

Title of Rule: Revision to the Medical Assistance Rule concerning the Program of All-Inclusive Care for the Elderly (PACE), Section 8.497
Rule Number: MSB 25-04-22-A
Division / Contact / Phone: Benefits & Services Division / Winter Roberts /

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

The purpose of the revision is to: 1) Incorporate changes made to the Federal PACE Rule that were applicable January 1, 2025 and 2) Strengthen PACE application requirements to ensure quality applicants and responsible growth of the PACE program.

2. An emergency rule-making is imperatively necessary

- to comply with state or federal law or federal regulation and/or
- for the preservation of public health, safety and welfare.

Explain:

N/A

3. Federal authority for the Rule, if any:

42 U.S.C. § 1395eee(f)

42 U.S.C. § 1396u-4(f).

42 C.F.R. Part 460

4. State Authority for the Rule:

Sections 25.5-1-301 through 25.5-1-303, C.R.S.
Section 25.5-5-412, C.R.S

Initial Review **09/12/25**
Proposed Effective Date **11/30/25**

Final Adoption **10/10/25**
Emergency Adoption

DOCUMENT #10

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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

The rule revisions affect PACE organizations, providing clarity on State requirements for new providers, service expansions, and aligning state requirements with federal requirements.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

By aligning State regulations with Federal regulations PACE providers will experience a decrease in administrative burden as there will no longer be differentiated requirements between Federal and State requirements, for example Federal and State requirements previously had different timelines for re-evaluation of participants following a hospitalization, by aligning these requirements PACE providers will no longer have to meet varying standards of follow-up visits.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

This change is not anticipated to have any budget impact to the Department or to any other agency because the rule change is technical in nature and is not changing services or benefits.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Aligning these rules with federal standards will decrease confusion and enable PACE providers or prospective providers to better comply with both. The changes to enrollment and expansion criteria will help ensure that providers are financially stable and capable of maintaining adequate staffing levels to provide care to Medicaid members who participate in PACE. The current lack of specific standards related to provider enrollment for PACE creates a risk of financial instability for possible programs. Because this program requires members to receive their health coverage through a PACE provider, financial instability can result in lower-quality care. There is no benefit of inaction.

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5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

There are no less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

The Department considered moratoriums on new provider enrollment or a Request for Proposal process. The current path still allows for new enrollment with heightened review of potential providers, which the Department views as the better option.

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8.497 PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

8.497.1 STATUTORY AUTHORITY AND APPLICABILITY

8.497.1.A. The statutory authority for these rules is set forth in § 25.5-5-412, C.R.S.

8.497.1.B. A PACE organization, as defined herein, must comply with all applicable federal, state, and local statutes, regulations, and laws including but not limited to the following:

1. Code of Federal Regulations (CFR), Title 42 – Public Health, Chapter IV – Centers for Medicare & Medicaid Services, Department of Health and Human Services, Subchapter E Programs of All-Inclusive Care for the Elderly (PACE), Part 460 – Programs of All-Inclusive Care for the Elderly (PACE). This will be referred to in this regulation as 42 CFR 460. [42 CFR Part 460 \(2024\) is hereby incorporated by reference. The incorporation of 42 CFR Part 460 \(2024\) excludes later amendments to, or editions of the referenced material. Pursuant to § 24-4-103\(12.5\), C.R.S., the Department maintains copies of this incorporated text in its entirety, available for public inspection during regular business hours at 303 E. 17th Ave., Denver, CO, 80203. Certified copies of incorporated materials are provided at cost upon request.](#)

2. Section 25.5-5-412, C.R.S.

8.497.1.C. A PACE organization must have an agreement with the CMS and the Department, as defined herein, for the operation of a PACE program.

8.497.2 SCOPE AND PURPOSE

8.497.2.A. The purpose of these rules is to implement § 25.5-5-412, C.R.S. which require the Department to establish, administer, and enforce minimum regulatory standards and rules for the PACE program, including for contracted entities of the PACE program, to ensure the health, safety and welfare of PACE participants.

8.497.2.B. Scope and purpose.

1. General. This regulation sets forth the following:

- a. The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicaid in the State of Colorado;

~~b. Marketing requirements for PACE organizations;~~

~~c. Requirements for ensuring fiscal soundness of PACE organizations;~~

~~d. Procedures for sanctions, enforcement actions, and terminations;~~

~~be. How individuals may qualify to enroll in a PACE program;~~

~~c.f. How Medicaid payments will be made Reimbursement for PACE services;~~

~~dg. Provisions for State monitoring of PACE programs;~~

- 1 ~~h. General PACE organization requirements and PACE services;~~
- 2 ~~i. Requirements to collect data, maintain records and report information, including~~
- 3 ~~encounter data; and~~
- 4 ~~j. Requirements for PACE quality improvement monitoring.~~
- 5 e. Procedures for sanctions, enforcement actions, and terminations.
- 6 2. Program purpose. PACE provides, prepaid, capitated, comprehensive health care
- 7 services designed to meet the following objectives:
- 8 a. Enhance the quality of life and autonomy for older adults who require the level of
- 9 care provided in a nursing facility;
- 10 b. Maximize dignity of, and respect for, older adults;
- 11 c. Enable older adults to live in the community as long as medically and socially
- 12 feasible; and
- 13 d. Preserve and support the older adult's family unit by relieving the family of the
- 14 sole responsibility of coordinating and providing care and services.

