

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES

SUBJECT: Program of All-Inclusive Care for the Elderly (PACE) Provider Manual, 20 CAR pt. 640

DESCRIPTION:

Statement of Necessity

The Division of Aging and Adult Behavioral Services (DAABHS) issues a new, streamlined Program of All-Inclusive Care for the Elderly (PACE) Medicaid Provider Manual. The primary need for revision is recent changes in the federal PACE regulations found at 42 CFR Part 460 and to comply with Act 144 of the 2025 Regular Session of the State of Arkansas 95th General Assembly. The reorganized and revised manual is more conducive for provider reference and use.

Summary of Changes

This new PACE Manual makes responsive changes to federal regulations regarding nomenclature for plans of care, medical personnel requirements, care coordination requirements and timelines, plan of care requirements, recipient rights, grievances and appeals, and licensure exemptions for PACE programs. The updates pursuant to Act 144 exempt PACE providers from the licensing requirements for home healthcare services. The current manual is being repealed in this rule.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on May 18, 2026. The agency indicated that it received no comments.

Lacey Johnson, an attorney with the Bureau of Legislative Research, asked the following questions and received the following responses:

1. The list of participant rights in 202.200 mirrors the list in 42 CFR § 460.112, with one exception. Is there a reason “right to treatment” is included in the CFR (§ 460.112(b)) but not in the provider manual? **RESPONSE:** [The agency changed the proposed rule to conform to the federal language.]
2. The list of medical specialty services in 220.200(L) mirrors the list in 42 CFR § 460.70, with one exception. Is there a reason “palliative medicine” is included in the CFR (§ 460.70(a)(1)(xvi)) but not in the provider manual? **RESPONSE:** [The agency changed the proposed rule to conform to the federal language.]

The proposed effective date is September 1, 2026.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The Department of Human Services has the responsibility to administer assigned forms of public assistance and is specifically authorized to maintain an indigent medical care program (Arkansas Medicaid). *See Ark.*

Code Ann. §§ 20-76-201(1), 20-77-107(a)(1). The Department has the authority to make rules that are necessary or desirable to carry out its public assistance duties. Ark. Code Ann. § 20-76-201(12). The Department and its divisions also have the authority to promulgate rules as necessary to conform their programs to federal law and receive federal funding. Ark. Code Ann. § 25-10-129(b).

This rule implements Act 144 of 2025. The Act, sponsored by Senator Dan Sullivan, exempted providers in the Program of All-Inclusive Care for the Elderly from the licensing requirements for home healthcare services.



Office of Policy and Rules

P.O. Box 1437, Slot S295, Little Rock, AR 72203-1437

P: 501.320.6383 F: 501.404.4619

April 17, 2026

Mrs. Rebecca Miller-Rice
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
#1 Capitol, 5th Floor
Little Rock, AR 72201

Dear Mrs. Rebecca Miller-Rice:

Re: Program of All-Inclusive Care for the Elderly (PACE) Provider Manual Update

Please arrange for this rule to be reviewed by the ALC-Administrative Rules Subcommittee. If you have any questions or need additional information, please contact me at 501-320-6383 or by emailing Mac.E.Golden@dhs.arkansas.gov.

Sincerely,

Mac Golden

Mac Golden
Attorney III
Office of Policy and Rules

Attachments

**QUESTIONNAIRE FOR FILING PROPOSED RULES WITH
THE ARKANSAS LEGISLATIVE COUNCIL**

DEPARTMENT Department of Human Services
BOARD/COMMISSION Division of Aging, Adult, and Behavioral Health Services
BOARD/COMMISSION DIRECTOR Jay Hill
CONTACT PERSON Mac Golden
ADDRESS P.O Box 1437, Slot S295, Little Rock, AR 72203-1437
PHONE NO. (501) 320-6383 EMAIL Mac.E.Golden@dhs.arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
Jay Hill
PRESENTER EMAIL(S) Jay.Hill@dhs.arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

1. What is the official title of this rule?
Program of All-Inclusive Care for the Elderly (PACE) Provider Manual Update
2. What is the subject of the proposed rule? 20 CAR Part 640
3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☒

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☒ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☒

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire? _____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☒ No ☐

If yes, please provide the federal statute, rule, and/or regulation citation.

[42 CFR Part 460](#)

6. Is this rule required to comply with a *state* statute or rule? Yes ☒ No ☐

If yes, please provide the state statute and/or rule citation.

[Arkansas Code Annotated 20-10-801 \(Act 144 of 2025\)](#)

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☒

If yes, please list the rules being repealed.

If no, please explain.

[Exception from the Governor](#)

8. Is this a new rule? Yes ☒ No ☐

Does this repeal an existing rule? Yes ☒ No ☐

If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☐ No ☒

If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Arkansas Code §§ 20-76-201, 20-77-107, and 25-10-129

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☒ No ☐

If yes, please provide the year of the act(s) and act number(s).

Act 144 of 2025

11. What is the reason for this proposed rule? Why is it necessary?

The Division of Aging and Adult Behavioral Services (DAABHS) issues a new, streamlined Program of All-Inclusive Care for the Elderly (PACE) Medicaid Provider Manual. The primary need for revision is recent changes in the federal PACE regulations found at 42 CFR Part 460 and to comply with Act 144 of the 2025 Regular Session of the State of Arkansas 95th General Assembly. The reorganized and revised manual is more conducive for provider reference and use.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

ar.gov/dhs-proposed-rules

13. Will a public hearing be held on this proposed rule? Yes ☐ No ☒

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. [05/18/2026](#)

15. What is the proposed effective date for this rule? [9/1/2026](#)

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

[Unknown.](#)

19. Is the rule expected to be controversial? Yes ☐ No ☒

If yes, please explain.

NOTICE OF RULE MAKING

The Department of Human Services (DHS) announces for a public comment period of thirty (30) calendar days a notice of rulemaking for the following proposed rule under one or more of the following chapters, subchapters, or sections of the Arkansas Code: §§ 20-76-201, 20-77-107, and 25-10-129. The proposed effective date is August 1, 2026. There is no fiscal impact.

The Director of the Division of Aging and Adult Behavioral Services (DAABHS) issues a new, streamlined Program of All-Inclusive Care for the Elderly (PACE) Medicaid Provider Manual. These changes are necessary to ensure that federal regulations concerning PACE plans of care, timelines, grievances, appeals, oversight, and service delivery are reflected in PACE Medicaid Provider Manual. To ensure consistency in nomenclature, "treatment plan" is being changed to "plan of care" to mirror federal regulations. The division also updates the manual to comply with Act 144 of the 2025 Regular Session of the State of Arkansas 95th General Assembly that provides that PACE Programs in good standing are exempted from home healthcare services licensing requirements.

The proposed rule is available for review at the Department of Human Services (DHS) Office of Policy and Rules, 2nd floor Donaghey Plaza South Building, 7th and Main Streets, P. O. Box 1437, Slot S295, Little Rock, Arkansas 72203-1437. You may also access and download the proposed rule at ar.gov/dhs-proposed-rules. Public comments can be submitted in writing at the above address or at the following email address: ORP@dhs.arkansas.gov. All public comments must be received by DHS no later than May 23, 2026. Please note that public comments submitted in response to this notice are considered public documents. A public comment, including the commenter's name and any personal information contained within the public comment, will be made publicly available and may be seen by various people.

If you need this material in a different format, such as large print, contact the Office of Policy and Rules at 501-320-6428. The Arkansas Department of Human Services is in compliance with Titles VI and VII of the Civil Rights Act and is operated, managed, and delivers services without regard to religion, disability, political affiliation, veteran status, age, race, color, or national origin. 4502292178

Jay Hill, Director
Division of Aging, Adult and Behavioral Health Services

From: [Legal Ads](#)
To: [Lisa Teague](#)
Subject: Re: Full Run AD (r. 287)
Date: Monday, April 20, 2026 5:34:01 PM
Attachments: [image001.png](#)

CAUTION: External Email

I'm very sorry about that, Lisa. I'll have that unintended duplicate no-charged.

I've scheduled this corrected version for Fri 4/24, Sat 4/25, and Sun 4/26.

Thanks,

Gregg Sterne, Legal Advertising
Arkansas Democrat-Gazette
legalads@arkansasonline.com

From: "Lisa Teague" <Lisa.Teague@dhs.arkansas.gov>
To: "legalads" <legalads@arkansasonline.com>
Cc: "Mac Golden" <Mac.E.Golden@dhs.arkansas.gov>
Sent: Monday, April 20, 2026 9:14:37 AM
Subject: FW: Full Run AD (r. 287)

Good morning,

I didn't see where the notice I sent you for rule 287 ran in the newspaper Sunday or today. It looks like a different notice was duplicated instead. I have changed the dates on the attached notice. Please run it on the dates below:

- Friday, April 24, 2026
- Saturday, April 25, 2026
- Sunday, April 26, 2026

I am aware that the print version will only be provided to all counties on Sundays.

Invoice to: AR Dept of Human Services

P.O. Box 1437

Slot S535

Little Rock, AR 72203

ATTN: Lakeya Gipson

(Lakeya.Gipson@dhs.arkansas.gov)

Or email invoices to: dms.invoices@arkansas.gov

NOTE: Please reply to this email using "REPLY ALL"

From: Lisa Teague

Sent: Wednesday, April 15, 2026 9:09 AM

To: legalads@arkansasonline.com

Cc: Jack Tiner <jack.tiner@dhs.arkansas.gov>; Mac Golden <Mac.E.Golden@dhs.arkansas.gov>; Lakeya Gipson <Lakeya.Gipson@dhs.arkansas.gov>; Elaine Stafford <elaine.stafford@dhs.arkansas.gov>

Subject: Full Run AD (r. 287)

Good morning,

Please run the attached Notice of Public Hearing in the *Arkansas Democrat-Gazette* on the following days:

- Sunday, April 19, 2026
- Monday, April 20, 2026
- Tuesday, April 21, 2026

I am aware that the print version will only be provided to all counties on Sundays.

Invoice to: **AR Dept of Human Services**

P.O. Box 1437

Slot S535

Little Rock, AR 72203

ATTN: Lakeya Gipson

(Lakeya.Gipson@dhs.arkansas.gov)

Or email invoices to: dms.invoices@arkansas.gov

NOTE: Please reply to this email using "REPLY ALL"



Lisa Teague

Rules & Regulations Coordinator

Arkansas Department of Human Services

Office of Policy and Rules

P: 501.396.6428

lisa.teague@dhs.arkansas.gov

humanservices.arkansas.gov

Privacy Notice: This email may contain confidential information protected by state/federal laws. If you are not the intended recipient, please let the sender know, and delete the message/attachment(s) from your system.

From: [Lisa Teague](#)
To: [Arkansas Register](#)
Cc: [Jack Tiner](#); [Mac Golden](#); [Lakeya Gipson](#); [Amanda Cox](#)
Subject: DHS/DMS - Proposed Filing -Program of All-Inclusive Care for the Elderly (PACE) Provider Manual Update (r. 287)
Date: Friday, April 17, 2026 8:02:00 AM
Attachments: [SOS Initial PACE Provider Manual Update.pdf](#)
[image001.png](#)

Good morning,

Attached is the proposed filing for “Program of All-Inclusive Care for the Elderly (PACE) Provider Manual Update”. The public notice will appear in the Arkansas Democrat-Gazette April 19, 20, & 21st, 2026. The public comment period ends 05/18/26. Please post.

Thank you,



Lisa Teague

Rules & Regulations Coordinator
Arkansas Department of Human Services
Office of Policy and Rules

P: 501.396.6428

lisa.teague@dhs.arkansas.gov

humanservices.arkansas.gov

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FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Department of Human Services

BOARD/COMMISSION Division of Aging, Adult, and Behavioral Health Services

PERSON COMPLETING THIS STATEMENT Michael Munnerlyn

TELEPHONE NO. (501) 320-6047 **EMAIL** Michael.Munnerlyn@dhs.arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE PACE Manual Update

1. Does this proposed, amended, or repealed rule have a financial impact?
Yes ☐ No ☒
2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
Yes ☒ No ☐
3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☒ No ☐

If no, please explain:

(a) how the additional benefits of the more costly rule justify its additional cost;

(b) the reason for adoption of the more costly rule;

(c) whether the reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

(d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

4. If the purpose of this rule is to implement a *federal* rule or regulation, please state the following:
 - (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

General Revenue \$0.00
 Federal Funds \$0.00
 Cash Funds \$0.00
 Special Revenue \$0.00
 Other (Identify) \$0.00
 Total \$ 0.00

Next Fiscal Year

General Revenue \$0.00
 Federal Funds \$0.00
 Cash Funds \$0.00
 Special Revenue \$0.00
 Other (Identify) \$0.00
 Total \$ 0.00

(b) What is the additional cost of the state rule?

Current Fiscal Year

General Revenue \$0.00
 Federal Funds \$0.00
 Cash Funds \$0.00
 Special Revenue \$0.00
 Other (Identify) \$0.00
 Total \$ 0.00

Next Fiscal Year

General Revenue \$0.00
 Federal Funds \$0.00
 Cash Funds \$0.00
 Special Revenue \$0.00
 Other (Identify) \$0.00
 Total \$ 0.00

5. What is the total estimated cost by fiscal year to any private individual, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year

\$ 0.00

Next Fiscal Year

\$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

\$ 0.00

Next Fiscal Year

\$ 0.00

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☒

If yes, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

- (1) a statement of the rule's basis and purpose;
- (2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;
- (3) a description of the factual evidence that:
 - (a) justifies the agency's need for the proposed rule; and
 - (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

Program of All-Inclusive Care for the Elderly (PACE) Provider Manual Update

Statement of Necessity

The Division of Aging and Adult Behavioral Services (DAABHS) issues a new, streamlined Program of All-Inclusive Care for the Elderly (PACE) Medicaid Provider Manual. The primary need for revision is recent changes in the federal PACE regulations found at 42 CFR Part 460 and to comply with Act 144 of the 2025 Regular Session of the State of Arkansas 95th General Assembly. The reorganized and revised manual is more conducive for provider reference and use.

Summary of Changes

This new PACE Manual makes responsive changes to federal regulations regarding nomenclature for plans of care, medical personnel requirements, care coordination requirements and timelines, plan of care requirements, recipient rights, grievances and appeals, and licensure exemptions for PACE programs. The updates pursuant to Act 144 exempt PACE providers from the licensing requirements for home healthcare services. The current manual is being repealed in this rule.

TOC Required

200.000 PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) GENERAL INFORMATION

200.100 Program Description

9-1-26

- A. The Program of All-Inclusive Care for the Elderly (PACE) is a comprehensive health and social services program that helps older adults, who need nursing home level of care, remain in their homes and communities. It is a joint Medicare/Medicaid program that provides and coordinates primary, acute, and long-term care for qualifying beneficiaries who are fifty-five (55) years of age or older. PACE relies on an interdisciplinary team approach to care management and comprehensive service delivery.
1. Social and medical services are provided primarily in a PACE center but are supplemented by in-home and referral services as needed by the PACE Organization (see section 202.000).
 2. Pursuant to Arkansas Code Annotated §20-10-801 (14) a licensed, certified PACE Program is exempted from any additional or separate home healthcare licensing requirements.
 3. Pursuant to 42 CFR Part 460, PACE providers must be in compliance with all federal regulations.
- B. PACE is designed to meet the following aims:
1. Enhance the quality of life and autonomy for frail, older adults.
 2. Maximize dignity of, and respect for, older adults.
 3. Enable frail, older adults to live in the community as long as medically and socially feasible.
 4. Preserve and support the older adult's family unit.
- C. PACE provides pre-paid, capitated, comprehensive health care services. The PACE assumes full financial risk. The PACE program must provide all the authorized care and services covered by Medicare and Medicaid, as well as additional medically-necessary care and services for program participants, as per 42 CFR §460.92.
- D. PACE is a State option under Arkansas Medicaid and is operated by the Division of Aging, Adult, and Behavioral Health Services (DAABHS).

Further programmatic information and guidelines for PACE are outlined by the Centers for Medicare and Medicaid Services (CMS) in their Programs of All-Inclusive Care for the Elderly (PACE) Manual online.

