



Common Sense Initiative

Mike DeWine, Governor
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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: 7/6/2022

Public Comment Period End Date: 7/13/2022

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Rescinded/___ rules (FYR?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.

These rules were initially submitted to CSIO to implement the first program year 2017 and again in subsequent years to incorporate any yearly program updates. These rules were recently moved from Chapter 5160-1 to Chapter 5160-19 of the Ohio Administrative Code (OAC). The rules contained in this package are being proposed for amendment to reflect changes to the CPC program for the upcoming 2023 program year.

Proposed for amendment: Rule 5160-19-01, "Comprehensive primary care (CPC) program

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Eligible providers,” is being proposed for amendment to reflect changes for the upcoming 2023 program year. This rule provides definitional information, identifies eligible entities and requirements for enrollment as a CPC entity, and describes the activity, efficiency, and quality measures including the performance thresholds that must be met. It provides requirements for group practices who participate as a partnership and informs the CPC entity that it may utilize reconsideration rights to challenge a decision of ODM concerning CPC enrollment or eligibility.

Upon enrollment and on an annual basis, this rule requires that each participating CPC entity attest that it will meet the activity requirements set forth in the rule. The CPC entity must also pass a number of efficiency and clinical quality requirements on an annual basis to continue participation under this rule.

For CPC entities who choose to participate in the optional CPC for Kids program, they will be subject to additional requirements and be eligible for additional payments and bonuses under the CPC for Kids program. This rule defines the CPC for Kids program and sets forth the additional requirements participating CPC entities must meet to enroll under the CPC for Kids program.

This rule provides clinical quality requirements specific to the CPC for Kids program and the threshold of metrics that must be passed annually to continue participation in the CPC for Kids program.

This rule is being amended to update terminology from “PCMH” to “CPC entity” to align with the program name, modify the terminology used for clinical quality metrics to align with Healthcare Effectiveness Data and Information Set (HEDIS) measure definitions. The attribution exceptions have been expanded to also exempt recipients attributed to other population health alternative payment models administered by ODM.

Proposed for amendment: Rule 5160-19-02, “Comprehensive primary care (CPC) program: Payments,” is being proposed for amendment to reflect updates for the upcoming 2023 program year, remove unnecessary language referencing the 2020 program year, and update terminology from “PCMH” to “CPC entity” to align with the program name. This rule provides eligibility criteria to qualify for CPC program payments, including per-member per-month payments (PMPMs), shared savings payments and bonus payments.

This rule outlines the payment structure and defines payment types specific to the CPC and CPC for Kids programs, describes payments, how they will be calculated and when payment to the participating CPC entity occurs. This rule identifies specific activities that CPC and CPC for Kids program participants must meet to qualify for bonus payments.

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This rule sets forth the eligibility requirements to receive a CPC shared savings payment and details payment calculations.

This rule outlines the eligibility requirements for the CPC for Kids program and states that a CPC entity 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 entities 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. CPC for Kids entities will be scored for performance in wellness activities and top scorers will receive a retrospective bonus payment.

- 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 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)?**

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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.

The Ohio CPC program was implemented by ODM in 2017 as a method to further the Department's initiative to shift from volume-based purchasing to value-based purchasing of medical services. As a performance-based model, the Ohio CPC program encourages Medicaid providers to deliver services more efficiently and economically through a PCMH model while continuing to emphasize quality of care.

In the long term and at full implementation, the Ohio CPC program is designed to produce savings for the healthcare system and taxpayers, and achieve greater health outcomes for the 3 million Ohioans covered by Medicaid. In the first two years of the CPC program, Ohio is estimated to have saved 2% per year on the total cost of care for members attributed to a CPC practice. ODM paid out a total of \$54 million dollars in shared savings to practices participating in the CPC program for the 2017 and 2018 program years, based on their estimated reductions to total cost of care for their Medicaid patients

These figures were projected based on savings from similarly structured PCMH-modeled programs in other states. The state of Minnesota implemented a medical home program which reached 54% of primary care clinics in the state. Over a five-year period, costs improved by an estimated \$1 billion dollars and the state saw higher patient satisfaction, and better provider performance on quality measures in asthma, diabetes, vascular disease, and depression.

In the first year of the Ohio CPC program (2017), ODM anticipated that approximately 350,000 to 525,000 Medicaid individuals would be attributed to a participating practice for linkage to primary care and care coordination. In the first program year, ODM enrolled 111 practices in the CPC program, representing over 830,000 Medicaid covered individuals who were attributed to a CPC practice. In 2020, the fourth year of the program, Ohio CPC had 197 CPC practices, representing 1.2 million Medicaid covered individuals who were attributed to a CPC practice, including 800,000 children age 20 and under. As of 2022, the Ohio CPC program has 303 practices, representing 1.64 million covered individuals who were attributed to a CPC practice, including 902,000 children age 20 and under.

