Ohio | Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

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Regulation/Package Title (a general description of the rules' substantive content): Medicaid Managed Care Unified Preferred Drug List (UPDL)

Rule Number(s): 5160-26-03; the following rule is attached for "information purposes only": OAC rule 5160-9-03

Date of Submission for CSI Review: September 5, 2019

Public Comment Period End Date: September 12, 2019

Rule Type/Number of Rules:

New/___ rules

Amended/ 1 **rules (FYR?** No**)**

No Change/____ rules (FYR? ___)

Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   In Ohio, approximately 90% of Medicaid recipients receive their Medicaid services, including prescribed drugs, through a Managed Care Plan (MCP) or MyCare Ohio Plan (MCOP). MCPs/MCOPs are health insurance companies licensed by the Ohio Department of Insurance and have a provider agreement (contract) with the Ohio Department of Medicaid (ODM) to provide coordinated health care to Medicaid beneficiaries. There are six MCPs/MCOPs (referred to as plans) in Ohio, each with a network of health care professionals. The rules outlined in Chapter 5160-26 of the Administrative Code set forth the requirements of MCPs and the Ohio Medicaid managed care program.

   OAC rule 5160-26-03, entitled "Managed health care programs: covered services", describes the services which must be covered by MCPs and addresses any exclusions or limitations for those services. Paragraph (C) is being added to the rule to require MCPs to provide pharmacy services in compliance with Ohio Administrative Code (OAC) rule 5160-9-03, including all prescribing and prior authorization guidelines and grandfathering any drug classes as established by the ODM preferred drug list at https://pharmacy.medicaid.ohio.gov/drug-coverage.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Revised Code Section 5167.02 authorizes ODM to adopt the rule, and 5167.03, 5167.04, and 5167.10 amplify that authority.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
If yes, please briefly explain the source and substance of the federal requirement.

   Yes. 42 C.F.R. Part 438 imposes comprehensive requirements on the state regarding Medicaid managed care programs, however the proposed changes to the rule are not related to changes to federal regulation.

5. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Federal regulations do not impose requirements directly on MCPs; instead they require state Medicaid agencies to ensure MCP compliance with federal standards. The rules are consistent with federal managed care requirements outlined in 42 C.F.R Part 438.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   The public purpose of this regulation is to ensure the provision of medically necessary services, preventative care, emergency services, post stabilization services and respite to promote the best outcomes for individuals enrolled in the Medicaid managed care program by requiring MCPs to follow established guidelines and to ensure providers are paid appropriately for services delivered. In addition, the rules ensure compliance with federal regulations governing Medicaid managed care.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

   ODM monitors compliance with the regulation through reporting requirements established within the managed care provider agreements. Successful outcomes are measured through a finding of compliance with these standards as determined by monitoring and oversight.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The Medicaid Managed Care Plans listed below were provided the draft rules electronically on August 29, 2019. The plans were given until September 4, 2019 to comment.

- Buckeye Health Plan
- CareSource
- Molina Healthcare of Ohio
- Paramount Advantage
- UnitedHealthcare Community Plan of Ohio

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    As a result of MCP outreach, no concerns were expressed. Therefore, no changes were made to the rules.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    No scientific data was used to develop this rule or the measurable outcomes of the rules.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    Language related to a single preferred drug list for both Medicaid fee-for-service and Medicaid managed care was requested during the most recent executive budget process. After review, it was determined that the provision did not need to be codified in order for ODM to move forward with the policy change. This language was not included in the final budget bill, however, ODM does agree that a unified preferred drug list is beneficial to the individuals we serve and Medicaid pharmacy providers. The unified preferred drug list will promote clinically appropriate utilization of pharmaceuticals in a cost-effective manner, and therefore ODM is proposing to is implement the pharmacy policy change in the Administrative Code rule. The Medicaid pharmacy rule (OAC 5160-9-03) that includes a reference to the preferred drug list is being updated and filed in the same package as this rule and has been included in this BIA package for reference.

13. **Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

    A performance-based regulation would not be appropriate because ODM is required to comply with detailed federal requirements set forth in 42 CFR Part 438. MCP performance requirements are outlined in the Medicaid Managed Care Plan Contracts available online at: https://medicaid.ohio.gov/Managed-Care/For-Managed-Care-Plans

14. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

All Medicaid regulations governing MCPs are promulgated and implemented by ODM only. No other state agencies impose requirements that are specific to the Medicaid program.

15. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

ODM will notify the MCPs of the final rule changes via email notification. Additionally, per the provider agreement, managed care plans are required to subscribe to the appropriate distribution lists for notification of all OAC rule clearances and final published rules including RuleWatch Ohio and the ODM Rule Notification system.