200.200 PACE Terms and Definitions

9-1-26

<u>Contract Year</u>	<u>The term of a PACE Program Agreement between the PACE Organization, DAABHS, and CMS, which is a calendar year that ends on December 31. A PACE Organization's initial contract year may last anywhere from 19 to 30 months as determined by CMS, but will end on December 31st.</u>
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<u>PACE Center</u>	<u>A facility which includes a primary care clinic and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.</u>
<u>PACE Organization</u>	<u>A provider that has a PACE Program Agreement in effect to operate a PACE program in the state.</u>
<u>PACE Program Agreement</u>	<u>An agreement between a PACE Organization, DAABHS, and CMS for the operation of a PACE program.</u>
<u>PACE Service Area</u>	<u>The designated area (zip-code specific) where a PACE Organization is permitted to provide services. This should not overlap with another PACE Organization.</u>
<u>Participant</u>	<u>A beneficiary who is enrolled in a PACE program.</u>

201.000 PACE Applicant Requirements**9-1-26**

- A. A PACE Organization is a not-for-profit, for-profit, or public entity that is primarily engaged in providing PACE services. The following characteristics must also apply to a PACE organization:
1. Have a governing body, or a designated person functioning as a governing body, that includes participant representation;
 2. Be able to provide the complete PACE service package regardless of frequency or duration of services;
 3. Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
 4. Have a defined service area;
 5. Have safeguards against conflict of interest;
 6. Have demonstrated fiscal soundness;
 7. Have a formal Participant Bill of Rights; and
 8. Have a process to address grievances and appeals.
- B. A provider must meet all of the following participation requirements to qualify as a PACE Organization that operates a PACE program under Arkansas Medicaid:
1. Submit a Notice of Intent to Apply (NOIA) PACE form to the Division of Aging and Adult Services as a letter of intention to establish or expand a PACE Program;
 2. Obtain an Adult Day Health Care facility license:
 - a. Adhere to all regulations established for the licensure of Adult Day Health Care (ADHC) facilities in Arkansas, overseen by the Division of Provider Services & Quality Assurance (DPSQA).
 - b. Refer to 'Rules and Regulations for Adult Day Health Care Providers' for more information. Guidance is subject to periodic revisions as warranted.
 3. Submit a PACE Provider Application and be approved by both Arkansas' Division of Aging and Adult Services and the Centers for Medicare and Medicaid Services (CMS), as per 42 CFR §460.18;
 - a. A PACE provider's past performance will be considered when determining approval or denial of new or expansion applications.
 - b. Submitting a completed PACE provider application to DAABHS after submitting

it to CMS, or failing to submit it to DAABHS altogether, may result in the denial or delay of the application's approval.

- c. A PACE Provider Application is also required for a pre-existing PACE Organization that seeks to expand its service area or add a new PACE Center (42 CFR 460.12(d)).
- 4. Execute a PACE Program Agreement, which acts as a three-party contract governing provider operations signed by the PACE provider, Division of Aging and Adult Services, and CMS; and
- 5. Complete the Medicaid provider participation and enrollment requirements contained within Section 140.000 of this Medicaid manual.
- C. A provider may request a waiver of certain regulatory requirements along with their PACE Provider Application. The purpose of the waiver is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).
 - 1. A provider should follow guidelines set forth in 42 CFR 460.26 for submission and evaluation of waiver requests.

Note: Click here for more information on the PACE Provider Application.

Note: Click here for more information on the PACE Program Agreement.

201.200 Violations, Sanctions, Civil Money Penalties, Suspension, and Termination 9-1-26

- A. CMS may impose any of the sanctions as specified in 42 CFR 460.40 if CMS determines that a PACE organization commits programmatic violations.
- B. CMS may suspend Medicare payment to the PACE organization and may deny payment to the State for medical assistance for services furnished under the PACE program agreement for one or more program violations as specified in 42 CFR 460.42.
- C. CMS may impose civil money penalties up to the maximum amounts specified by federal law as specified in 42 CFR 460.46.
- D. CMS in consultation with DAABHS, may take one or more of the following actions as specified in 42. CFR 460.48:
 - 1. Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.
 - 2. Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency.
 - 3. Terminate the PACE program agreement.

201.300 State Monitoring Activities for PACE Organizations 9-1-26

- A. DPSQA, or its vendor, conducts independent site visits annually, or as needed, in addition to CMS site visits, to compliance with regulations, state and federal laws.
- B. DPSQA, or its vendor, is responsible for conducting an exit conference with the PACE Organization to discuss any review findings, provide technical assistance in developing corrective action plans, and to assist the PACE Organization in their efforts to implement the required corrections.
- C. The PACE Organization must be licensed by the Arkansas Department of Human Services, Division of Provider Services and Quality Assurance, as an Adult Day Health Care. CMS can conduct an audit at any point after the first year of the trial period. At the

conclusion of the Three-year trial period, CMS in cooperation with DAABHS, continues to conduct reviews, as appropriate, of the PACE Organization considering the quality-of-service provision by the PACE Organization and compliance with all state and federal requirements.

D. The PACE Organization is required to disclose to current PACE participants and potential PACE participants information specific to the PACE Organization's performance and contract compliance deficiencies, in a manner specified by CMS (42 CFR §460.198).

E. DPSQA, or its vendor, upon annual inspection will review the following, in addition to ensuring a PACE provider is meeting the requirements of an Adult Day Health provider:

1. The PACE organization's physical environment to ensure a safe, sanitary, functional, accessible, and comfortable environment;
2. Suitable space and equipment to provide primary medical care and suitable space for treatment, restorative therapies, therapeutic recreation, socialization, dining and personal care;
3. Suitable meeting space for personnel to conduct team meetings and for participant's caregivers, and visitors;
4. Spaces which provide participant privacy and dignity during the delivery of services;
5. Proof that there are life safety code inspections from the fire marshal, Department of Health, and other required state agency inspections;
6. The PACE organization must provide evidence of a federal Clinical Laboratory Improvement Amendment (CLIA) exemption if the center is performing waived laboratory services on site or in the home, e.g., glucose meter testing, urine testing, fecal occult blood testing, blood testing, cholesterol screening or hemoglobin or hematocrit testing;
7. In addition, the PACE organization must meet all applicable Federal, State, and local laws and regulations, which include the Americans with Disabilities Act and Section 504 of the Rehabilitation Act;
8. A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the manufacturer's written recommendations. This maintenance may be performed by PACE staff or contracted entities and in compliance with the contract;
9. The PACE organization is required to have trained personnel, drugs, and emergency equipment immediately available at every PACE center at all times to adequately support participants until Emergency Medical Services (EMS) responds to the PACE center;
10. Each PACE center is required to have at least one staff member who has been trained in cardio-pulmonary resuscitation (CPR) and will be on site during the hours that participants are in attendance;
11. The PACE organization must have a written plan and procedure for handling emergency situations that may arise including, but not limited to, cardiac arrest, choking and seizure activity in accordance with 42 CFR 460.100;
12. PACE center must have a documented plan to obtain Emergency Medical Services from sources outside the PACE center when needed. At least annually, a PACE organization must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to the situations and needs that may arise from both medical and nonmedical emergencies;
13. The minimum emergency equipment that must be on the premises and immediately available includes: portable oxygen, airways, suction, and emergency drugs;

14. A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located;
15. A PACE provider must have an Emergency Preparedness Plan and an Infection Control Plan.

201.400 Emergency Preparedness**9-1-26**

In accordance with 42 CFR 460.84, the PACE organization must establish and maintain an emergency preparedness program that meets the federal requirements.

The PACE organization must establish, implement, and maintain documented procedures to manage medical and non-medical emergencies and disasters that are likely to threaten the health and safety of participants, staff, or the public. The Disaster Plan must address the organization's arrangements for emergency food, nutritional supplements, and potable water supplies.

201.500 Infection Control**9-1-26**

The PACE organization must, as specified in 42 CFR 460.74, establish, implement, and maintain a documented infection control plan that ensures a safe and sanitary environment and prevents and controls the transmission of disease and infection.

A. An infection control plan must include, but is not limited to:

1. procedures to identify, investigate, control, and prevent infections in every PACE center and in each participant's place of residence;
2. procedures to record any incidents of infection; and
3. procedures to analyze the incidents of infection, to identify trends and develop corrective actions related to the reduction of future incidents.

PACE organizations are required to follow accepted policies and standard procedures with respect to infection control, including, at the least, the standard precautions developed by the Center for Disease Control and Prevention (CDC).

PACE organizations are expected to establish written policies and procedures for the investigation, control, and prevention of infections including:

B. An OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff;

1. Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, e.g., influenza and pneumonia;
2. Initial and ongoing health screening and vaccinations for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases;
3. Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection;
4. Written plans and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports. Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials;
5. Plans and procedures for staff providing direct care to patients with infection(s);
6. Provision of adequate facilities and supplies necessary for infection control to include:

- a. Hand washing facilities and supplies;
 - b. Laundry facilities and supplies;
 - c. Isolation facilities and supplies;
- 7. Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements;
- 8. Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal;
- 9. Written plans and procedures for the appropriate handling and disposal of all waste products including blood and urine specimens for outside lab tests and other biohazardous wastes.
- C. DPSQA, or its vendor, is responsible for conducting an exit conference with the PACE Organization to discuss any review findings, provide technical assistance in developing corrective action plans, and to assist the PACE Organization in their efforts to implement the required corrections.
- D. The PACE Organization must be licensed by the Arkansas Department of Human Services, Division of Provider Services and Quality Assurance, as an Adult Day Health Care. CMS can conduct an audit at any point after the first year of the trial period. At the conclusion of the Three-year trial period, CMS in cooperation with DAABHS, continues to conduct reviews, as appropriate, of the PACE Organization considering the quality-of-service provision by the PACE Organization and compliance with all state and federal requirements.
- E. The PACE Organization is required to disclose to current PACE participants and potential PACE participants information specific to the PACE Organization's performance and contract compliance deficiencies, in a manner specified by CMS (42 CFR §460.198).

201.600 Office of Medicaid Inspector General**9-1-26**

- A. A PACE Organization must have a formal process in place to gather information and must be able to respond in writing to a request from CMS or DAABHS for information regarding:
 - 1. Persons with criminal convictions.
 - 2. A PACE Organization must not employ individuals or contract with organizations or individuals:
 - a. Who have been excluded from participation in the Medicare or Medicaid programs;
 - b. Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Social Security Act; or
 - c. In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.
 - 3. Direct or indirect interest in contracts. No member of the PACE Organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE Organization.

202.000 PACE Administrative Requirements**9-1-26**

- A. In addition to participation requirements listed in Section 201.000, a PACE Organization must adhere to all PACE Administrative Requirements as outlined in 42 CFR Part 460 Subpart E, including:

1. PACE Organizational Structure;
2. PACE governing body and participant advisory committee;
3. Compliance oversight requirements;
4. Program integrity;
5. Physical environment;
6. Infection control;
7. Fiscal soundness; and
8. Emergency Preparedness.

202.100 Interdisciplinary Team**9-1-26**

- A. The PACE Organization must establish an Interdisciplinary Team (IDT), composed of members that are qualified to fill the roles described below, at each PACE Center to comprehensively assess and meet the individual needs of each participant (42 CFR 460.102):
1. Primary Care Provider;
 2. Registered Nurse;
 3. Master's-level social worker;
 4. Physical therapist;
 5. Occupational therapist;
 6. Recreational therapist or activity coordinator;
 7. Dietitian;
 8. Home Care Coordinator;
 9. Personal Care Aide or their representative;
 10. Driver or their representative; and
 11. PACE Center Manager.
- B. The PACE Organization must assign each participant to an Interdisciplinary Team (IDT) functioning at the PACE Center that the participant attends.
1. The IDT is responsible for:
 - a. Assessing the needs of each PACE participant;
 - b. Developing a Plan of Care;
 - c. Providing and coordinating care that meets the needs of each participant across all care settings, twenty-four (24) hours a day, every day of the year (42 CFR 460.98);
 - d. Monitoring the participant's Plan of Care and making updates as needed; and
 - e. Reviewing and determining the necessity of recommended services from a hospital, emergency department, or urgent care provider, within forty-eight (48) hours of the participant's discharge, to determine if the service will appropriately meet the participant's social, emotional, physical, and medical needs.

202.200 Participant Rights**9-1-26**

- A. A PACE Organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the rights specified below (42 CFR 460.112):

1. Respect and nondiscrimination;
 2. Right to treatment;
 3. Information disclosure, including but not limited to:
 - a. Right to have all treatment options explained in a culturally competent manner.
 - b. Right to receive information regarding palliative, comfort, or end-of-life care services.
 4. Choice of providers;
 5. Participation in treatment decisions, including, but not limited to:
 - a. Right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.
 - b. Right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.
 6. Confidentiality of health information; and
 7. Complaints, requests, and appeals.
- B. The PACE Organization must inform a participant or their representative, upon enrollment, in writing, of their rights and responsibilities, and all rules and regulations governing participation. It is required to:
1. Have the participant's rights written and displayed in English in a prominent place in the PACE Center; and
 2. Have the participant's rights available in other principal languages of the community in which the PACE organization is located, as determined by the state.
- C. The PACE organization must protect and provide for the exercise of the participant's rights, including:
1. Have established documented procedures to respond to and rectify a violation of a participant's rights; and
 2. Comply with requirements through the CMS complaints tracking module, address and resolve complaints received by CMS against the PACE organization within the required timeframes (42 CFR 460.119).
- D. Grievance Processes- Each PACE Organization must have formal written procedures to promptly identify, document, investigate, and resolve all medical and non-medical grievances in accordance with the requirements (42 CFR §460.120).
1. A grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE Organization or any other entity or individual through which the PACE Organization provides services to the participant. All grievances must be remediated.
 2. Medicare recipients have the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

202.300 Restraints**9-1-26**

The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a physical restraint or a chemical restraint (42 CFR 460.114).

- A. A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.
- B. A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.
- C. If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:
 - 1. Be imposed for a defined, limited period of time, based upon the assessed needs of the participant.
 - 2. Be imposed in accordance with safe and appropriate restraining techniques.
 - 3. Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.
 - 4. Be removed or ended at the earliest possible time.
 - 5. The condition of the restrained participant must be continually assessed, monitored, and reevaluated.

202.400 Marketing**9-1-26**

- A. PACE Organizations that publicize their programs must include in their public marketing materials:
 - 1. An adequate description of the enrollment and disenrollment policies and requirements;
 - 2. PACE enrollment procedures;
 - 3. Description of benefits and services;
 - 4. Premiums;
 - 5. Information on the restriction of services; Materials must state clearly that PACE participants may be liable for the costs of out-of-PACE program agreement services; and
 - 6. Other information necessary for prospective participants to make an informed decision about enrollment.
- B. Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.
- C. Marketing information must be furnished in English and any other principal languages of the community in which the PACE Organization is located, as determined by the State. This includes Braille, when necessary.
- D. Marketing materials must be approved by CMS and DAABHS before distribution by the PACE Organization, including any revised or updated materials. Materials will be given a 45-day review period. If not disapproved within the review period, the organization can distribute it.
- E. More details about marketing regulations can be found in 42 CFR 460.82.

203.000 PACE STAFF PARTICIPATION REQUIREMENTS**203.100 PACE Staff Participation Requirements****9-1-26**

- A. A provider must meet the following requirements to serve as a PACE Organization's staff (employee or contractor):
1. Be legally authorized (active license, registration, or certification in good standing) to practice in Arkansas and only act within the scope of his or her licensed authority.
 - a. See specific Certification or Licensure Manual for specific provider types.
 2. Successfully pass the background and registry checks and searches required by Ark. Code Ann. §§ 20-33-213 and 20-38-101 et seq.

203.200 Qualifications of PACE Staff with Direct Participant Contact**9-1-26**

- A. Each member of the PACE Organization's staff (employee or contractor) that has direct contact with participants must meet all the following conditions (42 CFR 460.64):
1. Have one (1) year of experience working with a frail or elderly population or, if the individual has less than one (1) year of experience, must receive appropriate training from the PACE Organization on working with a frail or elderly population.
 2. Meet a standardized set of competencies, as described in Section 202.201 for the specific position description established by the PACE Organization, before working independently.
 3. Have all immunizations up to date before engaging in direct participant contact.
 4. Be medically cleared of communicable disease, and specifically determined free of active Tuberculosis, prior to providing direct care.
 - a. Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant.
 - b. A PACE Organization may alternatively choose to perform an individual risk assessment for symptoms and exposure (must meet requirements specified in 42 CFR 460.64(a)(5)(iii)) to determine when a physical exam would be required for staff. Results of risk assessment must be reviewed by RN, physician, nurse practitioner, or physician assistant.
 5. PACE Center staff must follow additional staffing regulations outlined in 'Rules and Regulations for Adult Day Health Care Providers,' the licensure manual for Adult Day Health Care (ADHC) facilities in Arkansas. Guidance is subject to periodic revisions as warranted.

203.300 Training for PACE Staff with Direct Participant Contact**9-1-26**

- A. A PACE Organization must ensure all its employees and contracted staff providing direct care to participants demonstrate the skills necessary for performance of their position (42 CFR §460.71).
1. The PACE Organization must provide all staff with an orientation that includes, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE Program, and any policies related to the job duties.
 2. The provider must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff.
 - a. Training shall be appropriate to job function and shall include but is not limited

to the ADHC's licensure manual for training.

3. The competency program must be evidenced as completed before performing participant care and on an on-going basis by qualified professionals.
4. Certification of the satisfactory completion of the competency program must be in the personnel files of all staff.

210.000 PROGRAM ELIGIBILITY

210.100 Scope

9-1-26

Arkansas Medicaid will pay qualified PACE Organizations a fixed monthly payment per enrolled Medicaid participant for comprehensive services delivered to those who meet the PACE eligibility requirements of this Medicaid manual. Medicaid payment is conditional upon compliance with this manual, manual update transmittals, and official program correspondence.

