Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: _The Ohio Department of Medicaid________

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

Episode Based Payments

Rule Number(s): 5160-19-04 (amend)

Date of Submission for CSI Review: 9/14/2021

Public Comment Period End Date: 9/21/2021

Rule Type/Number of Rules:

New/___ rules

Amended/_1___ rules (FYR? _1__)

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Rescinded/____ rules (FYR?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.

   The purpose of this proposed rule is to continue the suspension of the Episode Based Payment (EBP) program incentives for calendar year 2022.

   The EBP program encourages Medicaid providers to deliver medical services more efficiently and economically. This is accomplished by using claims data to evaluate the quality, efficiency and economy of care rendered by specific providers and to apply financial incentives to those providers based on their performance.

   The onset of COVID-19 changed the way individuals seek care, reduced the delivery of preventive and less acute services, and delayed needed services for severe conditions.

   One of the key elements of the EBP program is tying spend and quality performance, including the prevention of complications, to positive and negative incentive payments. Since the context of care and related claims submitted have changed dramatically, consistent claims data required to anchor the EBP program for 2022 remains unavailable. As a result, ODM will not assess positive and negative incentive payments for the performance periods of calendar years 2020, 2021, and 2022.

Rule to be amended: 5160-19-04, "Episode based payments" is being proposed for amendment to continue the suspension of incentive payments for the 2022 program year. This rule identifies affected parties, provides definitional information for episodes and other terms such as principal accountable providers (PAP), risk factors, and quality metrics. It describes the performance period, nature of incentive payments available under this rule, and the Medicaid covered services that are subject to episodes. It describes how the average risk-adjusted episode incentive for each episode is calculated for principle accountable providers. This rule describes the type of episodes that are excluded from measuring performance and how risk adjustments are applied after the excluded episodes and costs are removed. It describes the performance period, thresholds established by the department, and the type of incentive payments to a PAP based on performance. This rule describes how performance is measured for each PAP for each applicable episode type. It describes threshold determinations and how ODM applies quality metrics. This rule indicates that PAPs may utilize reconsideration rights but may not make use of hearing rights under Chapter 119. of the Revised Code to challenge a decision made by ODM.

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.**

   Ohio Revised Code sections 5162.05, 5164.02 and 5167.02

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.

   This rule does not implement a current federal requirement. When the EBP program was initially implemented, the rule implemented federal requirements under a State Innovation Model (SIM) test grant, a cooperative agreement between the federal government, state of Ohio, and the Centers for Medicare and Medicaid Services (CMS). The federal SIM test grant agreement ended on 3/14/2019 however the department has continued the program.

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

   This rule does not exceed federal requirements. ODM carried over the federal requirements in the continuation of the EBP program as they are necessary for enforcement and program integrity purposes.

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 for this regulation is to clearly communicate requirements in the EBP program to impacted providers so that it may be implemented consistently. Since this is a performance-based program, ODM has determined a regulation is needed to accomplish this and ensure program integrity. The overall purpose of the EBP program is to achieve better health, better care and cost savings through improvement in care delivery and management. As a performance-based model, EBP encourages Medicaid providers to deliver medical services more efficiently and economically.

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

   ODM will measure success of this regulation through a number of metrics and the ability to provide Medicaid providers with feedback on their quality and performance on a quarterly and annual basis. Additionally, ODM will be looking at the impact on overall quality, total cost of care and Medicaid cost trends.

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.

   Initially, development of the EBP program included engagement of diverse stakeholders in payment innovation including MCPs, Commercial plans, providers and Clinical Advisory Groups (CAGs).

   ODM notified providers of the proposed program suspension through a few different channels:

   - Letter to Providers posted on the Episodes of Care website and sent to interested parties over the Episodes of Care program listserv
   - Dissemination to providers through the Managed Care Plans

- Dissemination to known provider associations (~20) through our provider engagement liaison.
- Notification to providers on their Annual 2019 episode reports (planned delivery in Fall 2021)

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

ODM reached out to stakeholders with these proposed changes and no concerns were expressed.

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?

Medicaid provider claims data was used to inform and develop the definition for the various elements that make up an episode of care. For calendar years 2020 through 2022, the context of care and related claims submitted have changed dramatically and the design of this program no longer allows for accurate payments.

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 alternative means of regulation such as training or informational memos. The regulation describes financial incentives that will apply to certain Medicaid providers based on the quality, efficiency, and economy of care that they deliver. Alternative regulations or provisions would not allow ODM to consistently enforce the provisions or provide an adequate explanation for how financial incentives will be determined and applied.

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.***

EBP is performance based and is evaluated using claims data. Since the context of care and related claims submitted have changed dramatically due to the COVID-19 public health emergency, the design of this program no longer allows for accurate incentive payments in program years 2020, 2021, and 2022.

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

ODM staff reviewed OAC, ORC, and the code of federal regulations (CFR) and found no other rules that address EBP. All of regulation in this rule applies only to EBP and is not found elsewhere in Ohio Code.