Adverse Impact to Business

16. **Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**
    a. **Identify the scope of the impacted business community; and**
    This rule impacts Medicaid MCPs in the State of Ohio including: Buckeye Health Plan, CareSource, Molina Healthcare of Ohio, Paramount Advantage, and UnitedHealthcare Community Plan of Ohio.

    b. **Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**

    OAC rule 5160-26-03 holds MCPs financially responsible for payment of certain services including respite for children. Requirements in addition to the payment for covered services as outlined in this rule include:

    - Establishing, in writing, a process for the submission of claims for services delivered by non-contracting providers;
    - Designating a telephone line to receive provider requests for coverage of certain services; and
    - Submitting written requests or notifications to ODM, contracting providers and members.

    Respite provider agencies are required to:

    - Be accredited by at least one of several national accreditation entities;
    - Hold a Medicaid provider agreement;
    - Comply with applicable background check requirements; and
    - Behavioral health provider agencies must be OhioMHAS certified.

    Agency employees:

    - Long-term care providers must obtain a certificate of completion from the Ohio Department of Health or a Medicare competency evaluation program;

- All providers must obtain first aid certification; and
- Long-term care providers must obtain evidence of completion of twelve hours of in-services continuing education each year.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

Managed care plans (MCPs) are paid per member per month. ODM must pay MCPs rates that are actuarially sound, as determined by an outside actuary in accordance with 42 CFR 438.6(c) and CMS's "2018/2019 Managed Care Rate Setting Consultation Guide." Ohio Medicaid capitation rates are "actuarially sound" for the period covered by the certification, projected capitation rates and other revenue sources provide for all reasonable, appropriate and attainable costs. Costs include but are not limited to expected health benefits, health benefit settlement expenses, administrative expenses, the cost of capital and government mandated assessments, fees, and taxes.

All rates and actuarial methods can be found on the ODM website in Appendix E of the Medicaid Managed Care provider agreement. Through the administrative component of the capitation rate paid to the MCPs by ODM, MCPs will be compensated for the cost of the requirements found in this rule. For CY 2019, the administrative component of the capitation rate varies by program/population and ranges from 3.50% to 7.50% of the effective rate for MCPs. Note that these amounts exclude care management and risk margin included in the capitation rates.

Respite providers must hold a Medicaid provider agreement. The cost associated with obtaining a Medicaid provider agreement is currently $554. This fee may be paid to Ohio Medicaid, their designated agency or to Medicare. It is paid at initial application and then at revalidation every five years.

Fees for the BCII criminal records check for all applicants considered for employment may vary depending on the location or agency providing the service, but on average cost approximately $22.00. The fee for criminal records check from the FBI for each applicant considered for employment, who has not resided in Ohio for five years is currently $24.00 which may vary depending on the location or agency providing the service. BCII accepts and processes FBI background checks. Fees associated with criminal records checks are passed to the applicant/employee resulting in no impact to the agency.

Respite provider agencies must be certified through OhioMHAS. The cost of certification through OhioMHAS is based upon the budget of the agency that is applying for certification. The fee schedule showing the correlation between the agency's budget and the certification cost is

located in OhioMHAS OAC rule 5122-25-08. A provider already certified by OhioMHAS, requesting to add an additional service(s) pays a fee based only upon their budget for the new service(s), not their entire budget. When the agency has appropriate accreditation from The Joint Commission, CARF, or COA there is no certification fee owed to OhioMHAS.

Respite provider agencies are required to be accredited by at least one of several accreditation entities. The average cost of accreditation is between $1,295 and $2,300 annually. Costs vary depending on the size of the facility, the number of employees, facility type, the average daily population being served and whether there are satellite offices.

Individual respite providers working for an agency must be first aid certified. The City of Columbus Division of Fire offers a certification course for $30.00 per person. Individual providers also must obtain a certificate of completion of a competency evaluation program approved by the Ohio Department of Health (ODH) or a Medicare competency evaluation program for home health aides. Per ODH, the cost of this certification can range from approximately $200 to $500 depending on where they take the course and who is presenting the materials. Additionally, individual providers must maintain evidence of completion of twelve hours of in-service continuing education per year. On average, the cost for continuing education courses can range from free of charge to $12 per course.

17. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

Language related to a single preferred drug list for both Medicaid fee-for-service and Medicaid managed care was proposed to be included during the most recent executive budget process. Although this language was not included in the final budget bill, ODM believes that a unified preferred drug list (UPDL) would be beneficial to the individuals we serve and Medicaid pharmacy providers. This policy change will greatly benefit Medicaid recipients, especially those suffering from addiction, chronic conditions, long-term illnesses, and disabilities. These individuals will be able to receive the same prescribed drugs regardless of the Medicaid payer. Additionally, the provider community will greatly benefit from this change as the preferred drug list will be the same among all Medicaid payers, resulting in consistent prescribing and prior authorization requirements between all managed care plans and Medicaid fee-for-service.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

The requirements of this rule must be applied uniformly, and no exception is made based on a plan's size. Small Medicaid providers will benefit from this requirement on managed care plans.

19. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    This rule imposes no sanctions.