210.200 Program Participant Eligibility Requirements

9-1-26

A. Participation in PACE is available to individuals fifty-five (55) years of age and older who live in a PACE Service Area, meet nursing home level of care as determined by Division of Aging and Adult Services, can live safely in a community setting without risking health or safety, and agree to forgo their usual sources of care to receive all services through the PACE Organization.

1. Additional eligibility requirements include:

- a. Having proof of residency in the State of Arkansas;
- b. Being a US citizen or legal alien;
- c. Having proof of a valid Social Security Number;
- d. Meeting Intermediate I-S, I-A, II-B, or III-C nursing facility level of care; and
- e. Meeting one of the following medical criteria, as assessed by a DHS Registered Nurse:
 - i. Unable to perform at least one (1) of the three (3) activities of daily living (ADLs) of transferring or locomotion, eating, or toileting without extensive assistance or total dependence upon another person;
 - ii. Unable to perform at least two (2) of the three (3) activities of daily living (ADLs) of transferring or locomotion, eating, or toileting without limited assistance from another person;
 - iii. Primary or secondary diagnosis of Alzheimer's disease or related dementia and cognitively impaired so as to require substantial supervision from another individual; or
 - iv. Diagnosed medical condition which requires monitoring or assessment at least once a day by a licensed medical professional and if left untreated, would be life threatening.

Note: Individuals diagnosed with serious mental illness (SMI) or an intellectual disability are not eligible for PACE unless their medical needs are unrelated to their SMI/DD diagnosis and they meet the other qualifying criteria.

2. Medicare beneficiaries meeting the above requirements agree to participate in PACE by paying monthly premiums equal to the Medicaid capitation amount, but no deductibles, coinsurance, or any other type of Medicare or Medicaid cost-sharing.
3. Individuals not eligible for Medicaid or Medicare who meet the above requirements agree to participate in PACE by paying private premiums.

210.300 Evaluation Referral**9-1-26**

- A. A beneficiary may be initially referred to PACE by a PACE Organization or DHS Registered Nurse, however an outside referral is not required to apply.
- B. Beneficiaries apply for PACE through their local Division of County Operations (DCO) office for a determination of financial eligibility.
- C. The local DCO office will refer the beneficiary for an independent assessment, determination of financial eligibility notwithstanding.

210.400 Independent Assessment and Level of Care Determination**9-1-26**

- A. For individuals new to PACE, the individual must receive an Independent Assessment via the Arkansas Independent Assessment (ARIA) instrument, administered by a DHS-appointed Independent Assessment Contractor. The ARIA determines the individual's functional needs eligibility.
 - 1. The Division of County Operations (DCO) registered nurse determines the potential enrollee's nursing facility level of care via the DHS-704 based on the results of the Independent Assessment.
 - 2. The DCO registered nurse notifies the PACE Organization when all requirements have been met.
- B. For renewing PACE participants, a Division of Aging and Adult Services registered nurse completes an annual evaluation (Medical Needs Assessment Form DMS-703) to evaluate the potential enrollee's nursing facility level of care.
 - 1. To be eligible for PACE, beneficiaries must have a Medical Needs Assessment indicating they require Intermediate I-S, I-A, II-B, or III-C nursing facility level of care.
 - 2. The Division of Aging and Adult Services' registered nurse must certify that an assessment has been completed and that it is safe for the participant to live in the community.
 - 3. The Division of Aging and Adult Services' registered nurse notifies the local Division of County Operations (DCO) office and the PACE Organization when all requirements have been met.

210.500 Enrollment with PACE Organization**9-1-26**

- A. If the potential participant meets the eligibility requirements and wants to pursue enrollment with the PACE Organization, they must sign an enrollment agreement with the PACE Organization that serves their Service Area. For more details on the contents of the enrollment agreement, see 42 CFR 460.154.
 - 1. Enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. See 42 CFR 460.154(i).
 - 2. The PACE Organization is required to complete its own intensive assessment that includes a minimum of one (1) home visit for enrollment.
 - 3. The potential enrollee is required to complete one (1) visit to the PACE Center, unless otherwise approved by CMS.
 - 4. At the time of enrollment, the PACE Organization is required to do the following:
 - a. Verify whether the participant is dually eligible for Medicare and Medicaid and whether the participant has Medicare Part A, Part B, or both;
 - b. Remind participants that unless they are dually eligible, they will need to continue to pay their Medicare Part A premium (if not free), Part B premium (if

not eligible for State coverage), and Part D premium, if applicable; and

- c. Identify payers that are primary to Medicare, determine the amounts payable by those payers, and coordinate benefits to Medicare participants with the benefits of primary payers.

B. Involuntary Disenrollment

1. Involuntary disenrollments are to be handled pursuant to federal law.
2. Refer to 42 C.F.R. 460.164, 460.166 and 460.172.

210.600 Person-Centered Plan of Care

9-1-26

- A. After the individual is enrolled, the PACE Organization's Interdisciplinary Team (IDT) is responsible for individualized assessment, treatment planning, and care delivery. The IDT must meet the following requirements for the Plan of Care:

1. Complete an initial, in-person, comprehensive assessment by the following members promptly following the beneficiary's enrollment:
 - a. Primary care physician;
 - b. Registered nurse;
 - c. Master's-level social worker;
 - d. Physical therapist;
 - e. Occupational therapist;
 - f. Recreational therapist or activity coordinator;
 - g. Dietitian; and
 - h. Home care coordinator.
2. Develop, evaluate, and, if necessary, revise the comprehensive Person-Centered Plan of Care for the participant (42 CFR §460.106).
 - a. The Interdisciplinary Team must complete the initial Plan of Care within thirty (30) calendar days of the participant's date of enrollment.
 - b. The Interdisciplinary Team must involve the participant and their family members or circle of natural supports in the development of the Plan of Care. The PACE Organization should document beneficiary and/or family approval of the Plan of Care.
 - c. The Plan of Care must explain different treatment options, provide written information of those options, and obtain written consent prior to initiating any palliative, comfort, or end-of-life care services.
 - d. At least once every one hundred eighty (180) calendar days from the date the latest Plan of Care was finalized, the Interdisciplinary Team must complete a semi-annual Plan of Care evaluation, and if necessary, revisions to each participant's Plan of Care.
3. For requests from the participant, or their representative or caregiver, to initiate, modify, or continue a service during the development of the initial Person-Centered Plan of Care, the IDT must:
 - a. Document the request; and
 - b. Discuss the request during the care planning meeting and either:
 - i. Approve the requested service and incorporate it into the participant's initial Plan of Care; or
 - ii. Document the rationale for not approving the service in the initial Plan of Care.

4. Additional in-person Assessments and Treatment Plans corresponding to the overall Person-Centered Plan of Care must be completed, as applicable, by the:
 - a. Physical therapist;
 - b. Occupational therapist;
 - c. Dietitian; and
 - d. Home care coordinator.

B. Change of Condition

1. When a change of condition is noted by any provider delivering services to the PACE participant, the Interdisciplinary Team must update the Plan of Care within fourteen (14) days from the actual status change.
2. Re-assessments and Treatment Plan changes are also completed when the PACE participant experiences a change in health or psycho-social condition.

210.700 Service Determination Process

9-1-26

A. Service Determination Requests (42 CFR 460.121)

1. A Service Determination Request is a request made by a participant, their representative, or their caregiver to initiate a new service, modify an existing service, or continue coverage of a service that a PACE Organization is recommending being discontinued or reduced.
 - a. Requests can be made orally or in writing to any employee or contractor of the PACE Organization that provides direct care to a participant, including transportation personnel.
 - b. If a request is made prior to completing the development of the initial Person-Centered Plan of Care, it is not considered a Service Determination Request.
2. The PACE organization must bring a Service Determination Request to the Interdisciplinary Team (IDT) as expeditiously as the participant's condition requires, but no later than three (3) calendar days from the time the request is made.
 - a. If a member of the IDT is able to approve the Service Determination Request in full at the time the request is made, the PACE Organization:
 - i. Must provide oral or written notice of decision to approve a service determination request to the participant, in understandable language. The approval should include the conditions of the approval, including when the participant may expect to receive the approved service.
 - ii. Must follow recordkeeping requirements established in Part B below.
 - iii. Does not need a full IDT review.
 - b. In all other cases, the full IDT must review and discuss each Service Determination Request and decide to approve, deny, or partially deny the request based on that review.
 - i. IDT will consider all relevant information when evaluating a request, including, but not limited to, the findings and results of any reassessments.
 - c. The IDT may extend the timeframe for review and notification by up to five (5) calendar days if either of the following occur:
 - i. The participant or their representative request the extension; or
 - ii. The IDT needs additional information from an individual, not directly employed by the PACE Organization, that may change the interdisciplinary team's decision to deny a service.
 - d. The participant or their representative must be notified of any extension in

review timeframe either orally or in writing, no later than twenty-four (24) hours after the IDT decides to extend the review timeframe.

- e. If the IDT fails to provide the participant with timely notice of the resolution of the request, or does not furnish the services required by the revised Person-Centered Plan of Care, this constitutes an adverse decision. The participant's request must be automatically processed by the PACE organization as an appeal (42 CFR 460.121(l)).

B. Recordkeeping

1. The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for Service Determination Requests received both orally and in writing.
2. These records must be available to the IDT to ensure that all members remain alert to pertinent participant information.

C. Reassessments based on a Service Determination Request

1. If the IDT expects to deny or partially deny a Service Determination Request, the appropriate members of the IDT must conduct an in-person Reassessment before the IDT makes a final decision.
2. IDT members performing the Reassessment evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.
3. The IDT may conduct a Reassessment prior to approving a Service Determination Request, either in-person or through the use of remote technology, if the team determines that a Reassessment is necessary.

210.800 Service Determination Approvals and Denials

9-1-26

A. Notice of decision to approve a Service Determination Request

1. If the interdisciplinary team (IDT) decides to approve a Service Determination Request, it must provide the participant or representative either oral or written notice of the determination.
2. The approval must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

B. Notice of decision to deny a Service Determination Request (42 CFR 460.121(j))

1. If the IDT decides to deny or partially deny a service, it must provide the participant or representative both oral and written notice of the determination.
2. Notice of any denial must:
 - a. State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the Reassessment(s) in understandable language.
 - b. Inform the participant or representative of his or her right to appeal the decision.
 - c. Describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services.
 - d. For a Medicaid participant, inform the participant of both of the following:
 - i. His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.
 - ii. The conditions for continuing to receive disputed services.

C. Appeals

1. An appeal to a PACE Organization is a participant's action taken with respect to the PACE Organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. Refer to Appendix R in the PACE Program Agreement.
2. A request to initiate, modify, or continue a service must first be processed as a service determination request under Section 210.700 before the PACE organization can process an appeal under this section.
3. See further details on a PACE Organization's Appeals Process (42 CFR 460.122).
4. Additional appeal rights under Medicare or for those dually eligible for Medicare and Medicaid can be found 42 CFR 460.124.
5. Medicaid Administrative Reconsideration and Appeals:
 - a. Medicaid allows only one (1) reconsideration of an adverse decision. Reconsideration requests must be submitted in accordance with Section 160.000 Section 1 of this Medicaid Manual.
 - b. When the State Medicaid Agency or its designee denies a reconsideration request or issues any adverse decision, the beneficiary may appeal and request a fair hearing. A request for a fair hearing must be submitted in accordance with Sections 160.000, 190.000, and 191.000 of Section 1 of this Medicaid Manual.

220.000 PROGRAM SERVICES**220.100 Non-covered Services****9-1-26**

- A. Medicare and Medicaid services delivered solely through the PACE Organization are the only benefits covered while the participant is enrolled in a PACE program (42 CFR 460.90).
- B. The following services are excluded from coverage under PACE:
 1. Cosmetic surgery;
 2. Experimental medical, surgical, or other health procedures; and
 3. Services furnished outside the USA, except as permitted under the state's Medicaid Plan.

220.200 Covered Services**9-1-26**

The PACE benefit package for all participants, regardless of the source of payment, must include the following as prescribed by the Interdisciplinary Team (IDT) assessment:

- A. All Medicaid-covered services, as specified in the State's approved Medicaid plan.
- B. Interdisciplinary assessment and treatment planning.
- C. Primary care, including physician and nursing services.
- D. Social work services.
- E. Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services.
- F. Personal care and supportive services.
- G. Nutritional counseling.

H. For more detailed policies on meal requirements and sanitary conditions, see 42 CFR 460.78.

I. Recreational therapy.

J. Transportation.

1. For more detailed policies on required safety, accessibility, and equipment; maintenance of vehicles; vehicle communication with PACE center; personnel training; and inclusion in any changes to the person-centered service plan, see 42 CFR 460.76.

K. Meals as required by the interdisciplinary team's plan of care.

L. Medical specialty services including, but not limited to the following:

1. Anesthesiology;
2. Audiology;
3. Cardiology;
4. Dentistry;
5. Dermatology;
6. Gastroenterology;
7. Gynecology;
8. Internal medicine;
9. Nephrology;
10. Neurosurgery;
11. Oncology;
12. Ophthalmology;
13. Oral surgery;
14. Orthopedic surgery;
15. Otorhinolaryngology;
16. Palliative Medicine
17. Plastic surgery;
18. Pharmacy consulting services;
19. Podiatry;
20. Psychiatry;
21. Pulmonary disease;
22. Radiology;
23. Rheumatology;
24. General surgery;
25. Thoracic and vascular surgery; and
26. Urology.

M. Laboratory tests, x-rays, and other diagnostic procedures.

N. Drugs and biologicals.

- O. Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.
- P. Acute inpatient care, including the following:
1. Ambulance;
 2. Emergency room care and treatment room services;
 3. Semi-private room and board;
 4. General medical and nursing services;
 5. Medical, surgical, intensive care, and the Coronary Care Unit;
 6. Laboratory tests, x-rays, and other diagnostic procedures;
 7. Drugs and biologicals;
 8. Blood and blood derivatives;
 9. Surgical care, including the use of anesthesia;
 10. Use of oxygen;
 11. Physical, occupational, respiratory therapies, and speech language pathology services; and
 12. Social services.
- Q. Nursing facility care, including the following:
1. Semi-private room and board;
 2. Physician and skilled nursing services;
 3. Custodial care;
 4. Personal care and assistance;
 5. Drugs and biologicals;
 6. Physical, occupational, recreational therapies, and speech-language pathology, if necessary;
 7. Social services; and
 8. Medical supplies and appliances.
- R. Other services determined necessary by the IDT to improve and maintain the participant's overall health status.
1. Medications must be provided within twenty-four (24) hours of the Primary Care Provider's order.
 2. All services (other than medications) approved by the IDT must be set-up, scheduled, or arranged within seven (7) days of the approval. This does not include routine or preventative services.
 3. Notwithstanding, all services and medications are to be provided as expeditiously as the participant's health requires, so if needed, services must be provided more quickly than the timelines provided for in this section.
 4. Contracted Services.
- S. The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, including, at a minimum, the medical specialties listed previously in this Section (as per 42 CFR 460.70).

1. Contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services.
2. A PACE Organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE Organization is unable to directly contract or maintain a contract with a specific specialty, the PACE Organization must:
 - a. Ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization; and
 - b. Promptly report the contracting issue to CMS and DAABHS, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE Organization's plan to provide access to the necessary services.
3. A PACE Organization is not required to have a contract with a particular medical specialty if the PACE Organization directly employs one (1) or more individuals prior to contracting, who are legally authorized, and, if applicable, board certified in the particular medical specialty.
4. For more information about contract requirements, the mandatory list of contractors that must be kept on file, see 42 CFR 460.70.

TOC Required

200.000 PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) GENERAL INFORMATION

200.100 Program Description

9-1-26

- A. The Program of All-Inclusive Care for the Elderly (PACE) is a comprehensive health and social services program that helps older adults, who need nursing home level of care, remain in their homes and communities. It is a joint Medicare/Medicaid program that provides and coordinates primary, acute, and long-term care for qualifying beneficiaries who are fifty-five (55) years of age or older. PACE relies on an interdisciplinary team approach to care management and comprehensive service delivery.
1. Social and medical services are provided primarily in a PACE center but are supplemented by in-home and referral services as needed by the PACE Organization (see section 202.000).
 2. Pursuant to Arkansas Code Annotated §20-10-801 (14) a licensed, certified PACE Program is exempted from any additional or separate home healthcare licensing requirements.
 3. Pursuant to 42 CFR Part 460, PACE providers must be in compliance with all federal regulations.
- B. PACE is designed to meet the following aims:
1. Enhance the quality of life and autonomy for frail, older adults.
 2. Maximize dignity of, and respect for, older adults.
 3. Enable frail, older adults to live in the community as long as medically and socially feasible.
 4. Preserve and support the older adult's family unit.
- C. PACE provides pre-paid, capitated, comprehensive health care services. The PACE assumes full financial risk. The PACE program must provide all the authorized care and services covered by Medicare and Medicaid, as well as additional medically-necessary care and services for program participants, as per 42 CFR §460.92.
- D. PACE is a State option under Arkansas Medicaid and is operated by the Division of Aging, Adult, and Behavioral Health Services (DAABHS).