15 **8.497.3 DEFINITIONS**

16 As used in this regulation, unless the context indicates otherwise, the following definitions apply:

- 17 A. CMS means Centers for Medicare and Medicaid Services.
- 18 B. Dementia diseases and related disabilities means a condition where mental ability declines and is
- 19 severe enough to interfere with an individual's ability to perform everyday tasks. Dementia
- 20 diseases and related disabilities include Alzheimer's disease, mixed dementia, Lewy Body
- 21 Dementia, vascular dementia, frontotemporal dementia, and other types of dementia.
- 22 C. Department means the Colorado Department of Health Care Policy and Financing.
- 23 D. Designated Representative means a representative who is designated by the participant to act on
- 24 the participant's behalf.
- 25 E. Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a
- 26 PACE program.
- 27 F. PACE ~~stands for~~ means the programs of all-inclusive care for the elderly.
- 28 G. PACE center is a facility which includes a primary care clinic, and areas for therapeutic
- 29 recreation, restorative therapies, socialization, personal care, and dining, and which serves as the
- 30 focal point for coordination and provision of most PACE services.
- 31 H. PACE contract means the contract between the Department and a PACE organization.
- 32 I. PACE organization means an entity that has in effect a PACE program agreement to operate a
- 33 PACE program under this regulation.

- 1 J. PACE program means a program of all-inclusive care for the elderly that is operated by an
2 approved PACE organization and that provides comprehensive healthcare services to PACE
3 enrollees in accordance with a PACE program agreement.
- 4 K. PACE program agreement means an agreement between a PACE organization, CMS, and the
5 Department.
- 6 L. Participant means an individual who is enrolled in a PACE program.
- 7 M. Service, ~~as used in this regulation~~, means all services that could be required under Section
8 8.497.8.B., including items and drugs.
- 9 N. State administering agency means the Department.
- 10 O. Survey Agency means either the Colorado Department of Public Health and Environment or any
11 contractor the Department engages to conduct onsite inspections of a PACE center.
- 12 P. Subcontractor means a third party contracted with a PACE organization to aid in performance of
13 the PACE contract work.
- 14 Q. Telehealth means a mode of delivery of health care services through HIPAA-compliant
15 telecommunications systems, including information, electronic, and communication technologies,
16 remote monitoring technologies and store-and-forward transfers, to facilitate the assessment,
17 diagnosis, consultation, treatment, education, care management, or self-management of a
18 covered person's health care while the covered person is located at an originating site and the
19 provider is located at a distant site.
- 20 R. ~~The Act means the Social Security Act.~~
- 21 RS. Trial period means the first 3 contract years in which a PACE organization operates under a
22 PACE program agreement, including any contract year during which the entity operated under a
23 PACE demonstration waiver program.

24 **8.497.4 PACE ORGANIZATION APPLICATION AND WAIVER PROCESS**

- 25 8.497.4.A. ~~Purpose. This section sets forth the application procedures and the process by which a~~
26 ~~PACE organization may request a waiver of certain regulatory requirements, pursuant to 42 CFR~~
27 ~~§ 460.10.~~
- 28 1. Applications. This section sets forth the application procedures for the following:
- 29 a. An entity that seeks approval from the Department as a PACE organization.
- 30 b. A PACE organization that seeks to expand its service area or to add a new PACE center.
- 31 c. A PACE organization that seeks to expand its service area and to add a new PACE
32 center.
- 33 2. Waiver. This section sets forth the process by which a PACE organization may request waiver of
34 certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility
35 in adapting the PACE model to the needs of particular organizations (such as those in rural
36 areas).
- 37 8.497.4.B. Application requirements.

1 1. ~~The application requirements for PACE organizations shall be in accordance with 42 CFR~~
2 ~~§ 460.12.~~

3 2. ~~Letter of intent. Prior to submission of an application. Any individual authorized to act for~~
4 ~~an entity seeking to become a PACE organization or a PACE organization that seeks to~~
5 ~~expand its service area and/or add a PACE center site must notify the Department by~~
6 ~~submitting a letter of intent in the form and manner specified by the Department at least~~
7 ~~90 calendar days before the anticipated application date.~~

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9 3. ~~Department specific application requirements. An entity's application to the Department~~
10 ~~to become a PACE organization or to expand its service area and/or add a PACE center~~
11 ~~must contain information to demonstrate financial and operational stability. This includes,~~
12 ~~but is not limited to:~~

13 a. ~~Financial assets;~~

14 b. ~~Additional owners and/or financially invested organizations;~~

15 c. ~~Risk reserve;~~

16 d. ~~Reinsurance; and~~

17 e. ~~Staff recruitment and retention program.~~

18 4. ~~The Department may allow more than one PACE organization per zip code.~~

19 1. In addition to the application requirements set forth in 42 CFR § 460.10 and 42 CFR § 460.12, an
20 entity that seeks to become a PACE organization or a PACE organization that seeks to expand
21 its service area or add a PACE center, must comply with the following requirements:

22 a. Letter of intent. Submit a letter of intent in the form and manner specified by the
23 Department at least 90 days prior to submitting an application to the Department. The
24 letter must contain, at least, the following information:

25 i. The name and contact information of the person submitting the letter of intent;

26 ii. The name of the entity or PACE organization including the state-approved trade
27 name, also known as "doing business as" name, if different;

28 iii. The proposed service area, including counties, zip codes, and any zip codes that
29 overlap another PACE organization's service area, if applicable; and

30 iv. The proposed location of the PACE center, if applicable.

