



PUBLIC-COMMENT PERIOD

PACE

July 25, 2023

ODA reviewed rules 173-50-01 and 173-50-03 of the Administrative Code and now proposes to (1) amend rule 173-50-01 of the Administrative Code and (2) rescind rule 173-50-03 of the Administrative Code and to replace it with a new rule.

Please feel free to review the business impact analysis (BIA) and the proposed rule drafts, then offer recommendations for improving the BIA and rules. Submit recommendations to rules@age.ohio.gov no later than **September 26, 2023** at 11:59PM.



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

Chapter 173-50 of the Administrative Code regulates the eligibility, enrollment, reassessment, and disenrollment processes for PACE in Ohio.

Rule Number(s): 173-50-01 and 173-50-03.

Date of Submission for CSI Review: September 13, 2023

Public Comment Period End Date: September 26, 2023 at 11:59PM.

Rule Type/Number of Rules:

New/ # rules

No Change/ # rules (FYR?)

Amended/ 2 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Rescinded/ 0 rules (FYR?)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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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.

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

Rule 173-50-01 of the Administrative Code introduces this chapter and defines terms used throughout this chapter. ODA proposes to amend this rule to achieve the following:

- Delete the definition of "CDJFS" because the chapter does not use that term.
- Insert the definition of "ODA's designee."
- Refer to the statute that established the program in the definition of "PACE" rather than rules that regulate the program.
- 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. ODA's proposal to amend this rule will result in amending approximately more than 50% of the rule, so ODA proposes to rescind the current version of this rule and to adopt a new rule in its place to comply with the 50% guideline in §4.3.1 of LSC's [Rule Drafting Manual](#). In doing so, ODA proposes to achieve the following:

- Reduce the use of unnecessary regulatory restrictions (e.g., "shall") to comply with R.C. §§ [106.03](#) and [121.951](#).¹ This proposal includes the substantive change noted below. This proposal also includes numerous non-substantive changes, such as referring to requirements in federal rules rather than restating those requirements in this rule. This reduction comprises most of the changes being proposed in this rule.
- Require ODA or its designee to conduct the level-of-care assessment under [42 C.F.R. 460.152\(a\)\(3\)](#) and no longer require the PACE organization to "conduct [this] comprehensive assessment."

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.

R.C. §§ [121.07](#), [173.01](#), [173.02](#), [173.50](#).

¹ Senate Bill 9 (134th G.A.).

- 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, these rules implement 42 C.F.R. [460.6](#), [460.104](#), [460.106](#), [460.152](#), [460.154](#), [460.156](#), [460.158](#), and [460.160](#).

- 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.**

The rules exist to comply with the state laws (especially R.C. [§173.50](#)) 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?**

[42 C.F.R. 460.192](#) requires CMS and ODA to conduct ongoing monitoring of the PACE organization to ensure compliance. The rules are judged as being successful when CMS and ODA find few violations from its monitoring.

- 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 [Participating in ODA's Rule Development](#) and the [main rules webpage](#) 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 each rule's effective date to the date of this BIA, ODA received no input from stakeholders or the general public on any rule in this package by using this method.

A PACE organization is the only stakeholder to these rules that is an Ohio business. At the time of the drafting of this BIA, Ohio has only one PACE organization.

On June 29, 2023, ODA emailed McGregor PACE to announce that ODA was preparing to amend rules 173-50-01 and 173-50-03 of the Administrative Code and giving McGregor PACE an opportunity to make recommendations for improving those rules by July 13, 2023.

In the email, ODA explained that it was considering non-substantive updates and improvements to rule 173-50-01 of the Administrative Code. For rule 173-50-03 of the Administrative Code, ODA explained that it was considering the following:

- Delineating that (1) a PACE organization is responsible for completing its intake duties under 42 C.F.R. 460.152 and (2) ODA or its designee, and not the PACE organization, is responsible for conducting the level-of-care assessment under the same section.
- Referring to federal rules instead of duplicating federal requirements in this rule (e.g., with another "shall") to comply with new requirements for Ohio rules in R.C. §§ [106.03](#), [121.95](#), and [121.951](#). These would be non-substantive changes under consideration.

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

ODA did not receive a response from McGregor PACE.