[Further programmatic information and guidelines for PACE are outlined by the Centers for Medicare and Medicaid Services \(CMS\) in their Programs of All-Inclusive Care for the Elderly \(PACE\) Manual online.](#)

200.200 PACE Terms and Definitions

9-1-26

Contract Year	The term of a PACE Program Agreement between the PACE Organization, DAABHS, and CMS, which is a calendar year that ends on December 31. A PACE Organization's initial contract year may last anywhere from 19 to 30 months as determined by CMS, but will end on December 31 st .
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PACE Center	A facility which includes a primary care clinic and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.
PACE Organization	A provider that has a PACE Program Agreement in effect to operate a PACE program in the state.
PACE Program Agreement	An agreement between a PACE Organization, DAABHS, and CMS for the operation of a PACE program.
PACE Service Area	The designated area (zip-code specific) where a PACE Organization is permitted to provide services. This should not overlap with another PACE Organization.
Participant	A beneficiary who is enrolled in a PACE program.

201.000 PACE Applicant Requirements**9-1-26**

- A. A PACE Organization is a not-for-profit, for-profit, or public entity that is primarily engaged in providing PACE services. The following characteristics must also apply to a PACE organization:
1. Have a governing body, or a designated person functioning as a governing body, that includes participant representation;
 2. Be able to provide the complete PACE service package regardless of frequency or duration of services;
 3. Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
 4. Have a defined service area;
 5. Have safeguards against conflict of interest;
 6. Have demonstrated fiscal soundness;
 7. Have a formal Participant Bill of Rights; and
 8. Have a process to address grievances and appeals.
- B. A provider must meet all of the following participation requirements to qualify as a PACE Organization that operates a PACE program under Arkansas Medicaid:
1. Submit a Notice of Intent to Apply (NOIA) PACE form to the Division of Aging and Adult Services as a letter of intention to establish or expand a PACE Program;
 2. Obtain an Adult Day Health Care facility license;
 - a. Adhere to all regulations established for the licensure of Adult Day Health Care (ADHC) facilities in Arkansas, overseen by the Division of Provider Services & Quality Assurance (DPSQA).
 - b. Refer to 'Rules and Regulations for Adult Day Health Care Providers' for more information. Guidance is subject to periodic revisions as warranted.
 3. Submit a PACE Provider Application and be approved by both Arkansas' Division of Aging and Adult Services and the Centers for Medicare and Medicaid Services (CMS), as per 42 CFR §460.18;
 - a. A PACE provider's past performance will be considered when determining approval or denial of new or expansion applications.
 - b. Submitting a completed PACE provider application to DAABHS after submitting

- it to CMS, or failing to submit it to DAABHS altogether, may result in the denial or delay of the application's approval.
- c. A PACE Provider Application is also required for a pre-existing PACE Organization that seeks to expand its service area or add a new PACE Center (42 CFR 460.12(d)).
 4. Execute a PACE Program Agreement, which acts as a three-party contract governing provider operations signed by the PACE provider, Division of Aging and Adult Services, and CMS; and
 5. Complete the Medicaid provider participation and enrollment requirements contained within Section 140.000 of this Medicaid manual.
- C. A provider may request a waiver of certain regulatory requirements along with their PACE Provider Application. The purpose of the waiver is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).
1. A provider should follow guidelines set forth in 42 CFR 460.26 for submission and evaluation of waiver requests.

Note: [Click here for more information on the PACE Provider Application.](#)

Note: [Click here for more information on the PACE Program Agreement.](#)

201.200 **Violations, Sanctions, Civil Money Penalties, Suspension, and Termination** **9-1-26**

- A. CMS may impose any of the sanctions as specified in 42 CFR 460.40 if CMS determines that a PACE organization commits programmatic violations.
- B. CMS may suspend Medicare payment to the PACE organization and may deny payment to the State for medical assistance for services furnished under the PACE program agreement for one or more program violations as specified in 42 CFR 460.42.
- C. CMS may impose civil money penalties up to the maximum amounts specified by federal law as specified in 42 CFR 460.46.
- D. CMS in consultation with DAABHS, may take one or more of the following actions as specified in 42. CFR 460.48:
 1. Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.
 2. Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency.
 3. Terminate the PACE program agreement.

201.300 **State Monitoring Activities for PACE Organizations** **9-1-26**

- A. DPSQA, or its vendor, conducts independent site visits annually, or as needed, in addition to CMS site visits, to compliance with regulations, state and federal laws.
- B. DPSQA, or its vendor, is responsible for conducting an exit conference with the PACE Organization to discuss any review findings, provide technical assistance in developing corrective action plans, and to assist the PACE Organization in their efforts to implement the required corrections.
- C. The PACE Organization must be licensed by the Arkansas Department of Human Services, Division of Provider Services and Quality Assurance, as an Adult Day Health Care. CMS can conduct an audit at any point after the first year of the trial period. At the

conclusion of the Three-year trial period, CMS in cooperation with DAABHS, continues to conduct reviews, as appropriate, of the PACE Organization considering the quality-of-service provision by the PACE Organization and compliance with all state and federal requirements.

- D. The PACE Organization is required to disclose to current PACE participants and potential PACE participants information specific to the PACE Organization's performance and contract compliance deficiencies, in a manner specified by CMS (42 CFR §460.198).
- E. DPSQA, or its vendor, upon annual inspection will review the following, in addition to ensuring a PACE provider is meeting the requirements of an Adult Day Health provider:
 - 1. The PACE organization's physical environment to ensure a safe, sanitary, functional, accessible, and comfortable environment;
 - 2. Suitable space and equipment to provide primary medical care and suitable space for treatment, restorative therapies, therapeutic recreation, socialization, dining and personal care;
 - 3. Suitable meeting space for personnel to conduct team meetings and for participant's caregivers, and visitors;
 - 4. Spaces which provide participant privacy and dignity during the delivery of services;
 - 5. Proof that there are life safety code inspections from the fire marshal, Department of Health, and other required state agency inspections;
 - 6. The PACE organization must provide evidence of a federal Clinical Laboratory Improvement Amendment (CLIA) exemption if the center is performing waived laboratory services on site or in the home, e.g., glucose meter testing, urine testing, fecal occult blood testing, blood testing, cholesterol screening or hemoglobin or hematocrit testing;
 - 7. In addition, the PACE organization must meet all applicable Federal, State, and local laws and regulations, which include the Americans with Disabilities Act and Section 504 of the Rehabilitation Act;
 - 8. A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the manufacturer's written recommendations. This maintenance may be performed by PACE staff or contracted entities and in compliance with the contract;
 - 9. The PACE organization is required to have trained personnel, drugs, and emergency equipment immediately available at every PACE center at all times to adequately support participants until Emergency Medical Services (EMS) responds to the PACE center;
 - 10. Each PACE center is required to have at least one staff member who has been trained in cardio-pulmonary resuscitation (CPR) and will be on site during the hours that participants are in attendance;
 - 11. The PACE organization must have a written plan and procedure for handling emergency situations that may arise including, but not limited to, cardiac arrest, choking and seizure activity in accordance with 42 CFR 460.100;
 - 12. PACE center must have a documented plan to obtain Emergency Medical Services from sources outside the PACE center when needed. At least annually, a PACE organization must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to the situations and needs that may arise from both medical and nonmedical emergencies;
 - 13. The minimum emergency equipment that must be on the premises and immediately available includes: portable oxygen, airways, suction, and emergency drugs;

14. A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located;
15. A PACE provider must have an Emergency Preparedness Plan and an Infection Control Plan.

201.400 Emergency Preparedness**9-1-26**

In accordance with 42 CFR 460.84, the PACE organization must establish and maintain an emergency preparedness program that meets the federal requirements.

The PACE organization must establish, implement, and maintain documented procedures to manage medical and non-medical emergencies and disasters that are likely to threaten the health and safety of participants, staff, or the public. The Disaster Plan must address the organization's arrangements for emergency food, nutritional supplements, and potable water supplies.

201.500 Infection Control**9-1-26**

The PACE organization must, as specified in 42 CFR 460.74, establish, implement, and maintain a documented infection control plan that ensures a safe and sanitary environment and prevents and controls the transmission of disease and infection.

A. An infection control plan must include, but is not limited to:

1. procedures to identify, investigate, control, and prevent infections in every PACE center and in each participant's place of residence;
2. procedures to record any incidents of infection; and
3. procedures to analyze the incidents of infection, to identify trends and develop corrective actions related to the reduction of future incidents.

PACE organizations are required to follow accepted policies and standard procedures with respect to infection control, including, at the least, the standard precautions developed by the Center for Disease Control and Prevention (CDC).

PACE organizations are expected to establish written policies and procedures for the investigation, control, and prevention of infections including:

B. An OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff;

1. Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, e.g., influenza and pneumonia;
2. Initial and ongoing health screening and vaccinations for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases;
3. Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection;
4. Written plans and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports. Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials;
5. Plans and procedures for staff providing direct care to patients with infection(s);
6. Provision of adequate facilities and supplies necessary for infection control to include:

- a. Hand washing facilities and supplies;
 - b. Laundry facilities and supplies;
 - c. Isolation facilities and supplies;
7. Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements;
8. Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal;
9. Written plans and procedures for the appropriate handling and disposal of all waste products including blood and urine specimens for outside lab tests and other biohazardous wastes.
- C. DPSQA, or its vendor, is responsible for conducting an exit conference with the PACE Organization to discuss any review findings, provide technical assistance in developing corrective action plans, and to assist the PACE Organization in their efforts to implement the required corrections.
- D. The PACE Organization must be licensed by the Arkansas Department of Human Services, Division of Provider Services and Quality Assurance, as an Adult Day Health Care. CMS can conduct an audit at any point after the first year of the trial period. At the conclusion of the Three-year trial period, CMS in cooperation with DAABHS, continues to conduct reviews, as appropriate, of the PACE Organization considering the quality-of-service provision by the PACE Organization and compliance with all state and federal requirements.
- E. The PACE Organization is required to disclose to current PACE participants and potential PACE participants information specific to the PACE Organization's performance and contract compliance deficiencies, in a manner specified by CMS (42 CFR §460.198).

201.600 Office of Medicaid Inspector General**9-1-26**

- A. A PACE Organization must have a formal process in place to gather information and must be able to respond in writing to a request from CMS or DAABHS for information regarding:
 1. Persons with criminal convictions.
 2. A PACE Organization must not employ individuals or contract with organizations or individuals:
 - a. Who have been excluded from participation in the Medicare or Medicaid programs;
 - b. Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Social Security Act; or
 - c. In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.
 3. Direct or indirect interest in contracts. No member of the PACE Organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE Organization.

202.000 PACE Administrative Requirements**9-1-26**

- A. In addition to participation requirements listed in Section 201.000, a PACE Organization must adhere to all PACE Administrative Requirements as outlined in 42 CFR Part 460 Subpart E, including:

1. PACE Organizational Structure;
2. PACE governing body and participant advisory committee;
3. Compliance oversight requirements;
4. Program integrity;
5. Physical environment;
6. Infection control;
7. Fiscal soundness; and
8. Emergency Preparedness.

202.100 Interdisciplinary Team**9-1-26**

- A. The PACE Organization must establish an Interdisciplinary Team (IDT), composed of members that are qualified to fill the roles described below, at each PACE Center to comprehensively assess and meet the individual needs of each participant (42 CFR 460.102):
 1. Primary Care Provider;
 2. Registered Nurse;
 3. Master's-level social worker;
 4. Physical therapist;
 5. Occupational therapist;
 6. Recreational therapist or activity coordinator;
 7. Dietitian;
 8. Home Care Coordinator;
 9. Personal Care Aide or their representative;
 10. Driver or their representative; and
 11. PACE Center Manager.
- B. The PACE Organization must assign each participant to an Interdisciplinary Team (IDT) functioning at the PACE Center that the participant attends.
 1. The IDT is responsible for:
 - a. Assessing the needs of each PACE participant;
 - b. Developing a Plan of Care;
 - c. Providing and coordinating care that meets the needs of each participant across all care settings, twenty-four (24) hours a day, every day of the year (42 CFR 460.98);
 - d. Monitoring the participant's Plan of Care and making updates as needed; and
 - e. Reviewing and determining the necessity of recommended services from a hospital, emergency department, or urgent care provider, within forty-eight (48) hours of the participant's discharge, to determine if the service will appropriately meet the participant's social, emotional, physical, and medical needs.

202.200 Participant Rights**9-1-26**

- A. A PACE Organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the rights specified below (42 CFR 460.112):

1. Respect and nondiscrimination;
 2. Right to treatment;
 3. Information disclosure, including but not limited to:
 - a. Right to have all treatment options explained in a culturally competent manner.
 - b. Right to receive information regarding palliative, comfort, or end-of-life care services.
 4. Choice of providers;
 5. Participation in treatment decisions, including, but not limited to:
 - a. Right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.
 - b. Right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.
 6. Confidentiality of health information; and
 7. Complaints, requests, and appeals.
- B. The PACE Organization must inform a participant or their representative, upon enrollment, in writing, of their rights and responsibilities, and all rules and regulations governing participation. It is required to:
1. Have the participant's rights written and displayed in English in a prominent place in the PACE Center; and
 2. Have the participant's rights available in other principal languages of the community in which the PACE organization is located, as determined by the state.
- C. The PACE organization must protect and provide for the exercise of the participant's rights, including:
1. Have established documented procedures to respond to and rectify a violation of a participant's rights; and
 2. Comply with requirements through the CMS complaints tracking module, address and resolve complaints received by CMS against the PACE organization within the required timeframes (42 CFR 460.119).
- D. Grievance Processes- Each PACE Organization must have formal written procedures to promptly identify, document, investigate, and resolve all medical and non-medical grievances in accordance with the requirements (42 CFR §460.120).
1. A grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE Organization or any other entity or individual through which the PACE Organization provides services to the participant. All grievances must be remediated.
 2. Medicare recipients have the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

202.300**Restraints****9-1-26**

The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a physical restraint or a chemical restraint (42 CFR 460.114).

- A. A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.
- B. A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.
- C. If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:
 - 1. Be imposed for a defined, limited period of time, based upon the assessed needs of the participant.
 - 2. Be imposed in accordance with safe and appropriate restraining techniques.
 - 3. Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.
 - 4. Be removed or ended at the earliest possible time.
 - 5. The condition of the restrained participant must be continually assessed, monitored, and reevaluated.

202.400 Marketing**9-1-26**

- A. PACE Organizations that publicize their programs must include in their public marketing materials:
 - 1. An adequate description of the enrollment and disenrollment policies and requirements;
 - 2. PACE enrollment procedures;
 - 3. Description of benefits and services;
 - 4. Premiums;
 - 5. Information on the restriction of services; Materials must state clearly that PACE participants may be liable for the costs of out-of-PACE program agreement services; and
 - 6. Other information necessary for prospective participants to make an informed decision about enrollment.
- B. Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.
- C. Marketing information must be furnished in English and any other principal languages of the community in which the PACE Organization is located, as determined by the State. This includes Braille, when necessary.
- D. Marketing materials must be approved by CMS and DAABHS before distribution by the PACE Organization, including any revised or updated materials. Materials will be given a 45-day review period. If not disapproved within the review period, the organization can distribute it.
- E. More details about marketing regulations can be found in 42 CFR 460.82.

203.000 PACE STAFF PARTICIPATION REQUIREMENTS**203.100 PACE Staff Participation Requirements****9-1-26**

- A. A provider must meet the following requirements to serve as a PACE Organization's staff (employee or contractor):
1. Be legally authorized (active license, registration, or certification in good standing) to practice in Arkansas and only act within the scope of his or her licensed authority.
 - a. See specific Certification or Licensure Manual for specific provider types.
 2. Successfully pass the background and registry checks and searches required by Ark. Code Ann. §§ 20-33-213 and 20-38-101 et seq.

203.200 Qualifications of PACE Staff with Direct Participant Contact**9-1-26**

- A. Each member of the PACE Organization's staff (employee or contractor) that has direct contact with participants must meet all the following conditions (42 CFR 460.64):
1. Have one (1) year of experience working with a frail or elderly population or, if the individual has less than one (1) year of experience, must receive appropriate training from the PACE Organization on working with a frail or elderly population.
 2. Meet a standardized set of competencies, as described in Section 202.201 for the specific position description established by the PACE Organization, before working independently.
 3. Have all immunizations up to date before engaging in direct participant contact.
 4. Be medically cleared of communicable disease, and specifically determined free of active Tuberculosis, prior to providing direct care.
 - a. Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant.
 - b. A PACE Organization may alternatively choose to perform an individual risk assessment for symptoms and exposure (must meet requirements specified in 42 CFR 460.64(a)(5)(iii)) to determine when a physical exam would be required for staff. Results of risk assessment must be reviewed by RN, physician, nurse practitioner, or physician assistant.
 5. PACE Center staff must follow additional staffing regulations outlined in 'Rules and Regulations for Adult Day Health Care Providers,' the licensure manual for Adult Day Health Care (ADHC) facilities in Arkansas. Guidance is subject to periodic revisions as warranted.