31 b. Market feasibility study. All entities and PACE organizations must submit a market f
32 easibility study of the proposed service area with the letter of intent. The study
33 must include, but is not limited to at least, the following:

34 i. Estimate of the number of individuals eligible for PACE;

35 ii. Methodology for calculating potential participants;

1 iii. Projected market penetration, including assumptions made to support the rate of
2 projected market penetration, and justification that the entity or PACE
3 organization can reasonably serve the potential participants in the proposed
4 service area;

5 iv. Demonstration of an unmet need for PACE in the proposed service area;

6 v. Evidence the new PACE center, if applicable, has the capacity to adequately
7 serve the potential participants who reside in the proposed service area;

8 vi. Evidence, conducted by a qualified actuary, that the applicant will either be cost
9 neutral or save the Department money;

10 vii. Identification of all competitors and collaborators in the proposed service area;

11 viii. Mean travel time from the farthest points of the service area to the PACE center;

12 ix. Demographics of the proposed service area such as age, race, language, and
13 household income; and

14 x. Health outcomes of the proposed service area such as quality of life, social and
15 economic factors, and physical environment.

16 c. Department-specific application requirements.

17 i. Submission of application. An individual authorized to act for an entity or a PACE
18 organization that seeks to expand its service area or add a PACE center site
19 must submit to the Department a complete application in the form and manner,
20 including timeframes for submission, specified by the Department, that describes
21 how the entity or PACE organization meets all requirements in this part.

22 ii. Submission timeframe. An entity or a PACE organization must submit an
23 application to the Department at least 90 calendar days prior to its anticipated
24 CMS application date.

25 iii. Contents of application. An application to the Department must contain
26 information to demonstrate financial and operational stability, as specified in the
27 Department's application. The application must include, but is not limited to, the
28 following:

29 1. Financial assets;

30 2. Additional owners and/or financially invested organizations;

31 3. Risk reserve;

32 4. Reinsurance;

33 5. Staff recruitment and retention program.

34 2. The Department may allow more than one PACE organization per zip code.

1 8.497.4.C. Department evaluation of applications. The Department evaluates an application in
 2 accordance with the requirements of 42 CFR § 460.18 and Department-specific requirements,
 3 including and based on the following information.

- 4 1. Information contained in the application;
- 5 2. Information obtained by the Department or a Survey Agency through on-site visits or any
 6 other means;
- 7 3. Use of information from a current or prior PACE program agreement or State of Colorado
 8 Contract;
- 9 4. Department and/or state of Colorado budgetary considerations and constraints; and
- 10 5. Financial and operational stability of the applicant.

11 8.497.4.D. Notice of the Department's determination. ~~will be conducted in accordance with 42 CFR §~~
 12 ~~460.20.~~

13 _____
 14 1. Time limit for notification of determination. Within 90 days, or 45 days for applications set
 15 forth in 8.497.4.A.1.b., after an entity submits a complete application to the Department,
 16 the Department takes one of the following actions in the form and manner specified by
 17 the Department:

18 a. Approves the application.

19 b. Denies the application and notifies the entity in writing of the basis for the denial
 20 and the process for requesting reconsideration of the denial.

21 2. Complete application. An application is only considered complete when the Department
 22 receives all information necessary to make a determination regarding approval or denial.

23 3. Additional information requested. If the Department determines that an application is not
 24 complete because it does not include sufficient information to make a determination, the
 25 Department will request additional information within 90 days, or 45 days for applications
 26 set forth in 8.497.4.A.1.b., after the date of submission of the application.

27 a. The time limits in 8.497.4.D.1. do not begin until the Department receives all
 28 requested information and the application is complete.

29 b. If more than 12 months elapse between the date of initial submission of the
 30 application and the entity's response to the Department's request for additional
 31 information, the entity must update the application to provide the most current
 32 information and materials related to the application.

33 4. Date of submission. For purposes of the time limits described in this section, the date that
 34 an application is submitted to the Department is the date on which the application is
 35 delivered to the address designated by the Department.

36 8.497.4.E. Submission and evaluation of waiver requests. A PACE organization, or an entity
 37 submitting an application to become a PACE organization, must submit its waiver request in
 38 accordance with 42 CFR § 460.26. In addition to the requirements set forth in 42 CFR § 460.26,

1 an entity or PACE organization must submit the request to the Department at least 90 calendar
 2 days prior to its anticipated CMS application or waiver submission date.

3 ~~8.497.4.F. Notice of the Department's determination on waiver requests will be conducted in~~
 4 ~~accordance with 42 CFR § 460.28.~~

5 **8.497.5 PACE PROGRAM AGREEMENT**

6 8.497.5.A. A PACE program agreement must meet the requirements set forth at 42 CFR § 460.30.

7 8.497.5.B. Content and terms of PACE program agreement. The PACE program agreement must
 8 include all content required by 42 CFR § 460.32.

9 ~~1. The PACE program agreement must include:~~

10 ~~a. All content required by 42 CFR § 460.32.~~

11 ~~b. The criteria used to determine if an individual's health or safety would be jeopardized by~~
 12 ~~living in a community setting at the time of enrollment.~~

13 8.497.5.C. The duration of the PACE program agreement shall be in accordance with 42 CFR §
 14 460.34.

15 8.497.5.D. The PACE organization must comply with all requirements of the PACE program
 16 agreement. If the PACE program agreement is amended or modified in any way, the amendment
 17 or modification must be automatically incorporated herein as of the effective date of the
 18 amendment or modification, and the PACE organization must comply with all requirements of the
 19 amendment or modification as of that date.

20 **8.497.6 SANCTIONS, ENFORCEMENT ACTIONS, AND TERMINATION**

21 8.497.6.A. Violations for which the Department may impose sanctions.

22 1. In addition to other remedies authorized by law or contract, the Department may impose
 23 any of the sanctions specified in Section 8.497.6.B., if the Department or a Survey
 24 Agency determines that a PACE organization commits any of the violations specified in
 25 42 CFR § 460.40(a) or the following violations:

26 a. Makes payment to or employs or contracts with any individual or organization
 27 that has a criminal conviction as defined in 42 § CFR 460.68(a); or

28 b. Makes payment to individuals and entities excluded by the Office of Inspector
 29 General or included on the preclusion list as pursuant to 42 § CFR 460.86.

