



Common Sense Initiative

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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Comprehensive Primary Care (CPC) Program

Rule Number(s): 5160-19-01 (amend), 5160-19-02 (amend)

Date of Submission for CSI Review: 7/25/2024

Public Comment Period End Date: _____

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 2 rules (FYR? N)

Rescinded/___ rules (FYR?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.

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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.

These rules implement the Ohio Department of Medicaid's Comprehensive Primary Care Program (CPC) and the CPC for Kids program. These programs utilize a Patient Centered Medical Home (PCMH) model to emphasize primary care and encourage providers to deliver medical services more efficiently and economically to achieve better health outcomes for the more than 3 million Ohioans covered by Medicaid. This is a team-based care delivery model led by a primary care practitioner who comprehensively manages the health needs of individuals. ODM does not have another program similar to the CPC program in its Medicaid state plan or Administrative Code rules that would duplicate an existing regulation.

The rules contained in this package are being proposed for amendment to reflect changes to the CPC program for the upcoming 2025 program year.

OAC rule 5160-19-01: "Comprehensive primary care (CPC) program: eligible providers" is being amended to adjust the following provisions:

- 5160-19-01(A)(3)(e): ODM is removing specific reference of the Comprehensive Maternal Care program in the list of alternative payment models for clarity.
- 5160-19-01(C)(2): ODM is adding “certified nurse midwife” to the list of CPC eligible providers in to allow appropriate nursing providers to practice at the top of their license.
- 5160-19-01(F)(1)(b): ODM is adding clarification to this paragraph, noting that providers need to be able to provide twenty-four-seven and same-day access to a Primary Care Physician (PCP), rather than only have the capability to connect a patient to a PCP within 24 hours on initial request. ODM is making this change to better align with CPC reporting and improve access to primary care.
- 5160-19-01(F)(8)(b) and (c): ODM is modifying 5160-19-01(F)(8)(b) and 5160-19-01(F)(8)(c) to ensure all staff who provide direct care or otherwise interact with medicaid individuals to complete cultural competency training within six months of program enrollment and annually thereafter instead of within twelve months of enrollment, and to ensure any new staff who provide direct care or otherwise interact with attributed medicaid individuals complete cultural competency training within thirty days of their start date, respectively. These modifications better align cultural competency training timeliness requirements of the CPC program with the Comprehensive Maternal Care (CMC) program outlined in 5160-19-03: “Comprehensive maternal care program.”
- 5160-19-01(H) and (I): ODM is modifying the terminology used for clinical quality metrics to align with Healthcare Effectiveness Data and Information Set (HEDIS) measure definitions. HEDIS measure “Well-child visits for ages 15-30 months” is being added as a clinical quality metric to 5160-19-01(H) and (I), for both the CPC and CPC for Kids programs. New HEDIS measure “Oral evaluation, dental services” is being added as a payment metric in 5160-19-01(I) for the CPC for Kids program only.

OAC rule 5160-19-02: “Comprehensive primary care (CPC) program: payments” is being proposed for amendment to reflect updates for the upcoming 2025 program year including:

- 5160-19-02(C)(3): ODM is clarifying the shared savings payment exists to reward total cost of care savings, and adding language that a CPC entity has to meet quality, efficiency, and financial outcomes in order to be eligible for the shared savings payment.
- 5160-19-02(D)(2) and (3): ODM is clarifying that provider participation in the program will also be terminated too, not just payment, when program metrics are not met in both the CPC and CPC for Kids programs.

- 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.**

ODM is promulgating these rules under section 5164.02 of the Revised Code.

- 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.**

In 2017, CMS implemented a new health care delivery payment system known as Comprehensive Primary Care Plus (CPC+). This model increases access to primary care using a patient centered medical home (PCMH) model. Ohio implemented its state CPC program in alignment with the federal CPC+ program and has agreed in its Medicaid State Plan with CMS to continue to support the PCMH model to achieve better health, better care and cost savings through improvement. ODM's rules implement the Ohio CPC program, which furthers its goal to shift to value-based purchasing.

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

These regulations do not include provisions specifically required by the federal government. These regulations are a part of a state plan amendment that has been authorized by the federal government for ODM to implement the CPC program. The provisions that are not a federal requirement are still consistent with federal expectations for this type of program.