203.300 Training for PACE Staff with Direct Participant Contact**9-1-26**

- A. A PACE Organization must ensure all its employees and contracted staff providing direct care to participants demonstrate the skills necessary for performance of their position (42 CFR §460.71).
1. The PACE Organization must provide all staff with an orientation that includes, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE Program, and any policies related to the job duties.
 2. The provider must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff.
 - a. Training shall be appropriate to job function and shall include but is not limited

to the ADHC's licensure manual for training.

3. The competency program must be evidenced as completed before performing participant care and on an on-going basis by qualified professionals.
4. Certification of the satisfactory completion of the competency program must be in the personnel files of all staff.

210.000 PROGRAM ELIGIBILITY

210.100 Scope

9-1-26

Arkansas Medicaid will pay qualified PACE Organizations a fixed monthly payment per enrolled Medicaid participant for comprehensive services delivered to those who meet the PACE eligibility requirements of this Medicaid manual. Medicaid payment is conditional upon compliance with this manual, manual update transmittals, and official program correspondence.

210.200 Program Participant Eligibility Requirements

9-1-26

- A. Participation in PACE is available to individuals fifty-five (55) years of age and older who live in a PACE Service Area, meet nursing home level of care as determined by Division of Aging and Adult Services, can live safely in a community setting without risking health or safety, and agree to forgo their usual sources of care to receive all services through the PACE Organization.
 1. Additional eligibility requirements include:
 - a. Having proof of residency in the State of Arkansas;
 - b. Being a US citizen or legal alien;
 - c. Having proof of a valid Social Security Number;
 - d. Meeting Intermediate I-S, I-A, II-B, or III-C nursing facility level of care; and
 - e. Meeting one of the following medical criteria, as assessed by a DHS Registered Nurse:
 - i. Unable to perform at least one (1) of the three (3) activities of daily living (ADLs) of transferring or locomotion, eating, or toileting without extensive assistance or total dependence upon another person;
 - ii. Unable to perform at least two (2) of the three (3) activities of daily living (ADLs) of transferring or locomotion, eating, or toileting without limited assistance from another person;
 - iii. Primary or secondary diagnosis of Alzheimer's disease or related dementia and cognitively impaired so as to require substantial supervision from another individual; or
 - iv. Diagnosed medical condition which requires monitoring or assessment at least once a day by a licensed medical professional and if left untreated, would be life threatening.

Note: Individuals diagnosed with serious mental illness (SMI) or an intellectual disability are not eligible for PACE unless their medical needs are unrelated to their SMI/DD diagnosis and they meet the other qualifying criteria.

2. Medicare beneficiaries meeting the above requirements agree to participate in PACE by paying monthly premiums equal to the Medicaid capitation amount, but no deductibles, coinsurance, or any other type of Medicare or Medicaid cost-sharing.
3. Individuals not eligible for Medicaid or Medicare who meet the above requirements agree to participate in PACE by paying private premiums.

210.300 Evaluation Referral**9-1-26**

- A. A beneficiary may be initially referred to PACE by a PACE Organization or DHS Registered Nurse, however an outside referral is not required to apply.
- B. Beneficiaries apply for PACE through their local Division of County Operations (DCO) office for a determination of financial eligibility.
- C. The local DCO office will refer the beneficiary for an independent assessment, determination of financial eligibility notwithstanding.

210.400 Independent Assessment and Level of Care Determination**9-1-26**

- A. For individuals new to PACE, the individual must receive an Independent Assessment via the Arkansas Independent Assessment (ARIA) instrument, administered by a DHS-appointed Independent Assessment Contractor. The ARIA determines the individual's functional needs eligibility.
 - 1. The Division of County Operations (DCO) registered nurse determines the potential enrollee's nursing facility level of care via the DHS-704 based on the results of the Independent Assessment.
 - 2. The DCO registered nurse notifies the PACE Organization when all requirements have been met.
- B. For renewing PACE participants, a Division of Aging and Adult Services registered nurse completes an annual evaluation (Medical Needs Assessment Form DMS-703) to evaluate the potential enrollee's nursing facility level of care.
 - 1. To be eligible for PACE, beneficiaries must have a Medical Needs Assessment indicating they require Intermediate I-S, I-A, II-B, or III-C nursing facility level of care.
 - 2. The Division of Aging and Adult Services' registered nurse must certify that an assessment has been completed and that it is safe for the participant to live in the community.
 - 3. The Division of Aging and Adult Services' registered nurse notifies the local Division of County Operations (DCO) office and the PACE Organization when all requirements have been met.

210.500 Enrollment with PACE Organization**9-1-26**

- A. If the potential participant meets the eligibility requirements and wants to pursue enrollment with the PACE Organization, they must sign an enrollment agreement with the PACE Organization that serves their Service Area. For more details on the contents of the enrollment agreement, see 42 CFR 460.154.
 - 1. Enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. See 42 CFR 460.154(i).
 - 2. The PACE Organization is required to complete its own intensive assessment that includes a minimum of one (1) home visit for enrollment.
 - 3. The potential enrollee is required to complete one (1) visit to the PACE Center, unless otherwise approved by CMS.
 - 4. At the time of enrollment, the PACE Organization is required to do the following:
 - a. Verify whether the participant is dually eligible for Medicare and Medicaid and whether the participant has Medicare Part A, Part B, or both;
 - b. Remind participants that unless they are dually eligible, they will need to continue to pay their Medicare Part A premium (if not free), Part B premium (if

- not eligible for State coverage), and Part D premium, if applicable; and
 - c. Identify payers that are primary to Medicare, determine the amounts payable by those payers, and coordinate benefits to Medicare participants with the benefits of primary payers.
- B. Involuntary Disenrollment
- 1. Involuntary disenrollments are to be handled pursuant to federal law.
 - 2. Refer to 42 C.F.R. 460.164, 460.166 and 460.172.

210.600 Person-Centered Plan of Care**9-1-26**

- A. After the individual is enrolled, the PACE Organization's Interdisciplinary Team (IDT) is responsible for individualized assessment, treatment planning, and care delivery. The IDT must meet the following requirements for the Plan of Care:
- 1. Complete an initial, in-person, comprehensive assessment by the following members promptly following the beneficiary's enrollment:
 - a. Primary care physician;
 - b. Registered nurse;
 - c. Master's-level social worker;
 - d. Physical therapist;
 - e. Occupational therapist;
 - f. Recreational therapist or activity coordinator;
 - g. Dietitian; and
 - h. Home care coordinator.
 - 2. Develop, evaluate, and, if necessary, revise the comprehensive Person-Centered Plan of Care for the participant (42 CFR §460.106).
 - a. The Interdisciplinary Team must complete the initial Plan of Care within thirty (30) calendar days of the participant's date of enrollment.
 - b. The Interdisciplinary Team must involve the participant and their family members or circle of natural supports in the development of the Plan of Care. The PACE Organization should document beneficiary and/or family approval of the Plan of Care.
 - c. The Plan of Care must explain different treatment options, provide written information of those options, and obtain written consent prior to initiating any palliative, comfort, or end-of-life care services.
 - d. At least once every one hundred eighty (180) calendar days from the date the latest Plan of Care was finalized, the Interdisciplinary Team must complete a semi-annual Plan of Care evaluation, and if necessary, revisions to each participant's Plan of Care.
 - 3. For requests from the participant, or their representative or caregiver, to initiate, modify, or continue a service during the development of the initial Person-Centered Plan of Care, the IDT must:
 - a. Document the request; and
 - b. Discuss the request during the care planning meeting and either:
 - i. Approve the requested service and incorporate it into the participant's initial Plan of Care; or
 - ii. Document the rationale for not approving the service in the initial Plan of Care.

4. Additional in-person Assessments and Treatment Plans corresponding to the overall Person-Centered Plan of Care must be completed, as applicable, by the:
 - a. Physical therapist;
 - b. Occupational therapist;
 - c. Dietitian; and
 - d. Home care coordinator.

B. Change of Condition

1. When a change of condition is noted by any provider delivering services to the PACE participant, the Interdisciplinary Team must update the Plan of Care within fourteen (14) days from the actual status change.
2. Re-assessments and Treatment Plan changes are also completed when the PACE participant experiences a change in health or psycho-social condition.

210.700 Service Determination Process

9-1-26

A. Service Determination Requests (42 CFR 460.121)

1. A Service Determination Request is a request made by a participant, their representative, or their caregiver to initiate a new service, modify an existing service, or continue coverage of a service that a PACE Organization is recommending being discontinued or reduced.
 - a. Requests can be made orally or in writing to any employee or contractor of the PACE Organization that provides direct care to a participant, including transportation personnel.
 - b. If a request is made prior to completing the development of the initial Person-Centered Plan of Care, it is not considered a Service Determination Request.
2. The PACE organization must bring a Service Determination Request to the Interdisciplinary Team (IDT) as expeditiously as the participant's condition requires, but no later than three (3) calendar days from the time the request is made.
 - a. If a member of the IDT is able to approve the Service Determination Request in full at the time the request is made, the PACE Organization:
 - i. Must provide oral or written notice of decision to approve a service determination request to the participant, in understandable language. The approval should include the conditions of the approval, including when the participant may expect to receive the approved service.
 - ii. Must follow recordkeeping requirements established in Part B below.
 - iii. Does not need a full IDT review.
 - b. In all other cases, the full IDT must review and discuss each Service Determination Request and decide to approve, deny, or partially deny the request based on that review.
 - i. IDT will consider all relevant information when evaluating a request, including, but not limited to, the findings and results of any reassessments.
 - c. The IDT may extend the timeframe for review and notification by up to five (5) calendar days if either of the following occur:
 - i. The participant or their representative request the extension; or
 - ii. The IDT needs additional information from an individual, not directly employed by the PACE Organization, that may change the interdisciplinary team's decision to deny a service.
 - d. The participant or their representative must be notified of any extension in

review timeframe either orally or in writing, no later than twenty-four (24) hours after the IDT decides to extend the review timeframe.

- e. If the IDT fails to provide the participant with timely notice of the resolution of the request, or does not furnish the services required by the revised Person-Centered Plan of Care, this constitutes an adverse decision. The participant's request must be automatically processed by the PACE organization as an appeal (42 CFR 460.121(l)).

B. Recordkeeping

1. The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for Service Determination Requests received both orally and in writing.
2. These records must be available to the IDT to ensure that all members remain alert to pertinent participant information.

C. Reassessments based on a Service Determination Request

1. If the IDT expects to deny or partially deny a Service Determination Request, the appropriate members of the IDT must conduct an in-person Reassessment before the IDT makes a final decision.
2. IDT members performing the Reassessment evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.
3. The IDT may conduct a Reassessment prior to approving a Service Determination Request, either in-person or through the use of remote technology, if the team determines that a Reassessment is necessary.

210.800 Service Determination Approvals and Denials

9-1-26

A. Notice of decision to approve a Service Determination Request

1. If the interdisciplinary team (IDT) decides to approve a Service Determination Request, it must provide the participant or representative either oral or written notice of the determination.
2. The approval must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

B. Notice of decision to deny a Service Determination Request (42 CFR 460.121(j))

1. If the IDT decides to deny or partially deny a service, it must provide the participant or representative both oral and written notice of the determination.
2. Notice of any denial must:
 - a. State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the Reassessment(s) in understandable language.
 - b. Inform the participant or representative of his or her right to appeal the decision.
 - c. Describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services.
 - d. For a Medicaid participant, inform the participant of both of the following:
 - i. His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.
 - ii. The conditions for continuing to receive disputed services.

C. Appeals

1. An appeal to a PACE Organization is a participant's action taken with respect to the PACE Organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. Refer to Appendix R in the PACE Program Agreement.
2. A request to initiate, modify, or continue a service must first be processed as a service determination request under Section 210.700 before the PACE organization can process an appeal under this section.
3. See further details on a PACE Organization's Appeals Process (42 CFR 460.122).
4. Additional appeal rights under Medicare or for those dually eligible for Medicare and Medicaid can be found 42 CFR 460.124.
5. Medicaid Administrative Reconsideration and Appeals:
 - a. Medicaid allows only one (1) reconsideration of an adverse decision. Reconsideration requests must be submitted in accordance with Section 160.000 Section 1 of this Medicaid Manual.
 - b. When the State Medicaid Agency or its designee denies a reconsideration request or issues any adverse decision, the beneficiary may appeal and request a fair hearing. A request for a fair hearing must be submitted in accordance with Sections 160.000, 190.000, and 191.000 of Section 1 of this Medicaid Manual.

220.000 PROGRAM SERVICES

220.100 Non-covered Services

9-1-26

- A. Medicare and Medicaid services delivered solely through the PACE Organization are the only benefits covered while the participant is enrolled in a PACE program (42 CFR 460.90).
- B. The following services are excluded from coverage under PACE:
 1. Cosmetic surgery;
 2. Experimental medical, surgical, or other health procedures; and
 3. Services furnished outside the USA, except as permitted under the state's Medicaid Plan.

220.200 Covered Services

9-1-26

The PACE benefit package for all participants, regardless of the source of payment, must include the following as prescribed by the Interdisciplinary Team (IDT) assessment:

- A. All Medicaid-covered services, as specified in the State's approved Medicaid plan.
- B. Interdisciplinary assessment and treatment planning.
- C. Primary care, including physician and nursing services.
- D. Social work services.
- E. Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services.
- F. Personal care and supportive services.
- G. Nutritional counseling.

- H. For more detailed policies on meal requirements and sanitary conditions, see 42 CFR 460.78.
- I. Recreational therapy.
- J. Transportation.
 - 1. For more detailed policies on required safety, accessibility, and equipment; maintenance of vehicles; vehicle communication with PACE center; personnel training; and inclusion in any changes to the person-centered service plan, see 42 CFR 460.76.
- K. Meals as required by the interdisciplinary team's plan of care.
- L. Medical specialty services including, but not limited to the following:
 - 1. Anesthesiology;
 - 2. Audiology;
 - 3. Cardiology;
 - 4. Dentistry;
 - 5. Dermatology;
 - 6. Gastroenterology;
 - 7. Gynecology;
 - 8. Internal medicine;
 - 9. Nephrology;
 - 10. Neurosurgery;
 - 11. Oncology;
 - 12. Ophthalmology;
 - 13. Oral surgery;
 - 14. Orthopedic surgery;
 - 15. Otorhinolaryngology;
 - 16. Palliative Medicine
 - 17. Plastic surgery;
 - 18. Pharmacy consulting services;
 - 19. Podiatry;
 - 20. Psychiatry;
 - 21. Pulmonary disease;
 - 22. Radiology;
 - 23. Rheumatology;
 - 24. General surgery;
 - 25. Thoracic and vascular surgery; and
 - 26. Urology.
- M. Laboratory tests, x-rays, and other diagnostic procedures.
- N. Drugs and biologicals.

- O. Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.
- P. Acute inpatient care, including the following:
 - 1. Ambulance;
 - 2. Emergency room care and treatment room services;
 - 3. Semi-private room and board;
 - 4. General medical and nursing services;
 - 5. Medical, surgical, intensive care, and the Coronary Care Unit;
 - 6. Laboratory tests, x-rays, and other diagnostic procedures;
 - 7. Drugs and biologicals;
 - 8. Blood and blood derivatives;
 - 9. Surgical care, including the use of anesthesia;
 - 10. Use of oxygen;
 - 11. Physical, occupational, respiratory therapies, and speech language pathology services; and
 - 12. Social services.
- Q. Nursing facility care, including the following:
 - 1. Semi-private room and board;
 - 2. Physician and skilled nursing services;
 - 3. Custodial care;
 - 4. Personal care and assistance;
 - 5. Drugs and biologicals;
 - 6. Physical, occupational, recreational therapies, and speech-language pathology, if necessary;
 - 7. Social services; and
 - 8. Medical supplies and appliances.
- R. Other services determined necessary by the IDT to improve and maintain the participant's overall health status.
 - 1. Medications must be provided within twenty-four (24) hours of the Primary Care Provider's order.
 - 2. All services (other than medications) approved by the IDT must be set-up, scheduled, or arranged within seven (7) days of the approval. This does not include routine or preventative services.
 - 3. Notwithstanding, all services and medications are to be provided as expeditiously as the participant's health requires, so if needed, services must be provided more quickly than the timelines provided for in this section.
 - 4. Contracted Services.
- S. The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, including, at a minimum, the medical specialties listed previously in this Section (as per 42 CFR 460.70).

1. Contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services.
2. A PACE Organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE Organization is unable to directly contract or maintain a contract with a specific specialty, the PACE Organization must:
 - a. Ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization; and
 - b. Promptly report the contracting issue to CMS and DAABHS, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE Organization's plan to provide access to the necessary services.
3. A PACE Organization is not required to have a contract with a particular medical specialty if the PACE Organization directly employs one (1) or more individuals prior to contracting, who are legally authorized, and, if applicable, board certified in the particular medical specialty.
4. For more information about contract requirements, the mandatory list of contractors that must be kept on file, see 42 CFR 460.70.