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

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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.

In 2020, the fourth year of the program, Ohio CPC had 197 CPC practices, representing 1.2 million Medicaid covered individuals who were attributed to a CPC practice, including 800,000 children age 20 and under. In 2022, the Ohio CPC program has 303 practices, representing 1.64 million covered individuals who were attributed to a CPC practice, including 902,000 children ages 20 and under. Considering Ohio Medicaid covers more than 3 million individuals throughout the state, the positive impact on this population is expected to be significant.

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 5.59% from program year 2017 to program year 2019. Quality metric performance data is still being analyzed for program years 2020-2022. ODM believes data from 2020 may be skewed by COVID-19 related disruptions in care. 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.

All participating CPC practices were sent a copy of the proposed rules via e-mail to solicit feedback and comments. Additional stakeholder group meetings included discussion topics noted below:

1/21/21: *Patient Experience, Cultural Competency and Implicit Bias*

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3/25/21: *Best Practice: Integrated Behavioral Health-Prevention* Attendees include: The Christ Hospital, Rocking Horse Community Health Center, University Hospitals, Adena Health System, Five Rivers Health Center, Ohio Shared Information Services (OSIS), Cincinnati Children's Hospital Medical Center, Ohio Association of Community Health Centers, Nationwide Children's Hospital, Ohio Department of Developmental Disabilities, the Center for Community Solutions, Anthem Blue Cross and Blue Shield of Ohio, Cleveland Clinic, Fisher-Titus Medical Center, Family Resource Center, Humble Beginnings, Kettering Health, AmeriHealth Caritas of Ohio, Centene Healthcare Solutions, Buckeye Health Plan, The Village Network, Southeast Healthcare, Heartland Hospice Services, Madison Health, CliniSync, IngenioRx, Caresource, Child & Adolescent Specialty Care, Family Health Care, Akron Children's Hospital, iPro, The Ohio State University College of Medicine, Lawrence County Department of Disabilities, Ohio Department of Jobs and Family Services, Dayton Children's Hospital, Family Health Care of Northwest Ohio, ONE Health Ohio, United Healthcare of Ohio, Premier Physicians Centers Inc, NSL Analytical Services Inc, Netcare Access, The Ohio State University College of Social Work, Memorial Health System, Health Source of Ohio, Neighborhood Family Practice, Blanchard Valley Health System, Care Alliance Health Center, Crossroad Health Center, Primary Health Solutions, Breaking the Label LLC, The Metro Health Center, Center Street Clinic, AxessPointe Community Health Centers, Alta Behavioral Healthcare, Humana, Family Life Counseling and Psychiatric Services, Pediatric Associates Inc, Health Partners of Western Ohio, Advocacy & Community Solutions, Molina Healthcare, Northern Ohio Medical Specialists, Lorain County Health and Dentistry, Pomerene Hospital, Summa Health, and Mercy Health.

4/15/21: *Specialized Recovery Services Program (SRSP) and Care Management Activity Requirements*

7/14/21: *CPC and CPC for Kids Virtual Learning Summit 2021* Attendees included: University of Cincinnati Medical Center, Sellers Dorsey, The Christ Hospital, Wright State Physicians, The Health Collaborative, University Hospitals, Ohio Department of Jobs and Family Services, Pediatric Associates Inc, The Ohio State University College of Social Work, Rocking Horse Community Health Center, The Ohio State College of Nursing, Humana, Kettering Health System, Family Health Care of Northwest Ohio, Centene, Midwest Oral Surgery and Dental Implants, Ohio Association of Community Health Centers, Five Rivers Health Centers, United Healthcare of Ohio, Pediatric Consultants of Ashland and Mansfield, Community Health Centers, Rocking Horse Community Health Centers, Knox County Community Health Center, My Primary Health Solutions, Fisher-Titus Medical Center, Wayne HealthCare, Lima Memorial Health System, AmeriHealth Caritas of Ohio, TriHealth, Caro Pediatric Center, Cleveland Clinic, Compass Community Health, Madison