- 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)?**

Promulgating these regulations related to the optional Ohio CPC program is necessary to inform Ohio Medicaid providers of the program, to clearly communicate responsibilities of participation, maintain program integrity, and meet expectations of the Centers for Medicare and Medicaid Services (CMS) who provide federal financial participation to support this program. The public purpose for these regulations is to ensure the CPC program is implemented consistently across all participating provider types. Since the regulations require certain activities be performed and contain specific clinical quality and efficiency measures to be met, ODM believes codifying these rules is necessary to achieve the desired outcomes.

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

ODM will continue measuring the success of this regulation through reporting and monitoring. ODM provides quarterly reports to participating practices detailing how well they are meeting the objectives of the Ohio CPC program.

The success of this program has been demonstrated through a number of metrics. During the first year of the program in 2017, CPC-enrolled practices experienced cost growth at a rate 2.1% less than similar practices not enrolled in CPC, producing an estimated \$89 million in cost savings. Quality metric performance for CPC practices improved by an average of 8.21% from program year 2017 to program year 2021. Participating practices are evaluated continually and receive quarterly reports on cost and measure performance. Metrics and data related to Ohio CPC practice operation are derived from claims data submitted by Managed Care Plans and providers to ODM for traditional reimbursement. The full list of metrics is posted on the ODM website.

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.

ODM meets regularly with CPC practices to discuss program updates. Additional stakeholder group meetings included discussion topics noted below:

6/1/2023: *CPC Modernization Public Comment Meeting*

9/12/2023: *CPC Quarterly Webinar September 2023 Enrollment*

10/20/2023: *2023 CPC Fall Learning Collaborative*

2/15/2024: *CPC Quarterly Webinar February 2024*

4/18/2024: *CPC Quarterly Webinar April 2024*

The CPC program rule updates were also sent to all Managed Care plans through email for feedback.

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

These rules were developed in partnership with stakeholders, including current CPC providers and administrators, health care related associations, and managed care plans. Overall, stakeholders have been supportive of the minor revisions proposed for the next CPC program year.

Stakeholders provided input and responded with questions related to activity requirements and bonus activities. ODM explained the intent of updating the same day access to care requirement will not change with the amended language and assured the managed care plans ODM does not have any concerns that CPC entities will be able to continue meeting this activity requirement. Stakeholders were uncertain of the impact of adding oral evaluation and dental services as a bonus activity. ODM clarified that CPC entities are not expected to provide dental services within their PCP practice, but rather, reinforce how important oral evaluations are and suggested program providers support a referral system for dental services.

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?

Scientific data was not 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? *Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

ODM did not consider regulatory alternatives as the regulations in these rules need to be codified so that they can be enforced. The CPC program rules have been in effect since 10/1/2016 and serve the purpose intended, to maintain requirements of the Ohio CPC program. They continue to be applicable to the Ohio CPC program and CPC for Kids program and are necessary to clearly delineate responsibilities of participation, maintain program integrity, and to remain in alignment with the Centers for Medicare and Medicaid Services (CMS) program expectations.

The Ohio CPC and CPC for Kids programs are performance-based. Primary care practices that volunteer to participate in the Ohio CPC and CPC for Kids programs must meet the

activity requirements, clinical quality metrics, and efficiency metrics described in rule 5160-19-01.

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

In the development of these regulations, ODM conducted an internal review and worked with other state agencies and related entities to ensure these rules do not duplicate existing Ohio regulations or programs. As the designated state Medicaid agency, ODM is the only entity that can request federal financial participation from the Centers for Medicare and Medicaid Services (CMS) to support the CPC program.

14. 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 creates and delivers reports to participating practices on a quarterly basis. Ohio CPC entities serve Medicaid fee-for-service and Medicaid managed care plan members. These reports improve consistency, lessen administrative burden for CPC and CPC for Kids entities, and ensure they have timely and streamlined access to their performance data. All providers participating in the CPC program will receive a set of consistent and streamlined reports to review and reference. Rule updates for program year 2025 will be communicated to those affected prior to the rules going into effect.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

Business communities impacted include providers enrolled in Ohio's Medicaid fee-for-service program, Medicaid managed care plans, and providers who contract with Medicaid managed care plans that have chosen to participate in these programs. The Ohio CPC program and CPC for Kids program are voluntary; only practices that choose to enroll and participate will be impacted by these rules.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

