR 333-023-0800 to 333-023-0830.
- Statutory/Other Authority: ORS 413.042, 414.615, 414.625, 414.635, 414.651, 414.742
- Statutes/Other Implemented: ORS 414.610-414.685