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Health, Memorial Health System, Lower Lights Christian Health Center, Children's Cincinnati Medical Center, Molina Healthcare, Mercy Health, The Ohio State Wexner Medical Center, CareSource, American Health Network, Akron Children's Hospital, The Pediatric Center Inc, UNIK Foundation, Care Alliance Health Center, Humana, iPro, Centerpoint Health, Mercer Health, Premier Physicians, ONE Health Ohio, Southeast Healthcare, Shawnee Family Health Center, Anthem Blue Cross and Blue Shield of Ohio, Community Action Agency of Columbiana County, NSL Analytical Services, The Health Plan, University of Cincinnati Medical Center, Wayne Healthcare, Mercy Health, Southern Ohio Medical Center, American Health Network, Health Source of Ohio, Harding Hospital, ProMedica, Cleveland Clinic, Southeast Healthcare, Community Health and Wellness Partners of Logan County, OSU Physicians, Aultman Hospital, The Health Collaborative, Senders Pediatrics, United Way of Cleveland, Southern Ohio Medical Center, BS Bonyo D.O. & Associates, Health Source of Ohio, the Metro Health System, Ashtabula County Medical Center, TeamHealth, CliniSync, Firelands Health, Cincinnati Health Department, Child & Adolescent Specialty Care, Central Ohio Primary Care, AxxessPointe Community Health Centers, the Toledo Clinic, Summa Health, Nationwide Children's Hospital, Southwest General Health Center, University of Toledo Medical Center, Fairfield Community Health Center, OhioHealth, NOMS Healthcare, Neighborhood Health Association, Lifecare Ambulance, Neighborhood Family Practice, Cincinnati Pediatrics, Primary One Health, Providence Medical Group, Pomerene Hospital, Dayton Children's Hospital, Holmes Family Medicine, Community Health Services, Ohio Hospital Association, DeCoach Rehabilitation Center, Equitas Health, Health Partners of Western Ohio, Erie County Health Department and Community Health Center, Heart of Ohio Family Health, Community Action Agency of Columbiana County, and Talbert House.

9/30/21: *CPC 2022 Program Year Enrollment* Attendees included: Wright State Physicians, Humana, Family Health Services, Lima Memorial Hospital, Centene, Ohio Association of Community Health Centers, Five Rivers Health Centers, Ohio Pediatricians, Community Health Centers of Greater Dayton, the Ohio State Wexner Medical Center, AxxessPointe Community Health Centers, CareSource, Primary One Health, Fisher-Titus Medical Center, Signature Health, University of Cincinnati Medical Center, Kettering Health, Providence Medical Group, TriHealth, Northeast Ohio Neighborhood Health Services, Caro Pediatric Center, Madison Health, Mercy Health, the Health Collaborative, University Hospitals, AmeriHealth Caritas of Ohio, Cincinnati Children's Medical Center, CareSource, My Primary Health Solutions, Akron Children's Hospital, the Pediatric Center Inc, Cleveland Clinic, Salem Regional Medical Center, Dayton Children's Hospital, iPro, Child and Adolescence Specialty Care, Muskingum Valley Health Center, Family Health Care of Northwest Ohio, Third Street Family Health Services, United Healthcare of Ohio, Molina,

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Anthem Blue Cross and Blue Shield, Sellers Dorsey, Nationwide Children's Hospital, the Health Collaborative, ProMedica, Genesis Healthcare System, West Side Pediatrics, the Toledo Clinic, Cincinnati Pediatrics, Mercer Health, Aultman Hospital, ONE Health Ohio, Firelands Health System, Central Ohio Primary Care, Pomerene Hospital, Summa Health, Health Bridge, the Christ Hospital, TriHealth, Centene, Northshore Gastro, Heart of Ohio Family Health, Compass Community Health, Medical Mutual, Lorain Health, Winton Hills Health Services, Neighborhood Health Association, Papaya Healthkare, Pediatrics for Family Health, Salem Regional Health, Centerpoint Health, Care Alliance, the Talbert House, Adena Health System, Axess Point, Community Action Agency of Columbiana County, Lower Lights Christian Health Center, Senders Pediatrics, Community Health and Wellness Partners of Logan County, Family Physicians Inc. REACH, Wood County, Grand Lake Health System, Primary Care Development Corp., King's Daughters Medical Center, Blanchard Valley Health System, Lumeris, Neighborhood Family Practice, My Community Health Center, the Metro Health System, Center Street Clinic, Fairfield Medical Center, Bon Secours, Southern Ohio Medical Center, the Rocking Horse Center, Mount Carmel, Ohio Hills Health Services, Lake Health, Hopewell Health,