The revisions made for CPC program year 2025 are minimal and are expected to have little adverse impact to the overall business community. The requirements of this rule require practices to comply with the adverse impacts outlined below to remain in the program. Not complying with the rule provisions can put a practice's program payments and participation at risk for termination. Practices incur some costs through participation, however additional financial incentives are expected to offset any additional costs. CPC entities are required to enroll as an Ohio Medicaid provider and report specific information as outlined below. Entities that fail to comply with program requirements may be at risk of losing payment as outlined below. No new costs are expected for practices currently participating in the CPC and CPC for Kids programs. Practices newly enrolling in the Ohio CPC program may incur some costs to meet the requirements described in 5160-19-01. Costs will vary widely based on provider size, current level of staffing, and existing relationships with other providers and networks. Many costs are expected to be administrative and in time spent training existing staff, hiring additional staff, updating technology, providing attestations to ODM, and building relationships with other providers or networks.

Rule 5160-19-01 to be amended: To meet the provisions of this rule, it is likely that expenses will increase for newly participating practices. Expenses for participating practices may also increase or decrease based on changes in their attribution which impacts a practice's per member per month payment. To be eligible to enroll for participation in the 2025 program year, a practice must report specific information as a condition of compliance. Each participating practice must enroll as a CPC entity by completing the online application and have at least 150 attributed Medicaid individuals. To be eligible for participation in the CPC for Kids program, the CPC entity must enroll as a CPC for Kids entity by completing the online application and have at least 150 attributed Medicaid individuals under age 21 as determined through claims-only data. Practices newly enrolling as a CPC entity in the 2025 program year must report specific information by completing an application during the designated enrollment period and attesting that it will conduct certain activities throughout its participation. The CPC program requires entities that participated in the CPC program for the previous performance year to re-attest their desire continue as a CPC and/or CPC for Kids practice in 2025 by completing the enrollment application during the designated enrollment period.

Practices newly enrolling in the Ohio CPC program may incur some costs to meet the requirements described in 5160-19-01. Costs will vary widely based on provider size, current level of staffing, and existing relationships with other providers and networks. Many costs are expected to be administrative and in time spent training existing staff, hiring additional staff, updating technology, providing attestations to ODM, and building relationships with other providers or networks.

Because the CPC for Kids program builds on the existing requirements of the CPC program, and the additional quality metrics being evaluated for CPC for Kids entities are typically already performed as part of the pediatric standard of care, no additional costs beyond those stated for all CPC entities are expected. CPC for Kids entities may choose to perform additional activities as described in 5160-19-02 to position themselves to be more likely to receive a bonus payment.

Upon enrollment and on an annual basis, each CPC entity must report specific information and attest that it will meet all activity requirements. All CPC entities are required to attest to completing all activities at the beginning of program year 2025, including CPC entities that are re-attesting to meeting activity requirements based on their current program year enrollment.

Participating CPC entities have to pass a number of efficiency and clinical quality measures that represent at least 50% of applicable metrics on a yearly basis. Practices who choose to participate in the CPC for Kids program will need to pass at least 50% of the applicable pediatric metrics, as evaluated at the end of the performance period to maintain enrollment and avoid sanction.

There are ten pediatric metrics including five existing metrics that apply to all CPC entities and three metrics that will only be calculated for practices who participate in the CPC for Kids program. In addition to passing at least 50% of the applicable pediatric metrics, a CPC for Kids entity has to pass at least one of the three pediatric metrics as long as at least one of the three metrics is applicable (i.e., the practice has at least 30 members that meet the denominator criteria for the metric).

The estimated cost for a CPC entity to complete activity requirements and meet clinical quality measures in the voluntary CPC program will vary widely. Many entities that choose to participate may already have the required practitioners on staff. Entities who also participate in the Ohio Comprehensive Maternal Care (CMC) program may incur fewer costs as they have already established many of the same activities also required under the CPC program. Practices who form a partnership to participate as a CPC entity may combine resources and share in any costs that are incurred. Entities who are already participating in value-based care models with ODM or other payers may experience fewer costs as they are likely already conducting many of the activities required in this rule. This is largely dependent on provider size, current baseline operations, and available resources. Most CPC entities are expected to have many of these costs already incorporated into their practice infrastructure, and the per-member per-month payments provided prospectively through the CPC program are expected to offset most or all of the costs of meeting program requirements.