30 2. If the Department or a Survey Agency makes a determination that could lead to
 31 termination of a PACE program agreement under Section 8.497.6.C., the Department
 32 may impose any of the sanctions specified in Section 8.497.6.B. If the Department
 33 determines that the circumstances in Section 8.497.6.C.2.a. exist, the Department does
 34 not have to determine that the circumstances in Section 8.497.6.C.2.b. exist prior to
 35 imposing an enrollment and/or payment suspension.

36 8.497.6.B. Suspension of enrollment or payment by the Department.

- 1 1. Enrollment Suspension. If a PACE organization commits one or more violations specified
2 in 42 CFR § 460.40(a), the Department may suspend enrollments of Medicaid
3 beneficiaries or place a limit on enrollments after the date the Department notifies the
4 organization of the violation.
- 5 2. Payment Suspension. If a PACE organization commits one or more violations specified in
6 42 CFR § 460.40(a), for participants enrolled after the date the Department notifies the
7 PACE organization of the violation, the Department may suspend Medicaid payment to
8 the PACE organization.
- 9 3. Term of suspension. A suspension or denial of payment remains in effect until the
10 Department is satisfied that the following conditions are met:
 - 11 a. The PACE organization has corrected the cause of the violation; and
 - 12 b. The violation is not likely to recur.
- 13 4. Restrictions and Conditions. The Department may impose restrictions or conditions on a
14 PACE organization, which may include at least one of the following:
 - 15 a. Retaining a consultant to monitor the effectiveness of corrective measures for a
16 specific period determined by the Department;
 - 17 b. Monitoring the effectiveness of corrective measures by the Department for a
18 specific period; or
 - 19 c. Requiring additional training for personnel, owners, or operators of the PACE
20 organization.
- 21 5. Notification and Plan Requirements.
 - 22 a. If the Department imposes any restriction or condition that is not the result of a
23 serious and immediate threat to the health, safety, or welfare of a PACE
24 participant, the Department shall notify the PACE organization of the restriction
25 or condition in writing.
 - 26 b. If the Department imposes any restriction or condition that is the result of a
27 serious and immediate threat to the health, safety, or welfare of a PACE
28 participant, the Department shall notify the PACE organization of the restriction
29 or condition in writing, by telephone, or in person during an on-site visit.
 - 30 i. The PACE organization must remedy the circumstances creating the
31 harm or likelihood of harm immediately upon receiving notice of the
32 restriction or condition.
 - 33 c. If the Department initially provides notice of a restriction or condition by
34 telephone or in person, the Department shall send written confirmation of the
35 restriction or condition to the PACE organization.
 - 36 d. A PACE organization must complete corrective action as specified in Section
37 8.497.13.C.1.
- 38 8.497.6.C. Termination of a PACE program agreement. The Department may terminate a PACE
39 program agreement for cause, pursuant to 42 CFR § 460.50.

- 1 8.497.6.D. Transitional care during termination. The PACE organization must meet the transitional
2 care requirements set forth in 42 CFR § 460.52.
- 3 8.497.6.E. Termination procedures.
- 4 1. Except as provided in Section 8.497.6.E.2., if the Department terminates a PACE
5 program agreement with a PACE organization, it will furnish the PACE organization with
6 a reasonable opportunity to develop and implement a corrective action plan to correct the
7 deficiencies that were the basis of the Department's determination that cause exists for
8 termination:
- 9 2. The Department may terminate a PACE program agreement and PACE contact without
10 invoking the procedures in Section 8.497.6.E.1. if the Department determines that a delay
11 in termination, resulting from compliance with these procedures before termination, would
12 pose an imminent and serious risk to the health of participants enrolled with the
13 organization..
- 14 **8.497.7 PACE ADMINISTRATIVE REQUIREMENTS**
- 15 8.497.7.A. PACE organizational structure. The PACE organizational structure must comply with the
16 requirements set forth in 42 CFR § 460.60.
- 17 8.497.7.B. Governing body. The governing body of the PACE organization must comply with the
18 requirements set forth in 42 CFR § 460.62
- 19 8.497.7.C. Compliance oversight requirements. The PACE organization must adopt and implement
20 compliance oversight requirements in accordance with 42 CFR § 460.63.
- 21 8.497.7.D. Personnel qualifications for staff with direct participant contact. The PACE organization
22 must comply with the personnel qualifications set forth in 42 CFR § 460.64.
- 23 8.497.7.E. Training. The PACE organization must comply with the training requirements set forth in
24 42 CFR § 460.66.
- 25 ~~1. The PACE organization must provide training to maintain and improve the skills and~~
26 ~~knowledge of each staff member with respect to the individual's specific duties that~~
27 ~~results in their continued ability to demonstrate the skills necessary for the performance~~
28 ~~of the position.~~
- 29 21. In addition to the general qualification requirements specified in 42 CFR § 460.66, all
30 PACE organization personnel having direct participant contact must complete the
31 following trainings annually. Newly hired personnel must complete the training before
32 working independently:
- 33 a. Mandatory reporting of adult mistreatment. Staff members must complete training
34 that includes reporting requirements as specified in C.R.S. § 18-6.5-108;
- 35 b. The service determination process as specified in Section 8.497.9.G; and
- 36 c. Dementia diseases and related disabilities. The training must be culturally
37 competent and include at least the following content:
- 38 i. Activities of daily living. Dementia disease and related disabilities.