12/9/21: *CPC Program Year Enrollment* Attendees included: Wright State Physicians, Pediatric Associates Inc, the Rocking Horse Center, Family Health Services, Family Health of Northwest Ohio, Lima Memorial, Centene, Molina Healthcare, Ohio Association of Community Health Centers, My Primary Health Solutions, Nationwide Children's Hospital, Akron Children's Hospital, Five Rivers Health Center, Knox Health, Community Health Centers of Greater Dayton, Kettering Health, Signature Health, Sarepta Therapeutics, Caro Pediatrics, NEON Health, TriHealth, Providence Medical Group, Madison Health, University Hospitals, CareSource, Cleveland Clinic, the Ohio State University Wexner Medical Center, Fisher-Titus Medical Center, AmeriHealth Caritas of Ohio, Dayton Children's Hospital, Southeast Inc, Southeastern Med, Child and Adolescent Care, Centerpoint Health, Mercer Health, the Talbert House, Lower Lights Christian Health Center, Papa, OhioHealth, Project ECHO, Anthem Blue Cross and Blue Shield, iPro, Medical Mutual, ProMedica, Mercy Health, Lorain Health, Heart of Ohio Family Health, Ohio Pediatrics, Health Source of Ohio, Senders Pediatrics, Blanchard Valley Health System, Care Alliance, Third Street Family Health Services, Community Action Agency of Columbiana County, Firelands Regional Health Center, Child and Adolescent Care, Southeast Inc, the Toledo Clinic, Community Action of Pike County, West Side Pediatrics, Genesis Healthcare, Licking Memorial Health System, Ironton Lawrence Community Action Organization, NOMS Healthcare, Cincinnati Pediatrics, OSIS, Aultman Hospital, Primary One Health, Central Ohio Primary Care, Ohio Hospitals Association, Health Partners of Western Ohio, Humana, ProMedica, Family Health Services, Ohio Department of Jobs and Family Services, and the GW Center.

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3/25/22: OhioRISE. Attendees included patients, providers, managed care companies, and other stakeholders.

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 suggested changes to provide additional clarification in the proposed rules. Some stakeholders responded with questions about the changes and ODM was able to provide answers. Most suggestions to the rules were grammatical or related to varying requirements in different program years. In direct response to this feedback, ODM removed references to previous program years.

Some stakeholders suggested additional language to provide further detail concerning program operations such as how and when reports are distributed. ODM did not make changes in response to this feedback because such operational detail is not typically included in rules. This type of information can be found in CPC program materials found on the ODM website, which is referenced in the rule. ODM did not feel these changes were justified at this time

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 rule.

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?

ODM did not consider regulatory alternatives. 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 communicate responsibilities of participation, maintain program integrity and to remain in alignment with the Centers for Medicare and Medicaid Services (CMS) program expectations.

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.*

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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.

14. 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. 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.

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 creates and delivers reports to participating practices on a quarterly basis. These 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.

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

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 is voluntary; only practices that choose to enroll and participate will be impacted by these rules.

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

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The revisions made for CPC program year 2023 are minimal and are expected to have little adverse impact to the overall business community. Practices incur some costs through participation, however additional financial incentives are expected to offset any additional costs.

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. To be eligible to enroll for participation in the 2023 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 2023 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 2023 by completing the enrollment application during the designated enrollment period.

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 will be required to attest to completing all activities at the beginning of program year 2023, 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.

There are seven pediatric metrics including four 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

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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).

Rule 5160-19-02 to be amended: This rule identifies specific activities that CPC entities have to meet to qualify for bonus payments. To meet the provisions of this rule, it is likely that expenses will increase.

This rule provides that to be eligible for a shared savings payment in calendar year 2023 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 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.

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.

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.

Rule 5160-19-01 to be amended: To meet the provisions of this rule, it is likely that expenses will increase. To be eligible for participation, an eligible practice must be enrolled as a CPC entity and have at least 150 attributed Medicaid individuals. To be

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eligible for participation in the CPC for Kids program, the CPC entity must enroll as a CPC for Kids practice 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 2023 program year are expected to complete an application during the designated enrollment period. Existing CPC entities will re-attest for the next year if they desire to continue as a CPC and/or CPC for Kids entity by completing an 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 attest that it will meet all activity requirements. All CPC entities must attest to meeting all ten activity requirements at the beginning of each program year, including CPC entities that are re-attesting to meeting activity requirements based on their current program year enrollment.

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.

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Rule 5160-19-02 to be amended: This rule identifies specific activities that CPC and CPC for Kids program participants are expected to meet to qualify for bonus payments. 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 authorities the 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.

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 CPC and CPC for Kids program 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 alternate means of compliance; however, informational resources are available on the ODM website to support the CPC entity.

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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 does not apply as the rules do not impose any fine or penalty for a paperwork violation.

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.