20. **What resources are available to assist small businesses with compliance of the regulation?**

    While there are no small businesses negatively impacted by this rule, the managed care plans may contact ODM directly through their assigned Contract Administrator.

DRAFT - NOT FOR FILING

5160-26-03 Managed health care programs: covered services.

(A) Except as otherwise provided in this rule, a managed care plan (MCP) must ensure members have access to all ~~medically necessary~~medically necessary services covered by Ohio medicaid under the state plan. Specific coverage provisions for "MyCare Ohio" plans as defined in rule 5160-58-01 of the Administrative Code are described in Chapter 5160-58 of the Administrative Code. The MCP must ensure:

(1) Services are sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished;

(2) The amount, duration, or scope of a required service is not arbitrarily denied or reduced solely because of the diagnosis, type of illness, or condition;

(3) Prior authorization is available for services on which an MCP has placed a pre-identified limitation to ensure the limitation may be exceeded when medically necessary, unless the MCP's limitation is also a limitation for fee-for-service medicaid coverage;

(4) Coverage decisions are based on the coverage and medical necessity criteria published in agency 5160 of the Administrative Code and practice guidelines specified in rule 5160-26-05.1 of the Administrative Code; and

(5) If a member is unable to obtain ~~medically necessary~~medically necessary services offered by medicaid from a MCP panel provider, the MCP must adequately and timely cover the services out of panel, until the MCP is able to provide the services from a panel provider.

(B) The MCP may place appropriate limits on a service;

(1) On the basis of medical necessity for the member's condition or diagnosis; or

(2) For the purposes of utilization control, provided the services furnished can be reasonably expected to achieve their purpose as specified in paragraph (A)(1) of this rule.

(C) The MCP will provide pharmacy services in compliance with rule 5160-9-03 of the Administrative Code, including all prescribing and prior authorization requirements, and any grandfathered drug classes as estabslished by the Ohio department of Medicaid (ODM) preferred drug list located at https://pharmacy.medicaid.ohio.gov/. The MCP is not required to charge co-pays.

~~(C)~~ (D) The MCP must cover annual physical examinations for adults.

~~(D)~~ (E) At the request of the member, an MCP must provide for a second opinion from a qualified health care professional within the panel. If such a qualified health care professional is not available within the MCP's panel, the MCP must arrange for the member to obtain a second opinion outside the panel, at no cost to the member.

~~(E)~~ (F) The MCP must ensure emergency services as defined in rule 5160-26-01 of the Administrative Code are provided and covered twenty-four hours a day, seven days a week. At a minimum, such services must be provided and reimbursed in accordance with the following:

(1) The MCP cannot deny payment for treatment obtained when a member had an emergency medical condition, as defined in rule 5160-26-01 of the Administrative Code.

(2) The MCP cannot limit what constitutes an emergency medical condition on the basis of lists of diagnoses or symptoms.

(3) The MCP must cover all emergency services without requiring prior authorization.

(4) The MCP must cover medicaid-covered services related to the member's emergency medical condition when the member is instructed to go to an emergency facility by a representative of the MCP including but not limited to the member's primary care provider (PCP) or the MCP's twenty-four-hour toll-free phone number.

(5) The MCP cannot deny payment of emergency services based on the treating provider, hospital, or fiscal representative not notifying the member's PCP of the visit.

(6) For the purposes of this paragraph, "non-contracting provider of emergency services" means any person, institution, or entity who does not contract with the MCP but provides emergency services to an MCP member, regardless of whether that provider has a medicaid provider agreement with the ~~Ohio department of medicaid (ODM)~~ODM. An MCP must cover emergency services as defined in rule 5160-26-01 of the Administrative Code when the services are delivered by a non-contracting provider of emergency services and claims for these services cannot be denied regardless of whether the services meet an emergency medical condition as defined in rule 5160-26-01 of the Administrative Code. Such services must be reimbursed by the MCP at the lesser of billed charges or one hundred per cent of the Ohio medicaid program reimbursement rate (less any payments for indirect costs of medical education and direct costs of graduate medical education that is included in the Ohio medicaid program reimbursement rate) in effect for the date of service. If an inpatient admission results, the MCP is required to reimburse at this rate only until the member can be transferred to a provider designated by the MCP. Pursuant to section 5167.10 of the Revised Code, the MCP shall not compensate a hospital for inpatient capital costs in an amount that exceeds the maximum rate established by ODM.

(7) The MCP must cover emergency services until the member is stabilized and can be safely discharged or transferred.

(8) The MCP must adhere to the judgment of the attending provider when requesting a member's transfer to another facility or discharge. MCPs may establish arrangements with hospitals whereby the MCP may designate one of its contracting providers to assume the attending provider's responsibilities to stabilize, treat and transfer the member.

(9) A member who has had an emergency medical condition may not be held liable for payment of any subsequent screening and treatment needed to diagnose the specific condition or stabilize the member.

