



Common Sense Initiative

Mike DeWine, Governor Jon Husted, Lt. Governor Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: OHIO DEPT. OF AGING				
Rule Contact Name and Contact Information: Tom Simmons rules@age.ohio.gov				
Regulation/Package Title (a general description of the rules' substantive content): PACE: PARTICIPANT ELIGIBILITY AND ENROLLMENT Chapter 173-50 of the Administrative Code regulates the eligibility, enrollment, reassessment, and disenrollment processes for PACE in Ohio.				
Rule Number(s): 173-50-02 and 173-50-03.				
Date of Submission for CSI Review: February 13, 2025				
Public Comment Period End Date: February 27, 2025 at 11:59PM.				
Rule Type/Number of Rules: □ New/# rule □ No Change/# rules (FYR? □) □ Rescinded/0 rules (FYR?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?

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T	The rule(s):						
a.	☐ Requires a license, permit, or any other prior authorization to engage in or						
	operate a line of business.						
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- 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.

Chapter 173-50 regulates participant eligibility, enrollment, reassessment, and disenrollment processes for PACE in Ohio.

Rule 173-50-02 of the Administrative Code exists to establish qualifications for a person to participate in PACE. ODA proposes to amend this rule to achieve the following:

- Align the rule more closely with <u>42 CFR 460.150</u> by doing the following:
 - Adding Medicare and Medicaid prepayment programs and optional benefits to the list of programs in which a person may not be enrolled while enrolled in PACE.
 - Moving hospice from a program in which a person may not be enrolled while enrolled in PACE to an example of an optional Medicare and Medicaid benefit in which a person may not be enrolled while enrolled in PACE.
 - Removing RSS and the PACT Program from the list of programs in which a person may not be enrolled while enrolled in PACE.
- Remove unnecessary restatements of topics that other rules cover. Doing so will reserve this rule for participant eligibility. This involves removing the following from this rule:
 - The references to enrollment agreements and reassessments, since rule 173-50-03 of the Administrative Code covers these topics. ODA proposes to remove these references in response to recommendations from One Senior Care and Bold Age. (For more information, please review ODA's response to question #10 of this BIA.)
 - The reference to rule 173-50-05 of the Administrative Code.
- Remove the reference to premiums from paragraph (A)(5) of this rule since premiums are part of post-eligibility treatment of income (PETI), which is already listed in that paragraph.
- Make additional non-substantive changes to improve the rule.

Rule 173-50-03 of the Administrative Code exists to establish the following for PACE: the standards for enrollment, plans of care, reassessment, and continued enrollment. In response to a recommendation from Bold Age, ODA proposes to reference rule 5160-3-08 in paragraph (H) of this rule. Doing so will allow ODA to cover continued enrollment in only one rule and to

reference the state-specific requirement for continued enrollment in this rule. (For more information, please review ODA's response to guestion #10 of this BIA.)

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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173-50-02: RC §§ <u>121.07</u>, <u>173.01</u>, <u>173.02</u>, <u>173.50</u>.
173-50-03: RC §§ <u>121.07</u>, <u>173.01</u>, <u>173</u>.02, <u>173.50</u>, 173.501.
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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 ves, please briefly explain the source and substance of the federal requirement.

Yes, these rules implement the following:

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173-50-02: <u>42 CFR 460.150</u>. 173-50-03: 42 CFR 460.104, 460.106, 460.152, 460.154, 460.156, 460.158, 460.160.
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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 rules exist to comply with the state laws mentioned in ODA's response to #3, which establish ODA as the state agency administering PACE and authorize ODA to adopt rules for PACE to the extent authorized in ODA's interagency agreement with ODM.

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)?

These rules establish necessary safeguards to ensure that qualified applicants are enrolled and qualified participants who want to remain in the program remain enrolled.

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

<u>42 CFR 460.192</u> requires CMS and ODA to review each PACE organization to ensure compliance. ODA will determine that this rule is successful if these reviews find few violations.

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.

ODA's guide <u>Participating in ODA's Rule Development</u> and the <u>main rules webpage</u> on ODA's website encourage stakeholders and the general public to give input on improving ODA's rules and provide contact information for doing so. From this rule's effective date to the date of this BIA, ODA received no input on this rule from stakeholders or the general public by using this method.

A PACE organization is the only stakeholder to these rules that is an Ohio business.

On November 29, 2024, ODA emailed the following PACE organizations and affiliates to (1) announce that it was time to review the rule, (2) announce ODA's plan to align the rule more closely with 42 CFR 460.150 and 460.160, and (3) encourage those PACE organizations to provide any recommendations for improving the rule to ODA by December 17, 2024:

- Bold Age PACE.
- High Bridge Consulting.
- LeadingAge Ohio (PACE Association of Ohio).
- McGregor PACE.
- One Senior Care PACE.
- TriHealth PACE.

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

In response to its November 29 emails, ODA received responses from Bold Age PACE and One Senior Care PACE. The table below shows the input provided by these PACE organizations and ODA's responses.