Rule 5160-19-02 to be amended: This rule identifies specific activities that CPC entities have to meet to qualify for bonus payments and maintain enrollment in the CPC program. To meet the provisions of this rule, it is likely that expenses will increase for practices newly enrolling in the program. Expenses for participating practices may also increase or decrease based on changes in their attribution which impacts a practice's per member per month payment.

This rule identifies specific activities that CPC and CPC for Kids program participants are expected to meet to qualify for bonus payments and maintain enrollment in the CPC and CPC for Kids programs. To receive bonus payments as identified in this rule, the participating provider must be enrolled in the CPC program. Providers who enroll or re-attest their participation in the CPC program complete this process through an online application portal. There is no cost to submit the application or re-attestation that takes less than 20 minutes to complete. Any costs would be minimal and administrative in nature. There are no additional expected adverse impacts in terms of dollars as a result of this rule. Participation in the CPC program is voluntary, and this rule would impose no additional costs on primary care providers that deliver services under the authorities of §1905(t), §1905(a)(25) and §1905(t)(3) of the Social Security Act.

CPC entities receive per-member-per month payments to support the CPC entity in comprehensively managing a patient's health needs and provides the CPC entities with the opportunity to share savings in the total cost of care if they meet the requirements described in 5160-19-01.

This rule provides that to be eligible for a shared savings payment in calendar year 2025 and beyond, the CPC entity must meet all requirements found in rule 5160-19-01 of the Administrative Code. Details regarding payment calculations are included in the rule. In this rule, penalties are also stipulated should a CPC entity neglect to meet outcome measure requirements. If these measures are not met, a warning letter will be issued and after two consecutive warnings, the CPC entity may no longer receive payment under this rule.

This rule specifies that a CPC entity participating in the CPC for Kids program must be enrolled and meet all requirements set forth in rule 5160-19-01 of the Administrative Code. If those requirements are not met, a warning will be issued and after two consecutive warnings, CPC for Kids entity may no longer receive payment under this rule.

CPC for Kids entities are eligible under this rule to qualify for a bonus payment, to be assessed annually, based on their performance on pediatric bonus activities, including supports for children in foster care, behavioral health care linkages, school based health care linkages, transitions of care for children aging out of pediatric care, and select wellness activities including lead testing capabilities, community services and supports screening, tobacco cessation, fluoride varnish, and breastfeeding support. CPC for Kids entities will be

scored for performance in each of these categories and top scorers will receive a retrospective bonus payment.

- 16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).**

There are no proposed changes to the rules that will reduce a regulatory burden.

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

The regulatory intent justifies the adverse impact of these regulations to the regulated business community as it provides regulated business with incentives in the form of per-member-per-month payments and the opportunity to receive shared savings bonus payments for providing services in the form of comprehensive care that they are currently and expected to provide under §1905 of the Social Security Act. Furthermore, the purpose of the CPC and CPC for Kids programs is to achieve better health outcomes and cost savings through improvement. It is intended to support CPC entities in their transformation to achieve cost savings and improve health outcomes by focusing on and linking individuals to primary and preventive care. The implementation of these rules advances the shift to value-based purchasing. The CPC program is performance-based, and the incentives encourage Medicaid providers to deliver quality care more efficiently and economically.

Regulatory Flexibility

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

For small businesses that choose to enroll as a CPC entity, there are no alternative means of compliance; however, informational resources are available on the ODM website to support the CPC entity.

- 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?

A CPC entity must meet all requirements found in rule 5160-19-01 of the Administrative Code. In this rule, penalties are also stipulated should a CPC entity neglect to meet outcome measures. If these measures are not met, a warning letter will be issued and after two consecutive warnings, the CPC entity may no longer receive payment under this rule.

This rule specifies that a CPC entity participating in the CPC for Kids program must be enrolled and meet all requirements set forth in rule 5160-19-01 of the Administrative Code. If those requirements are not met, a warning will be issued and after two consecutive warnings, CPC for Kids entity may no longer receive payment under this rule. ODM does not impose other monetary fines.

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

Since implementation of the CPC program in 2017, ODM has developed a web page for the program and conducts periodic learning sessions and webinars. The ODM web page includes additional information for participating practices on the CPC and CPC for Kids programs including frequently asked questions, training, and educational materials. The ODM website, www.medicaid.ohio.gov, also houses additional information and resources for providers to assist with a variety of topics.

Providers may contact Provider Assistance by calling 1-800-686-1516.