~~(F)~~ (G) The MCP must establish, in writing, the process and procedures for the submission of claims for services delivered by non-contracting providers, including non-contracting providers of emergency services as described in paragraph (E)(6) of this rule. Such information must be made available upon request to non-contracting providers, including non-contracting providers of emergency services. An MCP shall not establish claims filing and processing procedures for non-contracting providers, including non-contracting providers of emergency services, that are more stringent than those established for their contracting providers.

~~(G)~~ (H) The MCP must ensure post-stabilization care services as defined in rule 5160-26-01 of the Administrative

Code are provided and covered twenty-four hours a day, seven days a week.

(1) The MCP must designate a telephone line to receive provider requests for coverage of post-stabilization care services. The line must be available twenty-four hours a day. An MCP must document that the telephone number and process for obtaining authorization has been provided to each emergency facility in the service area. The MCP must maintain a record of any request for coverage of post-stabilization care services that is denied including, at a minimum, the time of the provider's request and the time the MCP communicated the decision in writing to the provider.

(2) At a minimum, post-stabilization care services must be provided and reimbursed in accordance with the following:

(a) The MCP must cover services obtained within or outside the MCP's panel that are pre-approved in writing to the requesting provider by a plan provider or other MCP representative.

(b) The MCP must cover services obtained within or outside the MCP's panel that are not pre-approved by a plan provider or other MCP representative but are administered to maintain the member's stabilized condition within one hour of a request to the MCP for pre-approval of further post-stabilization care services.

(c) The MCP must cover services obtained within or outside the MCP's panel that are not pre-approved by a plan provider or other MCP representative but are administered to maintain, improve or resolve the member's stabilized condition if:

(i) The MCP fails to respond within one hour to a provider request for authorization to provide such services.

(ii) The MCP cannot be contacted.

(iii) The MCP's representative and treating provider cannot reach an agreement concerning the member's care and a plan provider is not available for consultation. In this situation, the MCP must give the treating provider the opportunity to consult with a plan provider and the treating provider may continue with care until a plan provider is reached or one of the criteria specified in paragraph (G)(3) of this rule is met.

(3) The MCP's financial responsibility for ~~post stabilization~~post-stabilization care services not pre-approved ends when:

(a) A plan provider with privileges at the treating hospital assumes responsibility for the member's care;

(b) A plan provider assumes responsibility for the member's care through transfer;

(c) An MCP representative and the treating provider reach an agreement concerning the member's care; or

(d) The member is discharged.

~~(H)~~ (I) MCP responsibilities for payment of other services.

(1) When an MCP member has a nursing facility (NF) stay, the MCP is responsible for payment of medically necessary NF services, until discharge or until the member is disenrolled in accordance with the

processes set forth in rule 5160-26-02.1 of the Administrative Code.

(2) The MCP is not responsible for payment of home and community-based services (HCBS) provided to a member who is enrolled in an HCBS waiver program administered by ODM, the Ohio department of aging (ODA), or the Ohio department of developmental disabilities (DODD).

(3) MCP members are permitted to self-refer to Title X services provided by any qualified family planning provider (QFPP). The MCP is responsible for payment of claims for Title X services delivered by QFPPs not contracting with the MCP at the lesser of one hundred per cent of the Ohio medicaid program fee-for-service reimbursement rate or billed charges, in effect for the date of service.

(4) The MCP must permit members to self-refer to any women's health specialist within the MCP's panel for covered care necessary to provide women's routine and preventive health care services. This is in addition to the member's designated PCP if that PCP is not a women's health specialist.

(5) The MCP must ensure access to covered services provided by all federally qualified health centers (FQHCs) and rural health clinics (RHCs).

(6) Where available, the MCP must ensure access to covered services provided by a certified nurse practitioner.

(7) ODM may approve an MCP's members to be referred to certain MCP non-contracting hospitals, as specified in rule 5160-26-11 of the Administrative Code, for medicaid-covered non-emergency hospital services. When ODM permits such authorization, ODM will notify the MCP and the MCP non-contracting hospital of the terms and conditions, including the duration, of the approval and the MCP must reimburse the MCP non-contracting hospital at one hundred per cent of the current Ohio medicaid program fee-for-service reimbursement rate in effect for the date of service for all medicaid-covered non-emergency hospital services delivered by the MCP non-contracting hospital. ODM will base its determination of when an MCP's members can be referred to MCP non-contracting hospitals pursuant to the following:

(a) The MCP's submission of a written request to ODM for the approval to refer members to a hospital that has declined to contract with the MCP. The request must document the MCP's contracting efforts and why the MCP believes it will be necessary for members to be referred to this particular hospital; and

(b) ODM consultation with the MCP non-contracting hospital to determine the basis for the hospital's decision to decline to contract with the MCP, including but not limited to whether the MCP's contracting efforts were unreasonable and/or that contracting with the MCP would have adversely impacted the hospital's business.