SECTION II—PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

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200.000 — PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) GENERAL INFORMATION

201.000 — Arkansas Medicaid Participation Requirements for Providers of the Program of All-Inclusive Care for the Elderly (PACE)

4-1-06

The Program of All-Inclusive Care for the Elderly (PACE) is an innovative model that enables individuals who are 55 years of age or older and certified by the state to need nursing facility

care, to live as independently as possible. Through PACE, fragmented health care financing and delivery system comes together to serve the unique needs of the enrolled individual with chronic care needs. The population served by PACE is historically very frail. The PACE organization must provide all needed services to the PACE participant.

201.100 PACE Provider Enrollment Requirements

4-1-19

To ensure quality and continuity of care, all PACE providers approved to receive Medicaid reimbursement for services provided must meet specific qualifications. PACE providers must meet the Provider Participation and enrollment requirements contained within Section 140.000 of this manual as well as the following criteria to be eligible to participate in the Arkansas Medicaid Program:

- A. PACE providers must be certified by the Division of Provider Services and Quality Assurance (DPSQA) as having met all Centers for Medicare and Medicaid Services (CMS) approved provider criteria for the service(s) they wish to enroll to provide.

Certification by the DPSQA does not guarantee enrollment in the Medicaid program.

All providers must maintain their provider files at the Provider Enrollment Unit by submitting current certification, licensure, etc., all DPSQA issued certification renewals and any other renewals affecting their status as a Medicaid eligible provider.

Copies of certifications and renewals required by DPSQA must be maintained by DPSQA to avoid loss of provider certification.

- B. A PACE provider application must be approved by the Centers for Medicare and Medicaid Services (CMS) and the Division of Aging, Adult and Behavioral Health Services (DAABHS). Failure to submit a PACE provider application to DAABHS at the same time or prior to submitting the application to CMS shall constitute grounds for DAABHS denying or delaying approval of the application.

- C. A three-way Provider Agreement must be signed by the DAABHS, CMS, and the provider.

- D. The PACE Organization must be licensed by the Arkansas Department of Human Services, DPSQA, as an Adult Day Health Care.

202.000 Staff Requirements (42 CFR §460.64)

4-1-06

Staff members (employees or contractors) of the PACE Organization must meet the following conditions:

- A. Be legally authorized, which means currently licensed, certified or registered, if applicable, to practice in the state; and
- B. Only act within the scope of his or her authority to practice.

202.100 Staff Training (42 CFR §460.66)

4-1-06

The PACE Organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

202.200 Staff Oversight Responsibility (42 CFR §460.71)

4-1-13

- A. The PACE Organization must ensure that all employees and contracted staff providing care directly to participants demonstrate the skills, licensure, and/or certifications necessary for performance of their position.

1. The PACE Organization must provide all staff with an orientation that includes, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, and the PACE Program and any policies related to the job duties.
 2. The provider must develop a competency evaluation program that identifies those skills, knowledge and abilities that must be demonstrated by direct participant care staff.
 3. The competency program must be evidenced as completed before performing participant care and on an on-going basis by qualified professionals. Certification of the satisfactory completion of the competency program must be in the personnel files of all staff.
- B. The PACE Organization must develop a program to ensure that all staff furnishing direct participant care services:
1. Comply with any state or federal requirements for direct patient care staff in their respective settings;
 2. Comply with the requirements of 42 CFR §460.68(a) regarding persons with criminal convictions;
 3. Have verified current certifications or licenses for their respective positions;
 4. Are free of communicable diseases and are up to date with immunizations before performing direct patient care;
 5. Have been oriented to the PACE Program; and
 6. Agree to abide by the philosophy, practices and protocols of the PACE Organization.

203.000 Office of Medicaid Inspector General**4-1-16**

A PACE Organization must have a formal process in place to gather information and must be able to respond in writing to a request from CMS and/or the State Administering Agency (SAA) for information regarding:

- A. Persons with criminal convictions.
- B. A PACE Organization must not employ individuals or contract with organizations or individuals:
1. Who have been excluded from participation in the Medicare or Medicaid programs;
 2. Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Social Security Act; or
 3. In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug or alcohol abuse.
- C. Direct or indirect interest in contracts. No member of the PACE Organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE Organization.

203.100 Infection Control (42 CFR §460.74)**4-1-06**

- A. The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

- The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:
 - 1. — Ensures a safe and sanitary environment
 - 2. — Prevents and controls the transmission of disease and infection
- B. — Contents of infection control plan. The infection control plan must include, but is not limited to, the following:
 - 1. — Procedures to identify, investigate, control, and prevent infections in every center and in each participant's place of residence.
 - 2. — Procedures to record any incidents of infection.
 - 3. — Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

203.200 — Transportation Services (42 CFR §460.76)**4-1-06**

A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

- A. — If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.
- B. — If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.
- C. — The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.
- D. — The PACE organization must train all transportation personnel (employees and contractors) in the following:
 - 1. — Managing the special needs of participants.
 - 2. — Handling emergency situations.
- E. — As part of the interdisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

203.300 — Dietary Services (42 CFR §460.78)**4-1-06**

Except as specified in paragraphs items B or C of this section, the PACE organization must provide each participant with a nourishing, palatable, well-balanced meal that meets the daily nutritional and special dietary needs of each participant.

- A. — Each meal must meet the following requirements:
 - 1. — Be prepared by methods that conserve nutritive value, flavor, and appearance;
 - 2. — Be prepared in a form designed to meet individual needs; and
 - 3. — Be prepared and served at the proper temperature.
- B. — The PACE organization must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:
 - 1. — Refuses the food served;
 - 2. — Cannot tolerate the food served; or

3. ~~Does not eat adequately.~~

C. ~~The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.~~

D. ~~To ensure that conditions are sanitary, the PACE organization must do the following:~~

1. ~~Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization;~~
2. ~~Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions; and~~
3. ~~Dispose of garbage and refuse properly.~~

204.000 Participant Eligibility

4-1-06

~~The State of Arkansas will utilize essentially the same non-medical and medical eligibility criteria for the PACE participants as that used for determining eligibility for nursing facility services.~~

~~An individual who does not meet the non-medical criteria may participate in the PACE Program as private pay if he or she meets the same medical criteria as Medicaid eligibles.~~

204.100 Non-Medical Criteria

4-1-06

~~Medicaid eligibility for the PACE Program will be based on the following requirements:~~

- A. ~~Age — 55 or older;~~
- B. ~~Care Need — The participant must require one of the following four levels of nursing facility care: Intermediate I-S, I-A, II-B, and III-C;~~
- C. ~~Citizenship — Must be a citizen of the U.S. or lawfully admitted alien;~~
- D. ~~Residency — Must be a resident of the State of Arkansas and reside in the PACE program service delivery area;~~
- E. ~~Social Security Enumeration required; and~~
- F. ~~Safety of the Participant — Health and safety of the participant will not be jeopardized by living in the community.~~

204.200 Medical Criteria

4-1-19

~~PACE participants must meet one of the following criteria:~~

~~The individual is unable to perform either of the following:~~

- A. ~~At least one (1) of the three (3) activities of daily living (ADL) of transferring and/or locomotion, eating or toileting without extensive assistance from or total dependence upon another person;~~
- B. ~~At least two (2) of the three (3) activities of daily living (ADL) of transferring and/or locomotion, eating or toileting without limited assistance from another person;~~
- C. ~~The individual has a primary or secondary diagnosis of Alzheimer's disease or related dementia and is cognitively impaired so as to require substantial supervision from another individual because he or she engages in inappropriate behaviors which pose serious health or safety hazards to themselves or others;~~

- D. The individual has a diagnosed medical condition which requires monitoring or assessment at least once a day by a licensed medical professional and the condition, if untreated, would be life threatening; or,
- E. Individuals diagnosed with a serious mental illness or mental retardation are not eligible for the Program of All-Inclusive Care for the Elderly unless they have medical needs unrelated to the diagnosis of mental illness or mental retardation and meet the other qualifying criteria. A diagnosis of severe mental illness or mental retardation must not bar eligibility for individuals having medical needs unrelated to the diagnosis of serious mental illness or mental retardation when they meet the other qualifying criteria.

205.000 — Records PACE Providers Are Required to Keep (42 CFR §460.210)**205.100 — Retention of Records**

4-1-13

All medical records of PACE participants must be completed promptly, filed and retained for a minimum of six (6) years from the date of service or until all audit questions, appeal hearings, investigations or court cases are resolved, whichever is longer. The records must be available upon request for audit by an authorized representative of the Arkansas Division of Medical Services, the State Medicaid Fraud Control Unit and representatives of the National Department of Health and Human Services.

205.200 — Documentation Requirements (42 CFR §460.210)

4-1-13

All services provided to the PACE participant must be properly documented in the PACE participant's record and signed by the service provider at the time the service is delivered. At a minimum, the medical record must contain appropriate identifying information and documentation of all services furnished including the following:

1. A summary of emergency care and other inpatient or long-term care services
2. Services furnished by employees of the PACE Organization
3. Services furnished by contractors and their reports
4. Interdisciplinary assessments, reassessments, plans of care, treatment and progress notes that include the participant's response to treatment
5. Laboratory, radiological and other test reports
6. Medication records
7. Hospital discharge summaries, if applicable; continuance of follow-up care post hospitalization
8. Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin)
9. Enrollment agreement
10. Physician orders
11. Discharge summary and Disenrollment justification, if applicable
12. Advance directives, if applicable
13. A signed release permitting disclosure of personal information
14. Accident and incident reports

205.300 — Medicaid Field Audit Review of Records

4-1-06

All documentation must be available to representatives of the Division of Medical Services at the time of an audit by the Medicaid Field Audit Unit. All documentation must be available at the provider's place of business. No more than thirty (30) days will be allowed after the date on the

~~recoupment notice in which additional documentation will be accepted. Additional documentation will not be accepted after the 30-day period.~~

210.000 PROGRAM COVERAGE

211.000 Scope (42 CFR §460.92)

4-1-06

A PACE Organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours per day, every day of the year.

The PACE benefit package for all participants, regardless of the source of payment, must include the following as prescribed by the interdisciplinary team assessment:

- A. All Medicaid covered services, as specified in the State's approved Medicaid plan
- B. Interdisciplinary assessment and treatment planning
- C. Primary care, including physician and nursing services
- D. Social work services
- E. Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services
- F. Personal care and supportive services
- G. Nutritional counseling
- H. Recreational therapy
- I. Transportation
- J. Meals as required by the interdisciplinary team's plan of care
- K. Medical specialty services including, but not limited to the following:
 - 1. Anesthesiology,
 - 2. Audiology,
 - 3. Cardiology,
 - 4. Dentistry,
 - 5. Dermatology,
 - 6. Gastroenterology,
 - 7. Gynecology,
 - 8. Internal medicine,
 - 9. Nephrology,
 - 10. Neurosurgery,
 - 11. Oncology,
 - 12. Ophthalmology,
 - 13. Oral surgery,
 - 14. Orthopedic surgery,
 - 15. Otorhinolaryngology,
 - 16. Plastic surgery,

17. —Pharmacy consulting services;
 18. —Podiatry;
 19. —Psychiatry;
 20. —Pulmonary disease;
 21. —Radiology;
 22. —Rheumatology;
 23. —General surgery;
 24. —Thoracic and vascular surgery, and
 25. —Urology.
- L. —Laboratory tests, x-rays and other diagnostic procedures
- M. —Drugs and biologicals
- N. —Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.
- O. —Acute inpatient care, including the following:
1. —Ambulance;
 2. —Emergency room care and treatment room services;
 3. —Semi-private room and board;
 4. —General medical and nursing services;
 5. —Medical surgical/intensive care/coronary care unit;
 6. —Laboratory tests, x-rays and other diagnostic procedures;
 7. —Drugs and biologicals;
 8. —Blood and blood derivatives;
 9. —Surgical care, including the use of anesthesia;
 10. —Use of oxygen;
 11. —Physical, occupational, respiratory therapies, and speech language pathology services, and
 12. —Social services
- P. —Nursing facility care
1. —Semi-private room and board
 2. —Physician and skilled nursing services
 3. —Custodial care
 4. —Personal care and assistance
 5. —Drugs and biologicals
 6. —Physical, occupational, recreational therapies, and speech language pathology, if necessary
 7. —Social services
 8. —Medical supplies and appliances

- Q. ~~Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.~~

211.100 Emergency Care

4-1-06

- A. ~~A PACE Organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE Organization does not pay for emergency services.~~
- B. ~~Emergency care is appropriate when services are needed immediately because of an injury or sudden illness, and the time required to reach the PACE organization or one of its contract providers would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:~~
- ~~1. Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area.~~
 - ~~2. Are needed to evaluate or stabilize an emergency medical condition.~~
- C. ~~An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:~~
- ~~1. Serious jeopardy to the health of the participant.~~
 - ~~2. Serious impairment to bodily functions.~~
 - ~~3. Serious dysfunction of any bodily organ or part.~~
- D. ~~The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services.~~
- E. ~~The plan must provide for the following:~~
- ~~1. An on-call provider, available 24 hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.~~
 - ~~2. Coverage of urgently needed out-of-network and post stabilization care services when either of the following conditions are met:~~
 - ~~a. The services are pre-approved by the PACE organization.~~
 - ~~b. The services are not pre-approved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.~~

211.200 Exclusions

4-1-06

~~The following services are excluded from coverage under PACE:~~

- A. ~~Any service that is not authorized by the interdisciplinary team, even if it is a required service, unless it is an emergency service;~~
- B. ~~In an inpatient facility, private room and private duty nursing services (unless medically necessary), and non-medical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant's plan of care);~~

- C. ~~Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy;~~
- D. ~~Experimental medical, surgical, or other health procedures; and~~
- E. ~~Services furnished outside of the United States, except as follows:~~
 - 1. ~~In accordance with §424.122 through 4424.124 of 42 CFR.~~
 - 2. ~~As permitted under the State's approved Medicaid plan.~~

212.000 Participant Enrollment/Disenrollment**4-1-06**

~~To enroll in the PACE program, an individual must meet the requirements specified in Sections 204.000 through 204.200.~~

212.100 PACE Enrollment**1-1-19**

~~Participant enrollment into the PACE Program is voluntary. Prospective PACE beneficiaries may apply for PACE services through their local Department of Human Services (DHS) county offices. Applicants may apply by referral from the PACE provider, by referral from a DHS RN, or without a referral from any source. Regardless of the origin of the inquiry, the prospective participant must meet the medical and financial eligibility criteria.~~

~~If the prospective PACE beneficiary makes the initial inquiry with the PACE provider or the DHS-Registered Nurse (RN), the provider or RN will instruct the applicant to make application at the local DHS county office for a determination of financial eligibility. The local DHS county office will make the proper referral to the DHS RN for the medical assessment.~~

~~The Office of Long Term Care, Division of Provider Services and Quality Assurance, of the Department of Human Services must determine, based on the functional assessment conducted by the Independent Assessment Contractor, that the potential enrollee meets the requirements for nursing facility care prior to enrollment. The DHS RN must certify that an assessment has been completed and that it is safe for the participant to live in the community. The DHS RN will notify the local DHS county office and the Provider Organization (PO) that all requirements have been met.~~

~~The PACE provider must explain to the potential enrollee that enrollment in PACE results in disenrollment in any other Medicare or Medicaid plan and the provider is required to complete an intensive assessment that includes a minimum of one home visit and one visit by the potential enrollee to the PACE center unless otherwise approved by CMS.~~

212.200 Disenrollment**1-1-19**

~~Participants may voluntarily disenroll from the PACE program at any time for any reason.~~

~~Participants may be involuntarily disenrolled due to:~~

- A. ~~Participant's failure to pay if he or she has a payment responsibility~~
- B. ~~Participant's disruptive or threatening behavior~~
- C. ~~Participant moves out of the PACE service delivery area~~
- D. ~~Participant no longer meets the nursing facility level of care requirement~~
- E. ~~The PACE program agreement with the Centers for Medicare and Medicaid Services (CMS) and the state is not renewed~~

~~F. The PACE organization cannot provide the required services due to loss of licensure or contracts with outside providers~~

~~To involuntarily disenroll a participant, the PACE Organization must obtain the prior review and approval of the Department of Human Services. The request to disenroll a participant and documentation to support the request must be sent to the DHS-RN. The DHS-RN will review the request and corresponding documentation and will make a recommendation to the DHS-RN Supervisor and DHS PACE Program Manager regarding whether the PACE Organization should proceed with the involuntary disenrollment. The DHS-RN Supervisor, in consultation with PACE Program management will make a final determination regarding the appropriateness of the involuntary disenrollment and will notify the PACE Organization and the DHS-RN.~~

~~The PACE Organization may request an administrative reconsideration pursuant to Section 190.003. A request for administrative reconsideration must be directed to the Division of Aging, Adult and Behavioral Health Services.~~

215.000 Interdisciplinary Teams

1-1-19

~~The PACE interdisciplinary team must meet regularly as indicated in the Provider Agreement between the PO, CMS, and the Division of Aging, Adult and Behavioral Health Services to provide overall assessment of care needs and subsequent management, supervision and provision of care for eligible individuals.~~

215.100 Composition of the PACE Interdisciplinary Team (42 CFR §460.102)

1-1-13

~~The PACE interdisciplinary team must be composed of at least the following members:~~

- ~~A. Primary care physician (PCP)~~
- ~~B. Registered nurse (RN)~~
- ~~C. Master Social worker (MSW)~~
- ~~D. Physical therapist (PT)~~
- ~~E. Occupational therapist (OT)~~
- ~~F. Recreational therapist (RT)/activity coordinator~~
- ~~G. Dietician~~
- ~~H. PACE center manager~~
- ~~I. Home care coordinator~~
- ~~J. Personal care attendant/aide~~
- ~~K. Transportation staff/driver~~

215.200 Assessment/Treatment Plan

1-1-19

~~An interdisciplinary team is responsible for assessment, treatment planning and care delivery after the Independent Assessment Contractor has completed an initial assessment using the ARIA assessment instrument to determine the individual's functional needs and eligibility for nursing facility level of care. The team must meet the following assessment requirements:~~

- ~~A. An initial in-person comprehensive assessment must be completed promptly following enrollment by the:~~
 - ~~1. Primary care physician;~~

2. — Registered nurse;
3. — Master's-level social worker;
4. — Physical therapist;
5. — Occupational therapist;
6. — Recreational therapist or activity coordinator;
7. — Dietitian and
8. — Home care coordinator.