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 C.F.R. Part 460 are not permissible, although the rules in this package implement items that are unique to Ohio such as references to Ohio's level-of-care assessment rules, home-first component of PACE under R.C. §[173.501](#), and the unified waiting list.

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

R.C. §[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 these rules take 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 monitoring activities under [42 C.F.R. 460.192](#), CMS and ODA will conduct ongoing monitoring of the 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, which is currently only 1 PACE organization, McGregor PACE.

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.

Rule 173-50-01 of the Administrative Code merely introduces the chapter and defines terms used throughout the chapter. It does not create any adverse impact.

Rule 173-50-03 of the Administrative Code references the PACE organization's responsibilities (1) under [42 C.F.R. 460.152](#) to conduct intake, (2) under [42 C.F.R. 460.154](#) (cf., [42 C.F.R. 460.156](#)) to notify a qualified applicant of the opportunity to enroll, and (3) under [42 C.F.R. 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.

16. Are there any proposed changes to the rules that will reduce 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. ODA proposes to reduce the regulatory impact of rule 173-50-03 of the Administrative Code upon the PACE organization by requiring ODA or its designee to conduct the level-of-care assessment under [42 C.F.R. 460.152\(a\)\(3\)](#) and no longer requiring the PACE organization to "conduct [this] comprehensive assessment."

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

ODA develops rules for PACE to ensure that qualified applicants are enrolled, participants who do not want to participate are voluntarily disenrolled, and those who no longer qualify are involuntarily disenrolled. Additionally, ODA is reducing adverse impact through this rule package.

Providers voluntarily apply to become a PACE organization. Compliance with Chapter 173-50 is only required if a provider chooses to become a PACE organization. ODA pays the PACE organization for the services it provides through PACE to Medicaid-enrolled participants.

Regulatory Flexibility

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

Although the rules would treat all PACE organizations the same, regardless of their size, Ohio currently has only one PACE organization. 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 and its designees are available to help providers of all sizes with their questions. Any person may contact [Tom Simmons](#), ODA's policy development manager, with questions about these rules.

173-50-01

PACE: introduction and definitions.

(A) Introduction: ~~Chapter 173-50 of the Administrative Code~~ This chapter regulates PACE. ~~PACE, which~~ is a managed-care program that provides its participants with all of their necessary health care, medical care, and ancillary services in acute, sub-acute, institutional, and community settings. Examples of PACE services are primary and specialty care, an adult day ~~services~~ service, personal care ~~services~~, inpatient hospital stays, prescription drugs, occupational therapy, physical therapy, and nursing facility care.

(B) Definitions for this chapter:

"Authorized representative" has the same meaning as in rule 5160-36-01 of the Administrative Code.

~~"CDJFS" means the "county department of job and family services."~~

"CMS" means "the centers for medicare and medicaid services."

"IDT" means "inter-disciplinary team."

"ODA" means "the Ohio department of aging."

"ODA's designee" has the same meaning as in rule 173-39-01 of the Administrative Code.

"ODM" means "the Ohio department of medicaid."

"ODM's administrative agency" has the same meaning as "administrative agency" in rule 5160:1-1-01 of the Administrative Code.

"PACE" means "the program of all-inclusive care for the elderly," which ~~is~~ was established ~~by 42 C.F.R. Part 460 (October 1, 2019)~~ under 42 U.S.C. 1396u-4 (August 5, 1997).

"PACE organization" means an entity that provides services to participants under a PACE program agreement with CMS and ODA.

"Participant" means a person who receives services through PACE.

TO BE RESCINDED

173-50-03

PACE: enrollment, plan of care, and reassessment.

(A) Oversight:

- (1) ODA manages the enrollment for PACE.
- (2) ODA determines if a slot is available in PACE.
- (3) ODA reserves the right to restrict enrollment based upon funding for PACE.
- (4) ODA reserves the right to increase or decrease the maximum number of PACE slots.

(B) Enrollment process, in general:

- (1) To begin the enrollment process, a person may apply through either ODM's administrative agency or a PACE organization.
- (2) ODM's administrative agency and the PACE organization shall coordinate efforts regarding the enrollment process.