(8) Paragraph (H)(7) of this rule is not applicable when an MCP and an MCP non-contracting hospital have mutually agreed to that hospital providing non-emergency hospital services to an MCP's members. The MCP must ensure that such arrangements comply with rule 5160-26-05 of the Administrative Code.

(9) The MCP is not responsible for payment of services provided through medicaid school program (MSP) pursuant to Chapter 5160-35 of the Administrative Code. An MCP must ensure access to medicaid-covered services for members who are unable to timely access services or unwilling to access services through MSP providers.

(10) The MCP is not required to cover services provided to members outside the United States.

(11) When a member is determined to be no longer eligible for enrollment in an MCP during a stay in an institution for mental disease (IMD), the MCP is not responsible for payment of that IMD stay after the date of disenrollment from the plan.

~~(I)~~ (J) "Respite services" are services that provide short-term, temporary relief to the informal unpaid caregiver of an individual under the age of twenty-one in order to support and preserve the primary caregiving relationship. The MCP shall be responsible for payment for respite services. Respite services can be provided on a planned or emergency basis. The provider must be awake when the member is awake during the provision of respite services.

(1) To be eligible for respite services, the member must:

(a) Reside with his or her informal, unpaid primary caregiver in a home or an apartment that is not owned, leased or controlled by a provider of any health-related treatment or support services;

(b) Not be a foster child, as defined in Chapter 5101:2-1 of the Administrative Code;

(c) Be under twenty-one years of age;

(d) Currently be participating in a care management /coordination arrangement; and

(e) Meet either of the following:

(i) Have long-term service and support (LTSS) needs as determined by the MCP through an institutional level of care determination as set forth in rule 5123:2-8-01, 5160-3-08 or 5160-3-09 of the Administrative Code, and

(a) Require skilled nursing or skilled rehabilitation services at least once per week,

(b) Be determined eligible for social security income for children with disabilities or supplemental security income,

(c) Had a need for at least fourteen hours per week of home health aide services for at least two consecutive months immediately preceding the date respite services are requested, and

(d) The MCP must have determined that the member's primary caregiver has a need for temporary relief from the care of the member as a result of the member's LTSS needs, or in order to prevent an inpatient, institutional or out-of-home stay; or

(ii) Have behavioral health needs as determined by the MCP through the use of a nationally recognized standardized functional assessment tool, and

(a) Be diagnosed with serious emotional disturbance as described in the appendix to this rule resulting in a functional impairment,

(b) Not be exhibiting symptoms or behaviors that indicate imminent risk of harm to himself or herself or others, and

(c) The MCP must have determined that the member's primary caregiver has a need for temporary relief from the care of the member as a result of the member's behavioral health needs, either:

(i) To prevent an inpatient, institutional or out-of-home stay; or

(ii) Because the member has a history of inpatient, institutional or out-of-home stays.

(2) Respite services are limited to one hundred hours per calendar year per member, however, this may be exceeded through MCP prior authorization on the basis of medical necessity.

(3) LTSS respite services must be provided by individuals employed by medicaid enrolled agency providers that are either medicare-certified home health agencies pursuant to Chapter 3701-60 of the Administrative Code, or accredited by the "Joint Commission," the "Community Health Accreditation Program," or the "Accreditation Commission for Health Care."

(a) LTSS respite providers must comply with the criminal records check requirements set forth in rules 5160-45-07 and 5160-45-11 of the Administrative Code.

(b) Before commencing service delivery, the LTSS provider agency employee must:

(i) Obtain a certificate of completion of either a competency evaluation program or training and competency evaluation program approved or conducted by the Ohio department of health under section 3721.31 of the Revised Code, or the medicare competency evaluation program for home health aides as specified in 42 C.F.R. 484.36 (October 1, ~~2018~~2019), and

(ii) Obtain and maintain first aid certification from a class that is not solely internet-based and that includes hands-on training by a certified first aid instructor and a successful return demonstration of what was learned in the course.

(c) After commencing service delivery, the LTSS provider agency employee must:

(i) Maintain evidence of completion of twelve hours of in-service continuing education within a twelve-month period, excluding agency and program-specific orientation, and

(ii) Receive supervision from an Ohio-licensed registered nurse (RN) and meet any additional supervisory requirements pursuant to the agency's certification or accreditation.

(4) Behavioral health respite services must be provided by individuals employed by OhioMHAS-certified and medicaid enrolled agency providers that are also accredited by the "Joint Commission," "Council on Accreditation" or "Commission on Accreditation of Rehabilitation Facilities."

(a) Behavioral health respite providers must comply with the criminal records check requirements set forth in rule 5160-43-09 of the Administrative Code when the service is provided in an HCBS setting.