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 suspend the EBP program's incentives by issuing informational memos and making necessary changes in the Medicaid Information Technology System (MITS). ODM plans to notify all impacted providers and include additional information on the ODM website: https://medicaid.ohio.gov/wps/portal/gov/medicaid/resources-for-providers/special-programs-and-initiatives/payment-innovation/episode-based-payments/episode-based-payments.

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

All Medicaid managed care plans, providers that subcontract with managed care plans, and Medicaid providers who participate in the Medicaid fee-for-service program who are determined to be the Principal Accountable Provider (PAP) for a given episode are impacted by this rule.

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

In the proposed amendments to this rule, PAPs that are typically subject to the EBP program requirements will not receive a positive or negative incentive payment in calendar years 2020, 2021, and 2022. Due to the COVID-19 public health emergency, positive and negative financial incentives will not be applied by ODM. In these calendar years, PAPs will continue to receive performance reports but only for select episodes. This information will help providers understand what type of incentive payments they may be eligible for when payments resume, allowing time to adjust processes and improve performance if needed. Additionally, some providers who otherwise would have earned positive incentive payments

will not receive these funds in these calendar years which could be considered a reduction in revenue for higher performing PAPs.

After calendar year 2022, providers are subject to positive and negative incentive payments. Under this regulation and once these requirements resume, a provider will not be subject to positive or negative incentive payments until it has at least five valid episodes in a designated performance period. This could financially impact the provider positively or negatively and may require minimal time from the provider to ensure compliance and improve performance through activities such as reviewing reports and making changes to internal processes that impact performance.

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.

Since ODM is proposing to suspend the positive and negative incentive payments under the EBP program, any adverse impact will be minimal. PAPs who may have been above the acceptable threshold will not incur a negative incentive payment as they would in previous years of the EBP program. For PAPs who may have been eligible for a positive incentive payment, this proposed rule may have a minimal financial impact. ODM believes this financial impact to be minimal compared to other challenges PAPs have faced during the public health emergency.

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

ODM determined that the regulatory intent justifies the adverse impact to the regulated business community because for calendar years 2020 through 2022, the context of care and related claims submitted have changed dramatically due to the COVID-19 public health emergency, the design of this program no longer allows for accurate incentive payments. As a result, the adverse impact to providers would be greater if these changes to the rule were not made.

Regulatory Flexibility

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

No alternate means of compliance is available, and no exception can be made on the basis of an entity's size.

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 rule does not impose any fine or penalty for a paperwork violation.

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

No action is required by providers to comply with the regulation. Medicaid providers in need of technical assistance can contact Medicaid Provider Assistance at 1-800-686-1516. Providers may also obtain information about EBP through the Ohio Department of Medicaid website at www.medicaid.ohio.gov.

DRAFT - NOT FOR FILING

5160-19-04 Episode based payments.

(A) Excluding calendar years 2020, ~~and~~ 2021, and 2022, all medicaid managed care plans, providers under contract with medicaid managed care plans, and medicaid providers who participate in the medicaid fee-for-service program will participate in episode-based payments. This participation is limited to those episodes in which the provider renders services.

(B) Definitions.

(1) An "episode" is a defined group of related medicaid covered services provided to a specific patient over a specific period of time. The characteristics of an episode will vary according to the medical condition for which a recipient has been treated. Detailed descriptions and definitions for each episode are found in the Ohio medicaid payment innovation website located at www.medicaid.ohio.gov.

(a) "Episode type" means a diagnosis, health care intervention, or condition which characterizes the episode.

(b) For each episode type there are specific parameters that define the episode including:

(i) "Episode trigger" means those diagnosis or procedures and corresponding claim types and care settings that characterize a potential episode.

(ii) "Pre-trigger window" means the time period prior to an applicable trigger event and includes all relevant care for the patient.

(iii) "Trigger window" means the duration of the potential trigger event and includes all care provided.

(iv) "Post trigger window" means the time period following the trigger event and includes all relevant care and any complications that might occur.

(v) "Episode level exclusions" means patient characteristics, comorbidities, diagnoses or procedures that may potentially indicate a type of risk that, due to its complexity, cost, or other factors, should be excluded entirely rather than adjusted.

(vi) "Potential risk factors" means those patient characteristics, comorbidities, diagnosis or procedures that may potentially indicate an increased level of risk for a given patient in a specific episode.

(vii) "Quality metrics" means measures determined by the department that will be used to evaluate the quality of care delivered during a specific episode.

(2) "Performance period" means a twelve-month period, beginning on the first day of a calendar year, for which the department will measure episode performance of all providers delivering services during the course of a specific episode. For an episode to be included within the performance period, the end date for the episode it has to fall within the performance period. Due to the COVID-19 emergency, there will be no performance period during which the department measures episode performance for calendar years 2020, ~~and~~ 2021, and 2022.

(3) "Principal accountable provider (PAP)" means the provider that is held accountable for both the quality

and cost of care delivered to a patient for an entire episode. The department designates a PAP based on factors such as decision-making responsibilities, influence over other providers, and episode expenditures.

(4) "Thresholds" are the upper and lower incentive benchmarks for an episode of care.

(a) "Acceptable" means the specific dollar value for each specific episode such that a provider with an average risk-adjusted reimbursement above the dollar value incurs a negative incentive payment.