	Comment	ODA's Response
1	One Senior Care: Replace ¶(A)(4) with language from 42 CFR 460.150(c) to avoid confusion with the requirement in 42 CFR 460.152(a)(4):	This rule does not establish any requirements for a PACE organization. ODA proposes to cite 42 CFR 460.150(c)(2) in this paragraph.
2	Bold Age: In ¶(A)(4), add "with the support of the PACE organization" after "health and safety."	ODA proposes to implement this recommendation by referencing 42 CFR 460.150(c)(2), which requires this determination to be made according to specific standards in each PACE program agreement.
3	Bold Age: ¶(A)(5)(a) is difficult to understand.	ODA understands your concern, Ohio's Medicaid- related programs sometimes need to use terminology found in the Ohio Department of Medicaid's rules {e.g., post-eligibility treatment of income (PETI)}.
4	One Senior Care: ¶(A)(6) is a condition of the enrollment agreement, but not an eligibility requirement.	ODA agrees. Because our enrollment rule, 173-50-03, covers enrollment agreements, we will delete ¶(A)(6) from rule 173-50-02.
5	Bold Age: Please clarify whether ¶(A)(7)(a) is simply an eligibility requirement for a participant or a requirement for a PACE organization or participant to disenroll the participant from other programs before enrolling in PACE vs. automatic disenrollment from other programs upon PACE enrollment.	This is an eligibility requirement for a participant. This rule does not require the PACE organization to disenroll a participant from another program to enroll in PACE. The state will automatically disenroll a new PACE participant from other Medicaid-funded state-administered programs.

	Comment	ODA's Response
6	One Senior Care: ¶(A)(7)(b) seems to preclude nursing home transitions.	¶(A)(7) lists conditions to exist at the time of enrollment. A person living in an institutional setting may qualify for PACE on the day the person transfers to a community setting. This aligns with 42 CFR 460.150(c)(1) which requires living in a community setting at the time of enrollment as an eligibility requirement.
7	Bold Age: In ¶(B), replace "if ODA does not reasonably expect the participant's health to improve" with "if ODA determines that there is no reasonable expectation of improvement or significant change in the participants condition because of the severity of a chronic condition or the degree of impairment of functional capacity."	The topic of continued enrollment appears in both rules 173-50-02 and 173-50-03. There is no need to add your proposed language to 173-50-02 because 173-50-03 already requires following 42 CFR 460.160, which contains the language that you recommend. ODA proposes to delete ¶(B) from 173-50-02 so that only one rule covers continued enrollment. ODA also proposes to amend ¶(H) in rule 173-50-03 so that the reference to Ohio's level-of-care assessment is not lost.

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?

These rules are not based upon scientific data.

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.

Alternatives to the requirements in 42 CFR Part 460 are not permissible, although these rules implement items that are unique to Ohio such as references to Ohio's level-of-care assessment rules and home-first component of PACE under <u>RC §173.501</u>, and the unified waiting list.

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

RC §173.50 authorizes ODA to develop standards for PACE. ODA did not find duplicate rules.

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.

Before the proposed amendments to this rule takes effect, ODA will post them on ODA's website. ODA will also send an email to subscribers of our rule-notification service to feature them.

Through regular review activities under 42 CFR 460.192, CMS and ODA will review each PACE organization to ensure compliance.

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

Every PACE organization in Ohio.

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.

Although rule 173-50-02 of the Administrative Code does not establish an adverse impact on any PACE organization, it refers to rule 173-50-05 of the Administrative Code, which permits a PACE organization to submit a request to ODA to involuntarily withdraw a participant's enrollment in PACE. Such a request requires the PACE organization to provide ODA with documentation reflecting the grounds for involuntary disenrollment and the PACE organization's efforts to remedy the situation.

ODA proposes to remove the reference to rule 173-50-05 of the Administrative Code from this rule because it is unnecessary.

Rule 173-50-03 of the Administrative Code references the PACE organization's responsibilities (1) under 42 CFR 460.152 to conduct intake, (2) under 42 CFR 460.154 (cf., 42 CFR 460.156) to notify a qualified applicant of the opportunity to enroll, and (3) under 42 CFR 460.104 and 460.106 for its interdisciplinary team (IDT) to conduct an assessment and develop a plan of care. The only requirements that this rule establishes for the PACE organization that are not based in federal rules are the requirements to enroll a qualified applicant on the unified waiting list and through the home-first component of the program (if applicable) when no slot is available in PACE for the qualified applicant. These requirements implement RC§173.501.

16. Are there any proposed changes to the rules that will <u>reduce</u> 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).

Yes. By removing the reference to rule 173-50-05 of the Administrative Code, ODA is removing a reference to a rule that contains a regulatory burden on a PACE organization.

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

As amended, rule 173-50-02 of the Administrative Code will not establish a regulatory burden on any PACE organization.

Rule 173-50-03 of the Administrative Code does not establish any requirements for a PACE organization that are not require under federal rules or the Ohio Revised Code as noted in ODA's response to BIA question #15b.

A provider voluntarily applies to become a PACE organization. Compliance with Chapter 173-50 is required only if (1) a provider responds to a request for proposals (RFP) to become a PACE organization, (2) the Centers for Medicare and

Medicaid Services (CMS) and ODA both agree that the provider qualifies to be a PACE organization, and (3) CMS and ODA enter into an agreement with the provider to be a PACE organization.

Depending on each participant's eligibility for Medicare, Medicaid, and private-pay options, the PACE organization may receive funds from Medicare and private pay to pay for providing services and related duties required by OAC Chapter 173-50 and 42 CFR Part 460.

Regulatory Flexibility

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

These rules treas all PACE organizations the same, regardless of their size. Additionally, the primary purpose of Chapter 173-50 is to ensure the health and safety of participants enrolled in PACE, regardless of the size of the PACE organization providing services to the participants.

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?

ODA is concerned primarily about ensuring that qualified applicants are enrolled. Whenever possible, ODA will treat administrative violations that do not involve health and safety as opportunities for improvement through warning notices and solicitation of corrective action.

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

ODA is available to help providers of all sizes with their questions. Any person may contact <u>Tom Simmons</u>, ODA's rules and policy administrator, with questions about these rules.