(b) Before commencing service delivery, the behavioral health provider agency employee must:

(i) Either be credentialed by the Ohio counselor, social worker and marriage and family therapist board, the state of Ohio psychology board, the state of Ohio board of nursing or the state of Ohio medical board or received training for or education in mental health competencies and have demonstrated, prior to or within ninety days of hire, competencies in basic mental health skills along with competencies established by the agency; and

(ii) Obtain and maintain first aid certification from a class that is not solely internet-based and that

includes hands-on training by a certified first aid instructor and a successful return demonstration of what was learned in the course.

(c) After commencing service delivery, the behavioral health provider agency employee must receive supervision from an independently licensed behavioral health professional credentialed by the Ohio counselor, social worker and marriage and family therapist board, the state of Ohio psychology board, the state of Ohio board of nursing or the state of Ohio medical board.

(5) Respite services must not be delivered by the member's "legally responsible family member" as that term is defined in rule 5160-45-01 of the Administrative Code or the member's foster caregiver.

~~(J)~~ (K) An MCP must provide all early and periodic screening, diagnosis and treatment (EPSDT) services, also known as healthchek services, in accordance with rule 5160-1-14 of the Administrative Code, to eligible members and ensure healthchek exams:

(1) Include the components specified in rule 5160-1-14 of the Administrative Code. All components of exams must be documented and included in the medical record of each healthchek eligible member and made available for the ODM annual external quality review.

(2) Are completed within ninety days of the initial effective date of enrollment for those children found to have a possible ongoing condition likely to require care management services.

Serious Emotional Disturbance - Qualifying Diagnoses

ICD-10 CODES	DIAGNOSIS CATEGORY DESCRIPTION
F20.81	Schizophreniform disorder
F20.9	Schizophrenia, unspecified
F22	Delusional disorders
F25.0	Schizoaffective disorder: bipolar type
F25.1	Schizoaffective disorder: depressive type
F23	Schizoaffective disorder: brief psychotic disorder
F29	Unspecified schizophrenia spectrum and other psychotic disorder
F31.12	Bipolar disorder: manic, moderate
F31.13	Bipolar disorder: manic, severe
F31.32	Bipolar disorder: depressed, moderate
F31.4	Bipolar disorder: depressed, severe
F31.2	Bipolar disorder: severe manic with psychotic features
F31.73	Bipolar disorder: in partial remission, manic
F31.75	Bipolar disorder: in partial remission, depressed
F31.74	Bipolar disorder: in full remission, manic
F31.76	Bipolar disorder: in full remission, depressed
F31.0	Bipolar disorder: unspecified, hypomanic
F31.10	Bipolar disorder: unspecified, manic
F31.30	Bipolar disorder: unspecified, depressed, mild/moderate severity
F31.81	Bipolar disorder: unspecified, bipolar II disorder
F31.89	Bipolar disorder: unspecified, other specified bipolar and related disorder
F31.9	Bipolar disorder: unspecified bipolar and related disorder
F33.1	Major depressive disorder, recurrent, moderate
F33.2	Major depressive disorder, recurrent severe w/o psych feature
F33.3	Major depressive disorder, recurrent, severe w psych symptoms
F34.8	Disruptive mood dysregulation disorder
F40.01	Agoraphobia with panic disorder
F40.02	Agoraphobia without panic disorder
F41.1	Generalized anxiety disorder
F41.0	Panic disorder
F40.00	Agoraphobia
F42	Obsessive-compulsive disorder
F94.1	Reactive attachment disorder
F94.2	Disinhibited social engagement disorder
F43.10	Post-traumatic stress disorder
F43.11	Post-traumatic stress disorder, acute
F43.12	Post-traumatic stress disorder, chronic
F43.0	Acute stress disorder
F50.00	Anorexia nervosa, unspecified
F50.01	Anorexia nervosa, restricting type
F50.02	Anorexia nervosa, binge eating/purging type
F50.2	Bulimia nervosa
F91.0	Conduct disorder confined to family context
F91.1	Conduct disorder, childhood-onset type

F91.2	Conduct disorder, adolescent-onset type
F91.3	Oppositional defiant disorder
F91.8	Other conduct disorders
F91.9	Conduct disorder, unspecified
F93.0	Separation anxiety disorder of childhood

DRAFT - NOT FOR FILING

5160-9-03 Pharmacy services: covered drugs and associated limitations.

(A) Covered prescribed drugs

Drugs covered by the Ohio department of medicaid (ODM) pharmacy program, or a managed care plan as defined in rule 5160-26-01 of the Administrative Code, are prescribed drugs as defined in rule 5160-9-05 of the Administrative Code that are dispensed to an eligible patient for use in the patient's residence, including a nursing facility (NF), as defined in section 5165.01 of the Revised Code, or intermediate care facilitiy for individuals with intellectual disabilities (ICF/IID), as defined in section 5124.01 of the Revised Code, and fall into one of the following categories:

(1) "Dangerous drugs" as defined in section 4729.01 of the Revised Code that meet the definition of a "covered outpatient drug (COD)" as defined in 42 C.F.R. 447.502 (~~April 1, 2017~~October 1, 2019) that are not non-covered drugs as described in paragraph (B) of this rule.