- 1 ii. ~~Care planning~~Person-centered care.
- 2 iii. ~~Dementia diseases and related disabilities.~~Care planning.
- 3 iv. ~~Dementia-related behaviors and communication.~~Activities of daily living.
- 4 v. ~~Person-centered care~~Dementia-related behaviors and communication.
- 5 3. All orientation, training, competency, and personnel action documentation must be
6 retained in the personnel files.
- 7 8.497.7.F. Program integrity. The PACE organization must comply with the program integrity
8 requirements set forth in 42 CFR § 460.68.
- 9 8.497.7.G. Contracted services. The PACE organization must comply with the contracted service
10 requirements set forth in 42 CFR § 460.70.
- 11 8.497.7.H. Oversight of direct participant care. The PACE organization must oversee direct
12 participant care in accordance with the requirements set forth in 42 CFR § 460.71.
- 13 8.497.7.I. Physical environment. The PACE center must meet the physical environment
14 requirements set forth in 42 CFR § 460.72.
- 15 8.497.7.J. Infection control. The PACE organization must comply with the infection control
16 requirements set forth in 42 CFR § 460.74.
- 17 8.497.7.K Transportation services.
- 18 1. Safety, accessibility, and equipment. A PACE organization's transportation services must
19 be safe, in good working order, accessible, and equipped to meet the needs of the
20 participant population and meet the transportation services requirements set forth in 42
21 CFR § 460.76.
- 22 2. Maintenance of vehicles. In addition to the requirements set forth in 42 CFR § 460.76(b),
23 PACE organizations must ensure safety inspections include the inspection of items as
24 described in Rules Regulating Transportation by Motor Vehicle, 4 CCR 723-6; § 6103
25 and § 6104. 4 CCR 723-6; § 6103-6104 (2024) is hereby incorporated by reference. The
26 incorporation of 4 CCR 723-6; § 6103-6104 (2024) excludes later amendments to, or
27 editions of the referenced material. Pursuant to § 24-4-103(12.5), C.R.S., the Department
28 maintains copies of this incorporated text in its entirety, available for public inspection
29 during regular business hours at 303 E. 17th Ave., Denver, CO, 80203. Certified copies
30 of incorporated materials are provided at cost upon request.
- 31 a. ~~If the PACE organization owns, rents, or leases transportation vehicles, it must maintain~~
32 ~~these vehicles in accordance with the manufacturer's recommendations.~~
- 33 b. ~~If a contractor provides transportation services, the PACE organization must ensure that~~
34 ~~the vehicles are maintained in accordance with the manufacturer's recommendations.~~
- 35 c. ~~Safety inspections must include the inspection of items as described in Rules Regulating~~
36 ~~Transportation by Motor Vehicle, 4 CCR 723-6; § 6103 and § 6104.~~
- 37 3. Drivers.

- 1 a. PACE organizations must ensure that each driver meets the following
2 requirements:
- 3 i. Drivers must be 18 years of age or older;
- 4 ii. Have at least one year of driving experience;
- 5 iii. Possess a valid Colorado driver's license.
- 6 iv. Provide a copy of their current Colorado motor driving vehicle record,
7 with the previous seven years of driving history; and
- 8 v. Complete a Colorado or National-based criminal history record check.
- 9 b. Drivers must be disqualified from serving as drivers for any program participants
10 for any of the following reasons:
- 11 i. A conviction of substance abuse occurring within the seven (7) years
12 preceding the date the criminal history record check is completed;
- 13 ii. A conviction in Colorado, at any time, of any Class 1 or 2 felony under
14 Title 18, C.R.S.;
- 15 iii. A conviction in Colorado, within seven (7) years preceding the date the
16 criminal history record check is completed, of a crime of violence, as
17 defined in C.R.S. § 18-1.3-406(2);
- 18 iv. A conviction in Colorado, within four (4) years preceding the date the
19 criminal history record check is completed, of any Class 4 felony under
20 Title 18, Articles 2, 3, 3.5, 4, 5, 6, 6.5, 8, 9, 12, or 15, C.R.S.;
- 21 v. A conviction of an offense in any other state that is comparable to any
22 offense listed in subparagraphs (f)(II)(A) through (D) within the same
23 time periods as listed in subparagraphs (f)(II)(A) through (D) of Rules
24 Regulating Transportation by Motor Vehicle, 4 C.C.R. 723-6; § 6114. [4](#)
25 [CCR 723-6; § 6114 \(2024\) is hereby incorporated by reference. The](#)
26 [incorporation of 4 CCR 723-6; § 6114 \(2024\) excludes later amendments](#)
27 [to, or editions of the referenced material. Pursuant to § 24-4-103\(12.5\),](#)
28 [C.R.S., the Department maintains copies of this incorporated text in its](#)
29 [entirety, available for public inspection during regular business hours at](#)
30 [303 E. 17th Ave., Denver, CO, 80203. Certified copies of incorporated](#)
31 [materials are provided at cost upon request.](#);
- 32 vi. A conviction in Colorado, at any time, of a felony or misdemeanor
33 unlawful sexual offense against a child, as defined in § 18-3-411, C.R.S.,
34 or of a comparable offense in any other state or in the United States at
35 any time;
- 36 vii. A conviction in Colorado within two (2) years preceding the date the
37 criminal history record check is completed of driving under the influence,
38 as described in § 42-4-1301(1)(f), C.R.S. or driving with excessive
39 alcoholic content, as described in §42-4-1301(1)(g), C.R.S.;

1 year, and must establish and implement a written plan to ensure that care is appropriately
2 furnished.

3 2. Provision of services.

4 a. The PACE organization must provide services in accordance with 42 CFR §
5 460.98(b).

6 b. The PACE organization must visit each participant in-person or via telehealth
7 across all care settings as often as the participant's condition requires, but no
8 less than once each calendar month.