(C) Enrollment process when a person initially applies for PACE:

- (1) The PACE organization shall conduct a comprehensive assessment (by telephone, video conference, or in person) of the applicant's medical, physical, emotional, and social needs and ability to remain in the community without jeopardizing his/her health or safety.
- (2) The PACE organization may help the applicant apply for medicaid (unless the applicant is already enrolled in medicaid).
 - (a) After the application is received, ODM's administrative agency shall determine if the applicant meets all financial eligibility requirements for medicaid in Chapters 5160:1-1 to 5160:1-6 of the Administrative Code.
 - (b) If ODM's administrative agency determines the applicant does not meet all financial eligibility requirements, it shall send a notice of denial and appeal rights to the applicant (or the authorized representative) in Chapters 5101:6-1 to 5101:6-9 of the Administrative Code. It shall also send a notice of denial to ODA and the PACE organization. An applicant

who is denied medicaid may still enroll in PACE if the applicant is willing to privately pay the premium that would have been covered by medicaid.

- (3) After completing the assessment, the PACE organization shall provide the information from its assessment to ODA.
 - (4) After receiving the information, ODA shall determine if the applicant meets all eligibility requirements in rule 173-50-02 of the Administrative Code.
 - (5) If ODA determines an applicant meets all eligibility requirements, then:
 - (a) ODA shall notify the PACE organization of its determination.
 - (b) Once the PACE organization receives the determination from ODA, it shall notify the applicant (or the authorized representative) of the opportunity to proceed with the process of enrolling into PACE.
 - (c) In order to be enrolled into the program, the applicant shall sign the enrollment agreement with the PACE organization.
 - (d) The applicant's enrollment into PACE is effective the first day of the month following the day ODA determines the applicant meets all eligibility requirements and the PACE organization received the signed enrollment agreement.
 - (6) If ODA determines an applicant does not meet all eligibility requirements, then:
 - (a) ODA shall notify the PACE organization of its determination.
 - (b) ODA shall provide the applicant (or the authorized representative) with a notice of denial and appeal rights under section 5101.35 of the Revised Code and division 5101:6 of the Administrative Code.
- (D) No available slot: If a slot is not available in PACE, the PACE organization shall enroll the applicant when a slot becomes available (if the individual continues to meet the eligibility requirements) by one of two means: the unified waiting list or the home-first component of PACE.
- (1) Unified waiting list: If the applicant meets the non-financial eligibility requirements for enrollment into PACE, but a slot in the program is not available, the PACE organization shall place the applicant on the unified waiting list under the terms of rule 173-44-04 of the Administrative Code.

- (2) Home first: If the applicant meets all requirements for the home first component of PACE in section 173.501 of the Revised Code, the PACE organization shall enroll the applicant in PACE before enrolling any applicant from the unified waiting list in PACE.
- (E) Plan of care: The PACE organization shall do all of the following for any participant enrolled into PACE:
- (1) The PACE organization shall collaborate with the participant to develop a plan of care for the participant that includes all of the following:
 - (a) The services necessary to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment in paragraph (C)(1) of this rule and the reassessment under paragraph (E)(3)(a) of this rule.
 - (b) The measurable outcomes to be achieved for the participant.
 - (2) The PACE organization shall implement, coordinate, and monitor the participant's plan of care.
 - (3) Reassessment:
 - (a) At least semiannually, or more often if the participant's condition dictates or if requested by the participant or the participant's authorized representative, the IDT shall conduct a comprehensive assessment (by telephone, video conference, or in person) of the applicant's medical, physical, emotional, and social needs and ability to remain in the community without jeopardizing his/her health or safety.
 - (b) If the comprehensive assessment in paragraph (E)(3)(a) of this rule indicates a need to revise the plan of care, the IDT shall collaborate with the participant to revise the plan of care.
 - (c) The PACE organization shall provide at least one of the semiannual comprehensive assessments in paragraph (E)(3)(a) of this rule to ODA at least once per year with no more than three hundred and sixty-five days between providing assessments to ODA.
 - (d) Deemed eligibility: ODA may deem a PACE participant to be eligible if at least one of the following conditions exist:
 - (i) The participant has a severe cognitive impairment (mini-mental of nine or less).