(2) Over-the-counter drugs listed in accordance with paragraph (C) of this rule.

(3) Compounded prescriptions in accordance with paragraph (E) of this rule, when compounded with ingredients described in paragraphs (A)(1) to (A)(2) of this rule or with active pharmaceutical ingredients (API) and excipients listed on the ODM pharmacy program web site at http://pharmacy.medicaid.ohio.gov.

(4) Vaccines, inoculations, and immunizations, other than seasonal and pandemic influenza vaccines, are covered by the pharmacy program only for residents of a NF or ICF/IID; otherwise these services shall be billed as physician services in accordance with Chapter 5160-4 of the Administrative Code. Seasonal and pandemic influenza vaccine may be billed by the pharmacy for an individual who is not a resident of a NF or ICF/IID if the vaccine will be administered at the pharmacy, or for an individual who is a resident of a NF or ICF/IID to be administered by facility staff.

(B) Non-covered drugs

Drugs that fall into one of the following categories are non-covered by the Ohio medicaid pharmacy program:

(1) Drugs for the treatment of obesity.

(2) Drugs for the treatment of infertility.

(3) Drugs for the treatment of erectile dysfunction.

(4) DESI drugs or drugs that may have been determined to be identical, similar, or related.

(5) Drugs that are covered or are eligible to be covered by medicare part D, when prescribed for an individual who is eligible for medicare, unless medicaid coverage for a dual eligible is indicated in accordance with paragraph (C) of this rule.

(6) Over-the-counter drugs that are not listed in accordance with paragraph (C) of this rule.

(7) Drugs being used for indications not approved by the food and drug administration unless there is compelling clinical evidence to support the experimental use.

(C) The prescribed drugs covered under the ODM pharmacy program without prior authorization are specified on the ODM web site at http://pharmacy.medicaid.ohio.gov. This list indicates the drugs that require co-payments in accordance with rule 5160-9-09 of the Administrative Code, and specifies whether the drug is covered for a dual eligible as described in rule 5160-1-05 of the Administrative Code. Drugs not listed that meet the requirements of paragratph (A)(1) of this rule and are antidepressants or antipsychotics will not require prior authorization if the pharmacy claim indicates that the prescriber is a physician who has registered his or her psychiatry specialty with ODM, and when the dosage form of the drug prescribed is a standard tablet or capsule.

(D) Prior authorization

Dangerous drugs not listed in accordance with paragraph (C) of this rule that are medically necessary for treatment require prior authorization; however, noncovered drugs listed in paragraphs (B)(1) to (B)(6) of this rule and APIs and excipients not on the list described in paragraph (A)(3) of this rule are not eligible for prior authorization.

(1) Prior authorization of pharmacy services will be administered in compliance with section 1927 of the Social Security Act (~~April 1, 2017~~January 1, 2020), including a response by telephone or other telecommunication device within twenty-four hours of receipt of a request for prior authorization, and provisions for the dispensing of a seventy-two-hour supply of a COD in an emergency situation.

(2) Drugs not listed in accordance with paragraph (C) of this rule may be covered with prior authorization if medical necessity is documented, the drug is not excluded per paragraphs (B)(1) to (B)(6) of this rule, and a drug that does not require prior authorization cannot be used.

(3) Prior authorization must be obtained from ODM or its designee before the drug claim may be paid. All requests must be submitted in accordance with instructions issued by ODM or its designee.

(a) Only the prescribing provider or a member of the prescribing provider's staff may request prior authorization except as described in paragraph (D)(3)(b) of this rule.

(b) A pharmacist may request prior authorization for an alternative dosage form of a drug to be administered through a tube for patients who are tube fed, if no comparable drugs that do not require prior authorization can be administered through a tube. A pharmacist may also request prior authorization of a seventy-two-hour supply of a dangerous drug that is a COD in an emergency situation if the prescribing provider or prescribing provider’s staff is not available to request prior authorization.

(4) Drugs in therapeutic classes that are covered or are eligible to be covered under medicare part D are not available for prior authorization for an individual who is eligible for medicare. Prior authorization may be requested for drugs in drug classes that may be covered by medicaid for a dual eligible as indicated in the list described in paragraph (C) of this rule and are subject to any stated limits.

(5) When a request for prior authorization is denied, the consumer will be informed in writing of the denial and the right to a state hearing.

(E) Compounded drugs

(1) Compounded drugs will be covered if at least one ingredient meets the requirements of paragraph (A) of this rule and the individual's medical need cannot be met by a covered product that is a COD.

(2) Compounded drug claims must be submitted to ODM or its designee using the national drug code (NDC) for each ingredient that is a part of the compound.