B. — At least semi-annually, an in-person assessment and treatment plan must be completed by the:

1. — Primary care physician;
2. — Registered nurse;
3. — Master's-level social worker and
4. — Recreational therapist/activity coordinator.

C. — Annually, an in-person assessment and treatment plan must be completed by the:

1. — Physical therapist;
2. — Occupational therapist
3. — Dietitian and
4. — Home care coordinator.

PACE organizations consolidate discipline specific plans into a single plan of care semi-annually through discussion and consensus of the interdisciplinary team. The consolidated plan is then discussed and finalized with the PACE participant and/or his or her significant others.

Reassessments and treatment plan changes are completed when the health or psychosocial situation of the participant changes.

245.300 — PACE Participant Appeal Process

6-1-25

When an adverse decision is received, the PACE participant may appeal. The appeal request must be submitted in accordance with Sections 160.000, 190.000, and 191.000 of Section I of this Manual.

220.000 — Quality Assurance and Monitoring Activities

1-1-13

The Department of Human Services will conduct site visits annually during the trial period in conjunction with CMS or as needed to review the quality of service provision by the PACE Organization. The annual site visit review will include a clinical and administrative component and a review of compliance with life safety codes. The annual on-site review will include but not be limited to a review of the PACE Organization's compliance with requirements in 42 CFR § 460, or its successor, in the following compliance areas:

1. — Administrative;
2. — PACE Services;
3. — Participant Rights;
4. — Quality Assessment and Performance Improvement;
5. — Participant Enrollment and Disenrollment;
6. — Payment;

7. ~~Federal and State Monitoring,~~
8. ~~Data Collection,~~
9. ~~Record Maintenance and~~
10. ~~Reporting, which includes a review of the marketing materials, financial reports, samples of documentation of proper licensure for PACE Organization staff, current contract arrangements to ensure the PACE Organization has the capability to provide all federally and state required services, and other items as deemed necessary to ensure compliance with state and federal requirements.~~

~~At the conclusion of the trial period, CMS, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with all of the requirements.~~

~~DHS will be responsible for conducting an exit conference with the PACE Organization to discuss any review findings, provide technical assistance in developing corrective action plans and to assist the PACE Organization in their efforts to implement the required corrections.~~

220.100 — Monitoring by the Division of Provider Services and Quality Assurance 1-1-19

~~Due to the requirement that PACE Organizations be licensed as Arkansas Adult Day Health Care Centers, the Division of Provider Services and Quality Assurance will be conducting monitoring and oversight of the PACE Center operations.~~

220.200 — Reserved 1-1-13

220.300 — Monitoring by RN Supervisor 1-1-13

~~The DHS RN Supervisor attends the PACE organization's weekly Interdisciplinary Team Meetings (IDT). The DHS RN Supervisor contributes to the IDT meetings as necessary to ensure the health, welfare and safety needs of the beneficiaries are met.~~

220.400 — Monitoring by the Centers for Medicare and Medicaid Services (CMS) and the State Administering Agency (SAA) 1-1-19

~~In compliance with federal requirements, each PACE Organization will enter required information for nine (9) key indicators into the Health Plan Management System (HPMS), or any successor data elements or data system on a quarterly basis. Both CMS and the State Administering Agency (SAA) will use the data entered into HPMS or its successor system to monitor the ongoing operations of the PACE Organization and identify potential problems or unusual events that may be the first indication of problems in patient care, site operations or financial solvency. These reviews will also be used to determine if further onsite monitoring will be necessary.~~

~~A. The nine (9) key indicators are as follows:~~

1. ~~Routine Pneumococcal Immunizations~~
2. ~~Grievances & Appeals~~
3. ~~Enrollments~~
4. ~~Disenrollments~~
5. ~~Prospective Enrollees~~
6. ~~Unscheduled Hospitalizations~~
7. ~~Emergency (Unscheduled) Care~~

8. Unusual Incidents for participants and the PACE site (such as falls, attempted suicides, staff criminal records, infectious diseases, food poisoning, participant injury, Medication errors, lawsuits, any type of restraint use, etc.)
9. Participant Deaths

221.000 Electronic Signatures**10-8-10**

Medicaid will accept electronic signatures provided the electronic signatures comply with Arkansas Code § 25-31-103 et seq.

230.000 PRIOR AUTHORIZATION**4-1-06**

Prior authorization of specific services does not apply to the PACE Program.

240.000 REIMBURSEMENT**241.000 Method of Reimbursement****1-1-16**

PACE services are financed primarily through Medicaid and Medicare capitated payments. Providers must provide all needed services for PACE participants with the monthly capitated funds.

The PACE rates are based on the Upper Payment Limit (UPL) methodology. The historical fee-for-service population data is extracted for claims and eligibility for PACE eligible populations for more than one fiscal period. Data for participant aged, blind and disabled aid categories for those 55 or greater is used in the UPL and rate calculations. The level of care codes are limited to nursing facility level of care eligible or the ARChoices waiver level of care.

The base rates are calculated using calendar year base data. The base year data is trended forward using the historical claims and eligibility information extracted for the fee-for-service population. The recent trend rates are compared to linear regression model trend rates to determine comparability, and to determine if any adjustments are necessary. The trend rates for future periods are expected to be consistent with the most recent cost data available.

The UPL amounts are reduced by a percentage amount to establish the PACE capitation rate. The percentage (%) amount will be based on the anticipated reductions in health care service costs due to the implementation of the managed care PACE program. Reductions in costs are anticipated to be realized through a reduction in nursing facility and in-patient hospital costs. The UPL will be reset and recalculated every two years.

Participants may be private pay if they choose the service, but do not meet the requirements for Medicaid eligibility.

242.000 Rate Appeal Process**5-1-08**

A provider may request reconsideration of a program decision by writing to the Assistant Director, Division of Medical Services. This request must be received within 20 calendar days following the application of policy and/or procedure or the notification of the provider of its rate. Upon receipt of the request for review, the Assistant Director will determine the need for a Program/Provider conference and will contact the provider to arrange a conference if needed. Regardless of the Program decision, the provider will be afforded the opportunity for a conference, if he or she so wishes, for a full explanation of the factors involved and the program decision. Following review of the matter, the Assistant Director will notify the provider of the action to be taken by the Division within 20 calendar days of receipt of the request for review or the date of the Program/Provider conference.

If the decision of the Assistant Director, Division of Medical Services is unsatisfactory, the provider may then appeal the question to a standing Rate Review Panel, established by the Director of the Division of Medical Services, which will include one member of the Division of Medical Services, a representative of the provider association and a member of the Department of Human Services (DHS) Management Staff, who will serve as chairman.

The request for review by the Rate Review Panel must be postmarked within 15 calendar days following the notification of the initial decision by the Assistant Director, Division of Medical Services. The Rate Review Panel will meet to consider the question(s) within 15 calendar days after receipt of a request for such appeal. The question(s) will be heard by the panel and a recommendation will be submitted to the Director of the Division of Medical Services.

REPEAL-EO 23-02

State of Arkansas
95th General Assembly
Regular Session, 2025

A Bill

SENATE BILL 180

By: Senator D. Sullivan
By: Representative Ladyman

For An Act To Be Entitled

AN ACT TO EXEMPT PROVIDERS IN THE PROGRAM OF ALL-
INCLUSIVE CARE FOR THE ELDERLY FROM THE LICENSING
REQUIREMENTS FOR HOME HEALTHCARE SERVICES; AND FOR
OTHER PURPOSES.

Subtitle

TO EXEMPT PROVIDERS IN THE PROGRAM OF
ALL-INCLUSIVE CARE FOR THE ELDERLY FROM
THE LICENSING REQUIREMENTS FOR HOME
HEALTHCARE SERVICES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. DO NOT CODIFY. Legislative findings and intent.

(a) The General Assembly finds that:

(1) Providers in the Program of All-Inclusive Care for the
Elderly are required to provide all-inclusive care for patients;

(2) All-inclusive care is often provided in homes;

(3) The agreements between the Centers for Medicare & Medicaid
Services, the providers in the Program of All-Inclusive Care for the Elderly
in this state, and the Department of Human Services provide that home
healthcare services shall be provided by providers in the Program of All-
Inclusive Care for the Elderly as part of their licensure; and

(4) However, providers in the Program of All-Inclusive Care for
the Elderly are not home healthcare service providers.

(b) It is the intent of the General Assembly to exempt or except
providers in the Program of All-Inclusive Care for the Elderly from the



1 licensing requirements under § 20-10-801 et seq., for home healthcare
2 services.

3
4 SECTION 2. Arkansas Code § 20-10-802, concerning the exceptions from
5 home healthcare services licensing requirements, is amended to add an
6 additional subdivision to read as follows:

7 (13) A licensed, certified Program of All-Inclusive Care for the
8 Elderly provider in good standing under the administration of the Arkansas
9 Medicaid Program and providing services to enrolled Program of All-Inclusive
10 Care for the Elderly participants as part of the participants' documented
11 individual care plans within the Program of All-Inclusive Care for the
12 Elderly.

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15 **APPROVED: 2/25/25**
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actuarially equivalent cost sharing does not apply to out-of-network services covered by MA regional plans; therefore, in evaluating whether the plan design—and cost sharing—of an MA regional plan complies with section 1852(a)(1)(B) of the Act, we do not consider out-of-network cost sharing. This is also reflected in § 422.100(j)(2), which excludes the out-of-network benefits covered by a regional MA plan from the cost sharing evaluations specified in § 422.100(j)(2)(i).

Comment: A few commenters expressed concern that the proposal would eliminate D–SNP PPOs which provide access to covered benefits outside of the plan's network while a few other commenters urged CMS to use its authority not to allow any D–SNP PPOs.

Response: We do not believe the requirements for increased cost sharing will force D–SNP PPOs to exit the markets. We note that, compared to non-D–SNP PPOs and to non-PPO D–SNPs, D–SNP PPOs had higher financial margins in the bids submitted for both the 2023 and 2024 plan years. And our final rule will not result in major changes to benefit design or other features that would cause disruption in the market. Not allowing any D–SNP PPOs is beyond the scope of this rulemaking.

Comment: Several commenters requested that CMS monitor the impact of finalizing and implementing the proposal, including on access to other supplemental benefits and on in-network cost sharing under D–SNP PPOs.

Response: We thank the commenters for this suggestion and will continue to monitor the offerings of D–SNP PPOs.

Comment: We received a number of comments that were beyond the scope of this rulemaking. These include several requests from commenters for CMS to improve access to in-network services, including for DME, teaching hospitals, and home care. A few commenters noted that the lesser-of policies employed by State Medicaid agencies can impede access to services for dually eligible individuals and disadvantage the providers who serve them. Several commenters noted that the materials used by D–SNP PPOs should provide an accurate picture of the cost sharing enrollees will face out-of-network. A few commenters requested that the proposed out-of-network cost sharing limits for D–SNP PPOs be applied to non-D–SNP PPOs as well.

Response: We thank the commenters for this input and will take it into

consideration in our ongoing oversight of the MA program.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendment at § 422.100(o)(1) that, starting in 2026, for an MA organization offering a local PPO plan or regional PPO plan, cost sharing for out-of-network services under D–SNP PPOs will be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans, as described in § 422.100(f)(6). We are also finalizing, with minor technical edits, our proposed amendment at § 422.100(o)(2) to limit out-of-network cost sharing to the cost sharing limits for such services established at § 422.100(j)(1) when such services are delivered in network by cross-referencing § 422.100(j)(1).

We also note that some of the public comments received for the provisions related to the integration of Medicare and Medicaid were outside of the scope of the proposed rule. These comments covered topics such as: opportunities for States to share in savings from integrated care and aligned enrollment; modernizing identification cards for dually eligible enrollees; impact of Medicare and Medicaid policies on rural areas; long term care pharmacy services for dually eligible enrollees eligible for institutional care; default enrollment; and private equity. We appreciate the input. However, as these comments are outside the scope of this rulemaking, they are not addressed in this final rule.

IX. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. PACE Past Performance (§§ 460.18 and 460.19)

Sections 1894(e)(4) and 1934(e)(4) of the Act establish CMS's authority to oversee the PACE program. To strengthen CMS's oversight of the PACE program, we proposed to amend the PACE regulation at § 460.18 (CMS evaluation of applications) to incorporate an evaluation of past performance into the review of applications submitted by PACE organizations that seek to offer a PACE program or expand an approved program by adding a geographic service area and/or PACE center site or sites. Our evaluation of past performance will be a criterion CMS will use to review a PACE organization's application. The addition of this evaluation criterion at § 460.18(c) will permit CMS to deny applications from PACE organizations

based on the organization's past performance. We also proposed to establish at § 460.18(d) that CMS may deny a PACE application if the PACE organization's agreement was terminated by CMS or not renewed during the 38 months preceding the date the application was first submitted to CMS.

The performance history of an organization is an important criterion for CMS to consider when evaluating a PACE application because the past performance of an organization may be a valuable predictor of an organization's ability to effectively operate a new PACE program or expand an existing program. Organizations that have performed well are more likely to continue their high performance while organizations that have not performed well may have even greater difficulty meeting regulatory requirements when operating a new or expanded PACE program in addition to their existing PACE program. CMS believes that adding the consideration of an organization's past performance will guard against poor-performing organizations expanding their footprint and putting the health and safety of future PACE participants they enroll at risk. It is important for CMS to ensure that the legal entities with whom we hold program agreements can safely, effectively, and appropriately provide health care services and benefits to PACE participants, who are frail and elderly and among the most vulnerable Medicare beneficiaries.

In the Medicare Advantage (MA) and Part D programs, CMS considers an organization's past performance during the evaluation of its application. We modeled the proposed PACE past performance review regulations after the MA and Part D past performance review regulations at 42 CFR parts 422 and 423, using applicable evaluation criteria. We believe modeling the PACE past performance review criteria after the criteria that appear in the MA and Part D regulations is appropriate given that consideration of past performance has been a long-standing part of application reviews under the MA and Part D programs, resulting in the denial of initial and expansion applications of poorly performing organizations. As with its reviews of MA and Part D applications, CMS seeks through its review of PACE applications to identify poorly performing organizations and to prevent such organizations from entering into new agreements or expanding their service area in the program.

As explained in the proposed rule, we believe modeling past performance

reviews in PACE on past performance reviews in MA and Part D is appropriate since PACE organizations that provide Part D benefits are subject to the Part D regulations at 42 CFR part 423, except for those regulations CMS has waived in accordance with § 423.458(d). In addition, modeling after past performance reviews in MA and Part D reduces burden for PACE organizations by not having a different set of criteria for the non-Part D PACE benefits. In keeping with this requirement, our proposal would ensure that all entities that submit PACE applications would be subject to past performance reviews, the same as PACE entities that submit Part D applications.

In the January 2021 final rule (86 FR 5864), we established in regulation the methodology and criteria used to decide to deny an MA or Part D application based on prior contract performance (§§ 422.502(b) and 423.503(b)). We noted in the final rule that we may deny applications based on past contract performance in those instances where the level of previous noncompliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees (86 FR 5999). In the January 2021 final rule and through subsequent rulemaking, we adopted the following factors as the basis for denying an MA or Part D application: (A) the organization was subject to an intermediate sanction; (B) the organization failed to maintain a fiscally sound operation; (C) the organization filed for bankruptcy or is under bankruptcy proceedings; (D) the organization had low Star Ratings for two or more consecutive years; or (E) the organization exceeded CMS's threshold for compliance actions (*see* 86 FR 6000 and 87 FR 27704). Each of these factors, on its own, represents significant noncompliance with an MA or Part D contract; therefore, the presence of any of these factors in an applicant's record during the past performance review period could allow CMS to deny its MA or Part D application.