9 i. If a participant does not receive a visit during a calendar month, the
10 PACE organization must notify the Department, in writing, within 15
11 calendar days of the following calendar month. The notice must explain
12 the reason(s) why the participant did not receive a visit.

13 ii. For the purposes of this requirement, a visit must be provided directly by
14 PACE staff or a contracted specialist. The delivery of items or
15 medications and services routinely provided by a contracted residential
16 care provider are not considered a visit.

17 iii. If the PACE organization provides these visits via telehealth, the PACE
18 organization must ensure the telehealth delivery option meets the
19 following requirements:

20 1) Participants must have an informed choice between in-person
21 and telehealth services;

22 2) The use of the telehealth delivery option will not prohibit or
23 discourage the use of in-person services;

24 3) Telehealth will not be used for the provider's convenience; and

25 4) Telehealth must be provided using technology compliant with
26 Health Insurance Portability and Accountability Act of 1996
27 (HIPAA) Privacy, Security and Breach Notification Rules.

28 iv. The telehealth permissions in this section do not apply to the in-person
29 assessment and reassessment requirements as described in 8.497.8.G.

30 3. Timeframes for arranging and providing services. The PACE organization must comply
31 with the requirements set forth in 42 CFR § 460.98(c).

32 4. Minimum services furnished at each PACE center. At a minimum, the PACE organization
33 must provide the services set forth in 42 CFR § 460.98(d)(e) at each PACE center.

34 5. PACE center operation. The PACE organization must operate its center(s) in accordance
35 with 42 CFR § 460.98(e)(4).

36 a. Services at the PACE center must be provided consistent with any applicable
37 standards of practice for that service, and, when applicable, by staff with the
38 requisite qualifications to perform the service.

1 ~~65.~~ Center attendance. The frequency of a participant's attendance at a center is determined
2 by the interdisciplinary team, based on the needs and preferences of each participant.

3 8.497.8.E. Emergency care. The PACE organization must comply with the emergency care
4 requirements set forth in 42 CFR § 460.100.

5 8.497.8.F. Interdisciplinary team. The PACE organization must comply with the interdisciplinary
6 team requirements set forth in 42 CFR § 460.102.

7 8.497.8.G. Participant assessment. The PACE organization must comply with the assessment and
8 plan of care requirements set forth in 42 CFR § 460.104.

9 ~~1.~~ ~~The PACE organization must comply with the assessment and plan of care requirements~~
10 ~~set forth in 42 CFR § 460.104.~~

11 ~~2.~~ ~~Unscheduled reassessments. In addition to the requirements set forth in 42 CFR §~~
12 ~~460.104(d), as it relates to a participant being discharged from a hospital, the appropriate~~
13 ~~members of the interdisciplinary team, as identified by the interdisciplinary team, must~~
14 ~~conduct an in-person assessment within 72 hours of a participant's hospital discharge for~~
15 ~~a participant who was admitted for 24 hours or more.~~

16 8.497.8.H. Plan of care.

17 1. The PACE organization must comply with the plan of care requirements set forth in 42
18 CFR § 460.106.

19 2. Residential care provider involvement in plan of care. For participants receiving
20 residential care, the PACE organization must seek input from ~~include~~ residential care
21 providers in the evaluation of the plan of care and share the plan of care with residential
22 care providers.

23 **8.497.9 PARTICIPANT RIGHTS**

24 8.497.9.A. Bill of rights. The PACE organization must comply with the requirements set forth in 42
25 CFR § 460.110.

26 8.497.9.B. Specific rights to which a participant is entitled. The PACE organization must comply with
27 the requirements set forth in 42 CFR § 460.112.

28 1. Information disclosure. In addition to the requirements set forth in 42 CFR § 460.112(~~cb~~),
29 the participant has the following rights:

30 a. To receive a current list of the employees of the PACE organization who furnish
31 direct care to the participant upon enrollment and upon request. At a minimum,
32 the list must include each discipline of the interdisciplinary team as set forth in 42
33 CFR § 460.102(b).

34 b. To have an equal opportunity to receive meaningful communication and to
35 participate fully in discussions involving the PACE program, services, activities,
36 eligibility, enrollment and other benefit information, in the language preferred by
37 the participant.

38 8.497.9.C. Restraints. The PACE organization must comply with the requirements set forth in 42
39 CFR § 460.114.

- 1 8.497.9.D. Explanation of rights. The PACE organization must comply with the requirements set
2 forth in 42 CFR § 460.116 and must display the contact information for the Colorado PACE
3 Ombudsman in a prominent place in the PACE center.
- 4 8.497.9.E. Violation of rights. The PACE organization must have established documented
5 procedures to respond to and rectify a violation of a participant's rights.
- 6 8.497.9.F. Grievance process. The PACE organization must comply with the requirements set forth
7 in 42 CFR § 460.120.
- 8 8.497.9.G. Service determination process.
- 9 1. The PACE organization must comply with the requirements set forth in 42 CFR §
10 460.121.
- 11 2. PACE organization decisions to reduce or terminate services.
- 12 a. If the PACE organization ~~terminates or reduces~~ reduces or terminates a service,
13 without the participant requesting the ~~reduction or termination~~ termination or
14 reduction, the PACE organization must provide written notice to the participant of
15 the right to file a service determination request to continue the service.
- 16 b. This requirement does not apply to services with a specified end date.
- 17 8.497.9.H. PACE organization's appeals process.
- 18 1. The PACE organization must comply with the requirements set forth in 42 CFR §
19 460.122.
- 20 2. A PACE participant must exhaust the internal appeals process described in this part prior
21 to requesting a State Fair Hearing as described in Sections 8.497.9.I. and ~~40 CCR 2505-~~
22 ~~40~~ 8.057.
- 23 8.497.9.I. Additional Appeal Rights Under Medicare or Medicaid.
- 24 1. A PACE organization must comply with the requirements set forth in 42 CFR § 460.124.
- 25 2. Medicaid participants have the right to a state fair hearing under Section 8.057. Appeals
26 must be filed within 60 calendar days of the date of the notice of ~~adverse~~ action.
- 27 **8.497.10 QUALITY IMPROVEMENT**
- 28 8.497.10.A. Quality improvement program and plan. A PACE organization must establish, implement,
29 maintain, and evaluate an effective data-driven quality improvement program and plan, pursuant
30 to 42 CFR § 460.130 and 460.132, that contains all requirements set forth in 42 CFR § 460.134.
- 31 8.497.10.B. Internal quality improvement activities. A PACE organization must comply with the
32 requirements set forth in 42 CFR § 460.136.
- 33 8.497.10.C. Committees with community input. A PACE organization must comply with the
34 requirements set forth in 42 CFR § 460.138.