(3) An ingredient in a compounded drug that is both a COD and a dangerous drug, not listed in accordance with paragraph (C) of this rule, will require prior authorization. If a prior authorization is not approved or if an ingredient is not eligible for authorization (i.e., not covered as described in paragraph (A) of this rule, excluded from coverage as described in paragraph (B) of this rule, or excluded from separate payment as described in paragraph (I) of this rule), the pharmacy provider may elect to receive payment only for those ingredients in the compound that are directly payable by ODM, in accordance with billing instructions issued by ODM or its designee.

(F) Dispensing limitations

(1) Days supply limits

(a) Acute medications are limited to a thirty-four-day supply.

(b) Chronic maintenance medications are limited to a one-hundred-two-day supply.

(2) Maximum quantity limits

Maximum prescription quantities are listed on the ODM pharmacy program web site and represent the largest number of units per drug that may be dispensed at any one time for a single prescription or the largest number of units per drug per day (or other time period) of therapy.

(3) Maximum equivalent daily dose limits

Maximum equivalent daily doses are listed on the ODM pharmacy program web site and establish the highest equivalent dose of certain therapeutic classes (e.g., opioid drugs expressed in morphine equivalent) that may be dispensed when equivalent doses of all drugs in the therapeutic class are summed.

(4) Maximum prescription claim limits

Maximum prescription claim limits are listed on the ODM pharmacy program web site and establish the maximum number of claims for drugs that are therapeutic duplicates that shall be paid within specified time limits (e.g., no more than five claims for opioid drugs within thirty days).

(5) Claims submitted that exceed the limits described in paragraphs (F)(1) to (F)(4) of this rule shall be denied. Denials may be overridden by ODM or its designee in cases where medical necessity has been determined through the prior authorization process.

(G) Refill prescriptions

(1) Unless the pharmacy is submitting an early refill for a shortened days supply to support medication synchronization described in section 5164.7511 of the Revised Code and the claim is submitted pursuant to billing instructions for medication synchronization issued by ODM or its designee, the following limitations apply:

(a) Refills of drugs not scheduled by the federal drug enforcement administration (DEA) requested before eighty per cent of the days supply has been utilized will be denied.

(b) Refills of drugs scheduled by the DEA requested before ninety per cent of the days supply has been utilized will be denied.

(2) If a new prescription has been issued by the prescriber that requires increased dosing frequency, the existing prescription must be utilized until the days supply per cent threshold has been met, calculated using the increased dosing frequency.

(3) Denials may be overridden by ODM or its designee for the following documented reasons:

(a) Previous supply was lost, stolen, or destroyed. ODM or its designee may limit the number of instances denials may be overridden in cases of suspected fraud or abuse, and may request additional documentation before an override is authorized.

(b) Previous claim was submitted with wrong days supply.

(c) Vacation or travel.

(d) Multiple supplies of the same medication are needed, for example in a school or workshop setting. Multiple supplies are limited to products that cannot be broken into multiple containers, such as inhalers or other unit-of-use containers.

(e) Hospital or police kept the medication.

(f) Brand or generic was ineffective and the patient was switched to generic or brand.

(H) Selected pharmaceuticals, including injectable drugs, are not covered under the pharmacy program if they are administered in a provider setting, other than a NF, ICF/IID, or pharmacy.

(1) Long-acting injectable pharmaceuticals used for substance use disorder or mental health conditions may be billed by the pharmacy for administration in a provider setting under the following circumstances:

(a) The pharmaceutical is dispensed pursuant to a valid prescription; and

(b) The pharmaceutical is labeled with the patient name; and

(c) The pharmaceutical will be administered by a qualified healthcare professional in a provider setting; and

(d) The pharmacy and administering provider follow any special handling requirements in the package labeling; and

(e) The pharmacy releases the pharmaceutical only to the administering provider or member of the provider's staff, and has followed all regulations for a prescription pick-up station required by the Ohio state board of pharmacy. The pharmacy shall not dispense the pharmaceutical directly to the patient, caregiver, or patient's representative.

(2) Pharmaceuticals not described in paragraph (H)(1) of this rule administered in the physician's office must be purchased by the physician's office and billed as a professional service claim.

(I) Selected over-the-counter drugs are not separately payable when prescribed for an individual residing in a NF. Such drugs are the responsibility of the NF and are included in the facility per diem payment. The over-the-counter drugs not separately payable are those that are classified into the following drug classes:

(1) Analgesics, including urinary analgesics;

(2) APIs and excipients used in compounded prescriptions;

(3) Cough and cold preparations and antihistamines;

(4) Ear preparations;

(5) Gastrointestinal agents, except histamine-2 receptor antagonists, proton pump inhibitors, and loperamide;

(6) Hemorrhoidal preparations;

(7) Nasal preparations, except nasal corticosteroids;

(8) Ophthalmic agents, except antihistamines;

(9) Saliva substitutes;

(10) Sedatives;

(11) Topical agents, except antifungal and acne preparations; or

(12) Vitamins and minerals, except prenatal vitamins and fluoride.