

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: MCD Authorizing PACE Rules - 5 Year Review

Rule Number(s): 5160-36-02

Date: _____

Rule Type:

New

X 5-Year Review

X Amended

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

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OAC 5160-36-02

Rule 5160-36-02, entitled “Program of All-inclusive Care for the Elderly (PACE) Administration” is being proposed for amendment pursuant to five-year rule review. Among other things, this authorization rule sets forth the program administration requirements for the PACE Program, including but not limited to designation of the Ohio Department of Aging (ODA) as the state administering agency. It also requires, in compliance with federal regulations, a three-party agreement among ODA, the Centers for Medicare and Medicaid Services (CMS) and each PACE organization approved by CMS to provide PACE services to participants in Ohio who reside in the PACE organization’s designated service area.

Proposed changes are limited to updated OAC cites, ODM references, CFR effective dates and updated references to “individual” instead of “consumer.” Additionally, paragraph (B)(3) has been modified to state that ODA shall “verify that PACE organizations providing PACE services have signed Medicaid provider agreements as required by rule 5160-1-17 of the Administrative Code.”

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Ohio Revised Code Section 5164.02.

3. 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 dually eligible for Medicare and Medicaid services. The program is operated pursuant to federal regulations set forth in 42 USC 1396u-4 and 42 CFR 460.

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

This authorization rule is consistent with federal requirements. It designates ODA as the state agency responsible for administering the program and requires ODA to adhere to and monitor implementation of all applicable requirements for the program's administration.

5. 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 these regulations is to comply with federal law to operate a PACE program in Ohio.

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

The success of this regulation 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.

Development of the Regulation

7. 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 shared drafts of this and other PACE rules with ODA. Opportunity for input was also provided through the department's clearance process. Two PACE organizations are operating in Ohio until August 31st, after which there will only be one. The clearance list included, but was not limited to, the PACE organization that will remain.

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

No comments were received from the PACE organizations, nor were any received through the department's clearance process.

9. 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?

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Not applicable.

10. 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 alternative regulations were considered by the agency as the requirements of this rule were dictated by federal law.

11. 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 regulation is not deemed appropriate because the requirements of this rule are dictated by federal law.

12. 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 providers and administrators of the PACE program. The regulations were reviewed by Medicaid's policy, legal and legislative staff to ensure that there was no duplication of the rule.

13. 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.

ODA is designated by ODM to serve as the state administering agency of the PACE program. Reimbursement by ODM for PACE program services will not be provided to any PACE organization that is out of compliance with the requirements set forth in this rule.

Adverse Impact to Business

14. 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;

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b. Identify the nature of the adverse impact (e.g., license 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.

Two providers are currently affected by this rule. After August 31st, there will only be one. The remaining PACE organization was queried about its projected cost of compliance with this rule. The estimated cost to the organization is approximately \$6,000.00, i.e., the cost of contract review by organization’s attorney, chief executive officers, the compliance officer and the director of nursing.

15. 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. However, compliance with federal program requirements is required for providers who choose to participate and may include administrative costs associated with filing an application and entering into the three-party agreement in compliance with the requirements of this rule.

Regulatory Flexibility

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

Not applicable.

17. 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?

Not applicable.

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

ODA and ODM may provide technical assistance upon request.