- 1 4. ~~Minimum program requirements. A PACE organization's quality improvement program~~
2 ~~must include, but is not limited to, the use of objective measures to demonstrate~~
3 ~~improved performance with regard to the following:~~

4 **8.497.11 PARTICIPANT ENROLLMENT AND DISENROLLMENT**

5 8.497.11.A. Eligibility to enroll in a PACE program. A PACE organization must comply with the
6 requirements set forth in 42 CFR § 460.150.

7 8.497.11.B. Enrollment process.

8 1. A PACE organization must comply with the requirements set forth in 42 CFR § 460.152.

9 2. Additional intake process requirements.

10 a. At least one member of an interdisciplinary team must assess the individual in
11 person in the individual's place of residence prior to enrollment. This assessment
12 must be completed by one of the following disciplines: a Registered Nurse,
13 Physical Therapist, Occupational Therapist, Home Care Coordinator, or
14 appropriate members of an interdisciplinary team as appointed by an
15 interdisciplinary team.

16 i. Registered Nurse.

17 ii. Physical Therapist.

18 iii. Occupational Therapist.

19 iv. Home Care Coordinator.

20 v. Other appropriate members of an interdisciplinary team as identified by an
21 interdisciplinary team.

22 b. The appropriate members of an interdisciplinary team, as identified by an
23 interdisciplinary team, must review and discuss each potential participant and
24 decide to approve or deny the individual's enrollment based on that review.

25 8.497.11.C. Enrollment agreement. If the potential participant meets the eligibility requirements and
26 wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the
27 information required by 42 CFR § 460.154.

28 8.497.11.D. Other enrollment procedures. The PACE organization must comply with the requirements
29 set forth in 42 CFR § 460.156.

30 8.497.11.E. Effective date of enrollment. A participant's enrollment in the program is effective on the
31 first day of the calendar month following the date the PACE organization receives the signed
32 enrollment agreement.

33 8.497.11.F. Continuation of enrollment.

34 1. The PACE organization must comply with the requirements set forth in 42 CFR §
35 460.160.

- 1 2. In addition to the waiver of annual requirement regulations set forth in 42 CFR §
2 460.160(b)(1), a participant who continues to meet nursing facility level of care during
3 their first annual recertification, is permanently waived from the annual recertification
4 requirement.
- 5 3. In addition to the deemed continued eligibility regulations set forth in 42 CFR §
6 460.160(b)(2), the following apply:
- 7 a. If the PACE organization believes the participant would be expected to meet the
8 nursing facility level of care within the next 6 months, the organization must
9 submit a request for deemed continued eligibility to the Department in the form
10 and manner specified by the Department.
- 11 b. Upon receipt of all requested information, the Department will make a
12 determination.
- 13 c. The Department will notify the PACE organization of the Department's decision in
14 writing within 15 calendar days upon receipt of all requested information in a
15 timely manner.
- 16 d. If the Department determines the participant does not qualify for deemed
17 continuous eligibility, the PACE organization must follow involuntary
18 disenrollment procedures as described in Section 8.497.11.H., unless the
19 participant chooses to voluntarily disenroll.
- 20 8.497.11.G. Voluntary disenrollment. The PACE organization must comply with the voluntary
21 disenrollment requirements set forth in 42 CFR § 460.162.
- 22 8.497.11.H. Involuntary disenrollment.
- 23 1. The PACE organization must comply with the involuntary disenrollment requirements set
24 forth in 42 CFR § 460.164.
- 25 2. In addition to the reasons for involuntary disenrollment regulations set forth in 42 CFR §
26 460.164(b), the following applies for involuntary disenrollment:
- 27 a. As it relates to 42 CFR § 460.164(b)(1) and 460.164(b)(2), the PACE
28 organization must provide written notice to the participant, designated
29 representative, or both explaining the amount due.
- 30 ~~b. A participant may be involuntarily disenrolled if the participant engages in~~
31 ~~noncompliant behavior, as described in 42 CFR § 460.164(e).~~
- 32 3. Involuntary disenrollment request requirements.
- 33 a. A PACE organization must submit an involuntary disenrollment request to the
34 Department in a timely manner and in the form and manner specified by the
35 Department.
- 36 b. Before an involuntary disenrollment is effective, the Department must review it
37 and determine in a timely manner that the PACE organization has adequately
38 documented acceptable grounds for disenrollment.

- 1 8.497.11.I. Disenrollment responsibilities. The PACE organization must comply with the
2 disenrollment responsibilities requirements set forth in 42 CFR § 460.166.
- 3 8.497.11.J. Reinstatement in Medicaid programs. The PACE organization must comply with the
4 reinstatement in other Medicaid program requirements set forth in 42 CFR § 460.168.
- 5 8.497.11.K. Reinstatement in PACE. The PACE organization must comply with the reinstatement in
6 PACE requirements set forth in 42 CFR § 460.170.
- 7 8.497.11.L. Documentation of disenrollment. The PACE organization must comply with the
8 documentation of disenrollment requirements set forth in 42 CFR § 460.172.

