



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. 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):

Program of All-Inclusive Care for the Elderly (PACE) FYRR

Rule Number(s): 5160-36-02 and 5160-36-05

For Informational Purposes Only: 5160-36-01, 5160-36-03, 5160-36-04, 5160-36-06

Date of Submission for CSI Review: 8/22/19

Public Comment Period End Date: 8/28/19

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/6 rules (FYR? 6)

Rescinded/___ rules (FYR?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.

OAC 5160-36-02 This rule establishes the Ohio Department of Aging as the administering agency and outlines the department's administrative responsibilities for the Program of All-Inclusive Care for the Elderly (PACE), including entering into an agreement with CMS and the CMS-approved PACE organization. Changes to language removing language related to slot allocation and re-allocation; updating OAC and CFR references and technical edits for clarity and consistency.

Rule 5160-36-05 This rule establishes the required elements of care coordination provided at each PACE center. Changes to the rule include: updating rule title; removing the word "program" after PACE because it is duplicative and for consistency; adding language to reflect the current requirement to ensure the health and safety of participants; updating OAC and CFR references; and technical edits for clarity and consistency.

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.**

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- 4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

If yes, please briefly explain the source and substance of the federal requirement.

Yes. PACE is a federally funded, capitated long-term services and support program that serves the needs of individuals who are Medicaid eligible or dually eligible for Medicare and Medicaid services. The program is operated pursuant to federal regulations set forth in 42 USC 1396u and 42 CFR 460.

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

The rules do not include provisions not specifically required by the federal requirements outlined §1902(a)(30)(A) of the Social Security Act or the related federal regulations at 42 CFR§460.

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

The public purpose of the amended rules is to operate the Ohio PACE program in compliance with federal law.

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

The success of OAC 5160-36-02 will be determined by the existence of PACE agreements signed by ODA, CMS and each PACE organization approved by CMS as required by federal law.

The success of OAC 5160-36-05 will be determined the oversight activities conducted by the State Administering Agency and by CMS.

- 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

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9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The proposed rule drafts were informed by input obtained from the Ohio PACE provider and the state administering agency. Opportunity for input was also provided through ODM's established clearance process.

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

Stakeholders provided recommendations for technical edits which were included in the draft regulation.

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

No scientific data was used to develop the rules or the measurable outcome 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?

No alternatives were considered. The proposed rule language is required to operate the Ohio PACE program in accordance with federal requirements.

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.*

No. A performance -based regulations is not deemed appropriate because the requirements of these rules are dictated by federal requirements.

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

All regulations regarding PACE are limited only to the CMS approved Ohio PACE provider and the state administering agency. The regulations were reviewed by Medicaid policy, legal, and legislative staff to ensure there was no duplication of the rules. Further, under Ohio Revised Code Section 5162.03, ODM is the single state agency to supervise the administration of the Medicaid program, and under Ohio Revised Code Section 5162.022, ODM's regulations governing Medicaid are binding on other agencies that administer components of the Medicaid program. No agency may establish, by rule or otherwise, a policy governing Medicaid that is inconsistent with a Medicaid policy established, in rule or otherwise, by the medical assistance director.

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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.

The Ohio Department of Aging, designated by ODM to serve as the state administering agency of the PACE program, is responsible for the implementation and ongoing monitoring of the regulations. Reimbursement by ODM for PACE services will not be provided to any PACE organization that is out of compliance with the requirements set forth in these rules.

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

The only business community impacted by these rules is the single PACE provider operating in the state. The nature of the adverse impact resulting from the rule are related to employer time for compliance. The PACE organization provided the following estimates:

- Estimated cost associated with complying with the program agreement requirement. **\$6,000.**
- Estimated costs associated with establishing and operating an interdisciplinary care team: **\$26,000.**

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

Provider participation in this program is optional and at the provider’s discretion. Compliance with federal and state regulations is required for provides who choose to participate and may include administrative costs associated with entering into a program agreement and establishing and operating an interdisciplinary team.

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Regulatory Flexibility

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

No. To ensure the PACE program is operated in accordance with federal regulations. The rules do not provide any exemptions or alternative means of compliance and no exception can be made specifically for small businesses.

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?

There are no fines or penalties for paperwork violations associated with these rules.

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

Businesses seeking technical assistance can contact the Ohio Department of Aging (1-800-266-4346)