(b) "Commendable" means the specific dollar value for each specific episode such that a provider with an average risk-adjusted reimbursement below the dollar value is eligible for a positive incentive payment if all quality metrics linked to the incentive payment are met.

(c) "Positive incentive limit" means a level set to avoid the risk of incentivizing care delivery at a cost that could compromise quality.

(C) Through the use of episode-based payments, the department provides incentive payments to recognize the quality, efficiency, and economy of services provided in the course of an episode.

(D) Episode definitions and appropriate quality measures are based on evidence-based practices derived from peer-reviewed medical literature, historical provider performance, clinical information furnished by providers of the care, and services typically rendered during the episodes of care.

(E) Any medicaid covered services provided in the delivery of care for an episode may be included in the calculation of the average risk-adjusted episode reimbursement. The services considered need not be limited solely to those provided by the PAP.

(F) For each PAP, the department calculates the average risk-adjusted episode reimbursement for each episode that occurs within the performance period. The average risk-adjusted episode reimbursement is specific to the episode type, and is derived in the following manner:

(1) All episodes ending within a performance period are identified for each potential PAP and the total reimbursement for each episode is calculated based on related covered services delivered during the duration of each episode.

(2) The department excludes certain episodes in measuring a PAP's performance.

(a) Business exclusions are non-clinical reasons for excluding an episode. Business exclusions for each episode are found within the episode definitions at the Ohio medicaid payment innovation website.

(b) Clinical exclusions include characteristics of the patient or episode. Clinical exclusions for each episode are found within the episode definitions at the Ohio medicaid payment innovation website.

(3) For the episodes that remain after business exclusions and clinical exclusions are applied, the department excludes costs that are not attributable to the episode cost of care for the medicaid recipient.

(4) After the excluded episodes and costs are removed from the episodes assessed for the performance year, the department applies any risk adjustments necessary to enable comparison of a PAP's performance relative to the performance of other providers in a way that takes patient health risk factors and other health complications into sufficient consideration. Risk adjustments are specific to each episode as described at the Ohio medicaid payment innovation website.

(5) The average risk-adjusted reimbursement of all episodes for the PAP during the performance period will be compared to thresholds established by the department.

(G) Incentive payments to a PAP are based upon episodes that end within a performance period. Incentive payments may be positive or negative and are calculated and made retrospectively after the end of the performance period. Incentive payments are based on the aggregate of valid, paid claims across a PAP's episodes and are not relatable to any individual provider's claim for payment. A PAP has to have a minimum volume of episodes during the course of a performance period in order to be eligible for a positive or negative incentive payment. Due to the COVID-19 emergency, and in accordance with paragraph (B)(2) of this rule, PAPs will not be eligible for incentive payments for services provided during calendar years 2020, ~~and~~ 2021, and 2022.

For each PAP for each applicable episode type:

(1) Performance will be aggregated and assessed over a specific period of time. For each PAP, the average risk-adjusted episode reimbursement across all relevant episodes completed during the performance period will be calculated, based on the set of services included in the episode definition.

(2) If the PAP's average risk-adjusted episode reimbursement is lower than the commendable threshold and the PAP has documented that the quality requirements established by the department for each episode type have been met, the department will make a positive incentive payment to the PAP. This incentive payment will be based on the difference between the PAP's average risk-adjusted episode reimbursement and the commendable threshold.

(3) If the PAP's average risk-adjusted episode reimbursement is higher than the acceptable threshold, the PAP will incur a negative incentive payment. This negative incentive payment will be based on the difference between the PAP's average risk-adjusted episode reimbursement and the acceptable threshold.

(4) If the average risk-adjusted episode reimbursement is between the acceptable and commendable thresholds, the PAP will not receive a positive incentive payment or incur a negative incentive payment.

(H) Threshold determination.

Thresholds are determined by taking into consideration several factors, including the potential to improve patient access, and the level and type of practice pattern changes essential for performance improvement.

(1) The acceptable threshold is set such that average cost per episode above the acceptable threshold reflects a PAP's unacceptable variation from typical performance without clinical justification.

(2) The commendable threshold is set such that outperforming the commendable threshold represents efficient, quality care.

(I) For each episode type, the department applies quality metrics to evaluate the quality of care delivered during the episode and applies these metrics to providers that are eligible for positive incentive payments in order to avoid the risk of incentivizing care delivery at a cost that could compromise quality. Included are quality metrics reflecting certain standards which support the delivery of adequate care during the course of the episode.

(J) Incentive payments are separate from, and do not alter, the reimbursement methodology for medicaid covered services set forth in department rules located in agency 5160 of the Administrative Code.

(K) Consideration of the aggregate cost and quality of care is not a retrospective review of the medical necessity of care rendered to any particular patient.

(L) Nothing in this rule prevents the department from engaging in any retrospective review or other program integrity activity.

(M) PAPs cannot make use of hearing rights under Chapter 119. of the Revised Code to challenge a decision made by the department; however, reconsideration rights as stated in rules 5160-70-01 and 5160-70-02 of the Administrative Code may be utilized.