9 **8.497.12 PAYMENT**

- 10 8.497.12.A. Medicaid payment.
- 11 1. The PACE organization shall receive Medicaid payments in accordance with 42 CFR §
12 460.182.
- 13
- 14 2. The Department may also recover, at the Department's discretion, payments made to the
15 PACE organization in error for any reason, including, but not limited to, overpayments,
16 improper payments, and excess funds received by the PACE organization by deduction
17 from subsequent payments as specified in the PACE contract, deduction from any
18 payment due under any other contracts, grants or agreements between Colorado and the
19 PACE organization, or by any other appropriate method for collecting debts owed to the
20 Department.
- 21 3. Payment Reconciliations. A PACE organization must adhere to the terms related to the
22 participant-specific amount reconciliation, participant-specific reconciliation payments,
23 and annual reconciliation as specified in the PACE contract.
- 24 8.497.12.B. Post-eligibility treatment of income.
- 25 1. The Department may provide for post-eligibility treatment of income for PACE
26 participants as set forth in Sections 8.482.33 and [8.7202.BB8-485-80](#).
- 27 2. Post-eligibility treatment of income is applied, as specified in 42 CFR § 460.184(b).
- 28 8.497.12.C. PACE premiums. The PACE organization must comply with the PACE premiums
29 requirements set forth in 42 CFR § 460.186.

30 **8.497.13 STATE MONITORING**

- 31 8.497.13.A. Monitoring during trial period. During the trial period, the Department conducts
32 comprehensive annual reviews of the operation of a PACE organization, in accordance with the
33 requirements and scope set forth in 42 CFR § 460.190.
- 34 8.497.13.B. Ongoing monitoring after trial period. At the conclusion of the trial period, the Department
35 continues to conduct review of a PACE organization, as appropriate, in accordance with the
36 requirements set forth in 42 CFR § 460.192.

- 1 8.497.13.C. Corrective action. The PACE organization must comply with the requirements set forth in
2 42 CFR § 460.194. In addition, as it relates to a corrective action plan, a PACE organization
3 must:
- 4 1. Submit an acceptable corrective action plan in the form, manner and timeframe specified
5 by the Department, when corrective action is deemed necessary by the Department. An
6 acceptable plan must include but is not limited to:
 - 7 a. The corrective action the PACE organization will take on behalf of the
8 participants affected by the deficient practice;
 - 9 b. How the PACE organization will identify other participants who could be affected
10 by the same deficient practice;
 - 11 c. The measures or systemic changes the PACE organization has or will implement
12 to ensure the deficient practice will not recur, including the responsible staff;
 - 13 d. How the PACE organization will monitor the corrective action to ensure the
14 deficient practice is corrected and the solution is sustained, including the
15 responsible staff; and
 - 16 e. The date each plan was or will be completed.
- 17 8.497.13.D. Disclosure of review results. The PACE organization [and the Department](#) must comply
18 with the requirements set forth in 42 CFR § 460.196.
- 19 [8.497.13.E Disclosure of compliance deficiencies. The Department may require a PACE organization
20 to disclose to its PACE participants or potential PACE participants the PACE organization's
21 performance and contract compliance deficiencies in a manner specified by the Department.](#)
- 22 **8.497.14 DATA COLLECTION, RECORD MAINTENANCE, AND REPORTING**
- 23 8.497.14.A. Maintenance of records and reporting of data. The PACE organization must collect data,
24 maintain records, and submit reports as required by the Department and in accordance with 42
25 CFR § 460.200.
- 26 8.497.14.B. Participant health outcomes data. The PACE organization must comply with the
27 requirements set forth in 42 CFR § 460.202.
- 28 8.497.14.C. Financial recordkeeping and reporting requirements. The PACE organization must
29 comply with the requirements set forth in 42 CFR § 460.204.
- 30 8.497.14.D. Financial statements.
- 31 1. The PACE organization must comply with the financial statement reporting requirements
32 set forth in 42 CFR § 460.208.
 - 33 2. Annual financial report. A PACE organization must submit the financial data as specified
34 in the PACE contract.
- 35 8.497.14.E. Medical records.
- 36 1. A PACE organization must maintain a single, comprehensive medical record for each
37 participant in accordance with the requirement set forth in 42 CFR § 460.210.

1 through the designated Fiscal Agent is accurate to the best of the PACE organization's
2 information, knowledge and belief.

3 a. The encounter data submission must comply with the format prescribed by the
4 Department or its designated Fiscal Agent. The encounter data submission must
5 include:

6 i. The name and provider ID of any ordering, referring, prescribing, or
7 attending provider and information on the rendering, operating, or other
8 professional.

9 1) Generic provider IDs shall be used only when specific Provider
10 IDs remain unknown after reasonable inquiry.

11 2) NPI numbers of providers not enrolled in Medicaid must be
12 reported.

13 3) If the NPI is not available, the PACE organization must report the
14 tax payer ID.

15 ii. The PACE organization must require subcontractors and non-contracting
16 providers to provide encounter data to the PACE organization.

17 b. The PACE organization must obtain an Annual Signed Encounter Data
18 Certification from either the Chief Executive Officer or the Chief Financial Officer,
19 or an individual who has delegated authority to sign for, and who reports directly
20 to, the Chief Executive Officer or Chief Financial Officer.

21 c. The PACE organization must provide an Annual Signed Encounter Data
22 Certification to the Department or its designees covering all of the submissions
23 for the preceding year of Encounter Data as specified in the PACE contract.
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