- (ii) The participant has complex medical conditions that require continual clinical oversight on a weekly basis by the IDT to remain medically stable.
- (iii) Within six months after the most-recent annual redetermination date, the participant has had two or more hospitalizations or two or more trips to an emergency department.
- (iv) The participant has a psychiatric diagnosis and/or behavior requiring coordination of continuous and ongoing intervention(s) by the IDT. In the absence of support and services from the PACE organization, the participant would not likely be able to comply with medical regimen for chronic disease.

173-50-03

PACE: application, assessment, enrollment, plan of care, reassessment, and continued enrollment.

(A) Oversight:

- (1) ODA manages the enrollment for PACE.
- (2) ODA determines if a slot is available in PACE.
- (3) ODA may restrict enrollment based upon funding for PACE.
- (4) ODA may increase or decrease the maximum number of PACE slots.

(B) Intake process:

- (1) A person may apply for PACE through either ODM's administrative agency or a PACE organization. The two agencies coordinate intake with ODA and its designee.
- (2) The PACE organization is responsible for completing its intake duties under 42 C.F.R. 460.152 and notifying ODA or its designee of any applicant and its determination under 42 C.F.R. 460.152(a)(4). The PACE organization may help the applicant apply for medicaid, unless the applicant is already enrolled in medicaid.
- (3) ODM's administrative agency is responsible for determining whether the applicant meets all financial eligibility requirements for medicaid in Chapters 5160:1-1 to 5160:1-6 of the Administrative Code, notifying ODA, the PACE organization, and the applicant (or the applicant's representative) of its determination, and, if the applicant does not meet all financial edibility requirements, notifying the applicant (or the applicant's authorized representative) of the denial and appeal rights under section 5101.35 of the Revised Code and division 5101:6 of the Administrative Code. An applicant who is denied medicaid may still enroll in PACE if the applicant is willing to privately pay the premium that would have been covered by medicaid.
- (4) ODA or its designee is responsible for conducting the level-of-care assessment under 42 C.F.R. 460.152(a)(3) and rule 5160-3-08 of the Administrative Code.

(C) Enrollment: If ODA or its designee determines that an applicant meets all eligibility requirements in rule 173-50-02 of the Administrative Code, then the following apply:

- (1) ODA notifies the PACE organization of its determination.
- (2) The PACE organization is responsible for notifying the applicant of the opportunity to proceed with the process of enrolling into PACE, providing

the applicant with the enrollment agreement under 42 C.F.R. 460.154, and completing the enrollment procedures in 42 C.F.R. 460.156 if the applicant signs the enrollment agreement.

(3) 42 C.F.R. 460.158 determines the effective date of the applicant's enrollment into PACE.

(D) Denial: If ODA or its designee determines that an applicant does not meet all eligibility requirements, then ODA or its designee shall notify the PACE organization of its determination and notify the applicant of the denial and appeal rights under section 5101.35 of the Revised Code and division 5101:6 of the Administrative Code.

(E) No available slot: If a slot is not available in PACE, the PACE organization shall enroll the applicant when a slot becomes available (if the individual continues to meet the eligibility requirements) by one of the following two means:

(1) Unified waiting list: If the applicant meets the non-financial eligibility requirements for enrollment into PACE, but a slot in the program is not available, the PACE organization shall place the applicant on the unified waiting list under rule 173-44-04 of the Administrative Code.

(2) Home first: If the applicant meets all requirements for the home first component of PACE in section 173.501 of the Revised Code, the PACE organization shall enroll the applicant in PACE before enrolling any applicant from the unified waiting list in PACE.

(F) Initial comprehensive assessment: The PACE organization's IDT is responsible for completing the initial in-person comprehensive assessment of the participant under 42 C.F.R. 460.104.

(G) Plan of care:

(1) The PACE organization's IDT is responsible for developing, implementing, and reevaluating a plan of care for the participant under 42 C.F.R. 460.104 and 460.106.

(2) The IDT may conduct the reevaluation under 42 C.F.R. 460.104 and 460.106 by telephone, video conference, or in person.

(3) The IDT is responsible for conducting the reassessment under 42 C.F.R. 460.106.

(H) Continued enrollment: Continued enrollment is dependent upon the annual recertification requirements in 42 C.F.R. 460.160.

(I) An authorized representative may represent an applicant in the enrollment process and

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[a participant in the reevaluation processes.](#)