In the December 2022 proposed rule, we proposed to apply a past performance methodology to entities that seek to offer a new PACE program or expand an existing program. We proposed to modify the PACE regulations at 42 CFR part 460 to permit CMS to consider an entity's past performance in determining whether to approve or deny a new application or an application to expand a current program. Our proposed methodology for

taking into account past performance when evaluating PACE applications is similar to the methodology we use when deciding whether to deny MA and Part D applications based on past performance. As with our MA and Part D past performance reviews, the purpose of the proposed PACE past performance reviews is to prevent organizations from expanding their PACE operations in circumstances where the organization's past conduct indicates that allowing the organization to expand would pose a high risk to the success and stability of PACE and the welfare of PACE participants. Like MA organizations and Part D sponsors, PACE organizations that have been under sanction, failed to meet fiscal soundness requirements, or been issued compliance actions above a certain threshold have demonstrated that they have had significant failures in operating their program. Consistent with the past performance standards for MA and Part D and discussed in the December proposed rule beginning on page 79637, we proposed that CMS would have the authority to deny an initial or service area expansion (SAE) application based on the same factors (other than low Star Ratings) that serve as the basis for denying an MA or Part D application. We did not propose to include Star Ratings in the past performance reviews for PACE because we do not calculate these measures for PACE organizations.

We accept applications on designated quarterly submission dates from entities seeking to either establish a PACE program or expand an existing program. Like MA applications, and in accordance with § 460.18, CMS evaluates a PACE application based on information contained in the application itself, as well as information obtained by CMS (or the applicable State Administering Agency (SAA), which serves as the designated State agency for PACE), through on-site visits, or any other means. If an organization meets all application requirements, we approve the application.

We proposed to incorporate past performance reviews into the PACE application process to safeguard the program and ensure PACE participants are protected from the expansion of poorly performing organizations. The PACE program has seen significant growth in recent years, with increased numbers of both initial and expansion applications and steady increases in overall enrollment. This growth can be attributed in part to the statutory not-for-profit restriction no longer being applied beginning in May 2015, which allowed for-profit entities to operate

PACE programs (see sections 1894(h) and 1934(h) of the Act).

From 2012 to 2013, Mathematica Policy Research, under contract with CMS, conducted a study to address the quality of and access to care for participants of for-profit PACE programs. Based on the 2012 Mathematica study and a prior study in 2008, HHS prepared and submitted the report to the Congress on May 19, 2015. Based on the findings in the report to Congress, we determined that under sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act, the requirement that a PACE program be a not-for-profit entity would no longer apply after May 19, 2015 (the submission date of the report to Congress).

Prior to that change, only not-for-profit entities were eligible to offer PACE programs. At the end of calendar year 2016, a total of 121 approved PACE organizations were in operation, serving 37,584 predominantly dually eligible participants. In calendar year 2022, we received 35 initial applications and 29 expansion applications. As of August 2023, there were 154 PACE organizations serving 70,209 participants in 32 States and the District of Columbia.

PACE participants are some of the most vulnerable Medicare beneficiaries. To enroll in a PACE program, the SAA must determine that the beneficiary needs the level of care required under the State Medicaid plan for coverage of nursing facility services (§ 460.150(b)(2)). Beneficiaries who need this level of care are generally frail, may have multiple chronic conditions, and require extensive assistance with activities of daily living. The PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year (§ 460.98(a)). Each PACE organization must have a center, which PACE participants can visit weekly or even daily, based on each participant's needs and preferences. The PACE center must provide primary care services, nursing services, social services, restorative therapies (including physical therapy and occupational therapy), personal care and supportive services, nutritional counseling, recreational therapy, and meals (§ 460.98(c)).

As discussed in the proposed rule given the recent and anticipated future growth in PACE and the vulnerable populations that PACE organizations serve, we believe that the past performance of a PACE organization should be reviewed as part of the application process. Past performance evaluations ensure CMS only approves

initial PACE applications and applications for service area expansions from existing PACE organizations that have a strong and positive record of performance. The ability to deny initial PACE applications or service area expansion applications submitted by organizations that we determine are poor performers helps to ensure that the organizations with which we have an agreement will be able to provide health care services to beneficiaries in a high-quality manner.

The PACE application review process is unique, and we finalized rules with that process in mind. Per the regulations at § 460.20(a) and (c), upon receipt of a complete PACE application, CMS must: (1) approve the application; (2) deny the application; or (3) issue a request for additional information (RAI) in the event there are deficiencies. CMS's deadline for these actions is within 90 days of submission of an initial application or for a service area expansion (SAE) application that includes both a proposed geographic expansion and a new center site, or within 45 days of submission of an SAE application that includes either a proposed geographic expansion or a new center site. If CMS issues an RAI, the applicant must respond to the RAI only when ready and able to submit a complete response that addresses all deficiencies cited in the RAI, which includes a complete State readiness review (SRR) report, as applicable. If CMS issues an RAI, the first review clock ends and the second and final review clock does not begin until the applicant submits a complete RAI response, which starts the second and final 45- or 90-day review clock, as applicable. As part of the application process, the applicable SAA must conduct an SRR at the applicant's proposed PACE center site (if applicable) to ensure that the PACE center meets the State's regulatory requirements. Applicants are required to submit documentation of the completed SRR report to CMS for applications that include a new PACE center site (*see* § 460.12(b)(2)). Per application instructions, the SRR report is the only required document that may be uploaded after the initial application submission, in response to CMS's RAI. In our experience, a response to a RAI may take anywhere from a few weeks to more than a year to receive, often because of the renovation or construction of a center site, attainment of building permits, and/or the need for a readiness review to be completed. The MA and Part D past performance review currently has a 12-month look-back

period which is defined as the most recent 12 months preceding the application deadline (*see* § 422.502(b) and 423.503(b)). Since MA and Part D applications are generally due in February of each year, this review period results in a 12-month look-back period that covers the previous March through February of the year the applications are due. We proposed to use a 12-month review period for PACE past performance, which is the same lookback period that applies to MA and Part D past performance reviews. Under our proposal, CMS would review an organization's past performance for the 12 months preceding the deadline established by CMS for the submission of PACE applications. We proposed that, if CMS sends a Request for Additional Information (RAI) to the organization, the 12-month look-back review period would apply upon receipt of the applicant's response to CMS's RAI. As explained in the proposed rule, a 12-month look-back period provides recent information on the operations of a PACE organization, which we believe is the best indicator of the PACE organization's current and future performance.

We proposed to specify at § 460.18(c)(1)(i) that CMS would evaluate the following components of an applicant organization's past performance, starting with the March 2025 quarterly application submission cycle: whether the organization was subject to an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40, even if the reasons for the sanction have been corrected and the sanction has been lifted; whether the organization failed to maintain fiscal soundness; whether the organization has filed for or is under State bankruptcy proceedings; and whether the organization has exceeded CMS's proposed 13-point threshold for compliance actions with respect to the PACE program agreement. We proposed that, if any of those circumstances applies to the applicant organization, CMS may deny its initial or expansion application.

Specifically, we proposed at § 460.18(c)(1)(i)(A) to include the imposition of enrollment or payment sanctions under § 460.42 for one of the violations listed in § 460.40 as a reason for which we may deny a PACE application, as noted in the previous paragraph. Currently, § 460.42 authorizes CMS to impose a suspension of enrollment or payment if a PACE organization commits one or more of the violations listed in § 460.40. Violations in § 460.40 include the failure of the

PACE organization to provide medically necessary services, discrimination in enrollment or disenrollment of individuals eligible to enroll in a PACE program based on health status or need for health services, and involuntary disenrollment of a PACE participant in violation of § 460.164. These violations are serious and egregious actions by the PACE organization. Organizations that have been sanctioned (enrollment or payment) based on their failure to comply with CMS's regulations have either admitted they failed to comply with PACE requirements or have appealed and a third party has upheld CMS's determination that the PACE organization failed to comply with requirements. Because of the egregiousness of the actions that led to the PACE organizations' sanctions, we do not believe these organizations should be permitted to enter into new agreements, add new PACE sites, or expand their service area until the PACE organization corrects the issues that resulted in the sanction and ensures that such issues are not likely to recur.

We proposed at § 460.18(c)(1)(i)(B) to include, as a basis for application denial, the failure to maintain a fiscally sound operation after the end of the trial period. For purposes of fiscal soundness, the trial period ends when CMS has reviewed independently audited annual financial statements covering three full 12-month financial reporting periods. The regulation at § 460.80(a) requires a PACE organization to have a fiscally sound operation. Under § 460.80(a)(1), a PACE organization must have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities. To monitor compliance with § 460.80(a)(1), we require PACE organizations to submit certified financial statements on a quarterly basis during the trial period, and annually thereafter, unless CMS or the SAA determines that the organization requires more frequent monitoring and oversight due to concerns about fiscal soundness, in which case the organization may be required to submit certified financial statements on a monthly or quarterly basis (or both) (§ 460.208). Fiscal soundness is a key factor in our evaluation of past performance because we have a responsibility to ensure the organizations that provide health care services to Medicare beneficiaries have sufficient funds to allow them to pay providers and otherwise maintain operations. The failure of an organization to have a positive net worth puts PACE participants in

jeopardy of not receiving necessary health care. In addition, organizations that are not fiscally sound may not be able to continue operations, causing the organization to close its PACE physical site, leaving PACE participants without PACE access to their PACE organization. Based on this, we believe it is in the best interest of the program to add failure to maintain a fiscally sound operation—specifically, failure to have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities—to the list of reasons CMS may deny a new application or an expansion application from a PACE organization.

We proposed to establish at § 460.18(c)(1)(i)(C) that CMS may deny the application of an organization that has filed for or is currently in State bankruptcy proceedings. Like an organization that lacks fiscal soundness, an organization that has filed for or currently is in State bankruptcy proceedings is at great risk of having insufficient funds to cover costs associated with administering a PACE program. In circumstances where an organization has filed for bankruptcy or is currently in State bankruptcy proceedings, the outcome often results in the closure of an organization's operations, putting beneficiaries at great risk. Examples of participants being at risk may include the inability to find adequate and timely care, lack of care coordination, loss of access to providers (especially primary care providers who are employed by the PACE organization), and loss of the social and emotional support the PACE organization provides to participants. Thus, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the PACE program, and as CMS is responsible for oversight of PACE, we believe it is appropriate for us to have the authority to deny an application from any organization that has filed for or is in State bankruptcy proceedings.

Finally, we proposed to establish at § 460.18(c)(1)(i)(D) that CMS may deny an initial application or an expansion application for a PACE organization that exceeds the proposed 13-point threshold with respect to CMS-issued compliance actions. We proposed to specify at new § 460.19(a) that CMS may take compliance actions as described at § 460.19(c) (discussed in this section of this rule) if CMS determines that a PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and an SAA. PACE organizations are required to adhere to requirements in sections 1894 and 1934 of the Act and

at 42 CFR part 460. As proposed, § 460.19(a)(1) would provide that CMS may determine that a PACE organization is noncompliant with requirements if the PACE organization fails to meet set performance standards articulated in sections 1894 and 1934 of the Act, regulations at 42 CFR chapter IV, and guidance. In addition, we proposed to establish at § 460.19(a)(2) that if CMS has not previously articulated a measure for determining compliance, CMS may determine that a PACE organization is non-compliant if its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

Currently, we issue three types of compliance actions: Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).²⁵⁷ These actions are our formal way of recording an organization's failure to comply with statutory and regulatory requirements as well as providing notice to the organization to correct its deficiencies or risk further compliance and/or enforcement actions. They also serve to document the problem and, in some instances, request details regarding how the organization intends to address the problem.

First, we proposed to specify that NONCs may be issued for any failure to comply with the requirements of the PACE organization's current or previously terminated program agreement. We typically use a NONC to document small or isolated compliance problems. NONCs represent the lowest level of compliance action issued by CMS. We typically issue NONCs for the least egregious failures, such as a first-time offense, a failure that affects only a small number or percentage of participants, or issues that have no participant impact. An example of a failure that would lead to a NONC would be a failure to upload marketing materials or incorrectly uploading these materials.

Second, we proposed to specify that a WL may be issued for a serious failure or continued failure to comply with the requirements of the PACE organization's current or previously terminated prior program agreement. WLs are typically issued as an intermediate level of compliance action and when discussing compliance actions on a continuum, would be issued for compliance issues

²⁵⁷ The CAPs we proposed to issue for purposes of compliance and take into account during past performance evaluations to determine whether to deny PACE organizations' applications would be separate and distinct from CAPs issued under § 460.194(a)(2), which are corrective action plans that are requested and received in the course of audits.

that fall in terms of the level of their egregiousness between a NONC and a CAP. WLs are issued when an organization has already received a NONC and the problem continues to persist without correction, or they may be issued after a first offense when the offense concerns a larger or more concerning problem, such as failure to provide medically necessary services. Unlike NONCs, WLs contain language informing the PACE organization of the potential consequences to the organization should the non-compliant performance continue. An example of when a WL might be issued would be when, for example, a PACE organization has failed to have the full interdisciplinary team (IDT) involved in the review of participant care plans, which may result in participants not receiving necessary care. We might determine that the PACE organization's non-compliance in this regard warrants a higher level of compliance, such as a WL in place of a lower level of compliance. Our determination to issue a WL instead of a NONC, in this case, might be based on a review of factors, such as the type of care that was not received and the consequence of the care, not being properly provided, due to the PACE organization's failure to ensure that the IDT was reviewing all care plans.

Third, we proposed to specify that the last type of compliance action, the CAP, is the most serious type of compliance action and may be issued for particularly egregious or continued non-compliance. We may determine that the PACE organization has repeated, not corrected, or has a new deficiency which substantially impacts participants. In these types of scenarios, we require the PACE organization to implement a CAP. The CAPs contemplated here are not the same as corrective actions issued under § 460.194(a)(2). CAPs issued under § 460.194(a)(2) require PACE organizations to take action to correct deficiencies identified by CMS or the SAA through reviews and audits of the PACE organization (§ 460.194(a)(2)). We have a formal audit process, which separately identifies non-compliance. We issue CAPs under § 460.194(a)(2) resulting from finding of our reviews or audits. CMS routinely requests these CAPs and responses are submitted to CMS by PACE organizations as they address deficiencies identified during CMS reviews or audits. We expect to continue to request CAPs as necessary under § 460.194(a)(2) in response to deficiencies identified through reviews

or audits; nothing about this rule would change that process.

Consistent with the past performance methodology applicable to MA, we proposed to assign points to each type of compliance action taken by CMS against PACE organizations. We then proposed to apply a compliance action threshold to determine if the PACE organization that submitted the application exceeds the threshold and should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. We will then sum the total of the points accrued by the applicant organization, and if the total meets or exceeds 13 points during the 12-month review period, we may deny the organization's new or expansion application on the basis of past performance.

With the addition of compliance actions as a basis for the denial of applications, we proposed to specify at new § 460.19(b) the factors we currently use to determine whether to issue a compliance action and the level of compliance action that should be issued.

At § 460.19(b)(1) through (6), we proposed to codify in regulation the factors CMS currently uses when determining whether and at what level of a compliance action should be issued. As discussed in the paragraphs that follow, we consider the following factors: the nature of the conduct; the degree of culpability of the PACE organization; the actual or potential adverse effect on participants, which resulted or could have resulted from the conduct of the PACE organization; the history of prior offenses by the PACE organization or PACE organization's contractors or subcontractors; whether the non-compliance was self-reported; and other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

We proposed to add § 460.19(b)(1) to establish that CMS considers the nature of the PACE organization's non-compliant conduct. The nature of the conduct is relevant to our determination of whether to issue a compliance action and the level of compliance action to take because failure to comply can range from an administrative issue to failure to provide necessary health care. Compliance issues that are less egregious in nature generally result in lower-level compliance actions.

We proposed to specify at § 460.19(b)(2) that CMS considers the degree of culpability of the PACE organization. This factor is relevant

because the PACE organization's failure may have been avoided if the PACE organization had performed differently. For example, if the PACE organization failed to properly train or failed to hire properly trained staff to assist participants in activities of daily living, such as bathing, and a participant fell and injured themselves in the shower, the PACE organization would be more culpable than if staff were properly trained and the participant still injured themselves. The PACE organization has a responsibility to do everything possible to ensure the safety of the participants, and its failure, either intentional or unintentional (for example, lack of training, lack of oversight, lack of staff) would be a factor in our decision about the type of compliance action to take.

As proposed, § 460.19(b)(3) would provide that CMS considers the effects or potential effect of a PACE organization's conduct on PACE participants. This factor is relevant because a PACE organization's failure to comply may have very different effects (or potential effects) on PACE participants and may affect varying numbers of participants. For example, an organization's failure to timely arrange for primary care could affect many or all of the participants enrolled with that organization. However, an organization's failure to timely arrange for a very specific type of specialty care may affect only a few participants.

At § 460.19(b)(4), we proposed to specify that CMS considers the history of prior offenses of a PACE organization or its related entities. A PACE organization's (or its related entity's) failure to comply is relevant because the PACE organization should have ongoing processes in place to correct deficiencies as they occur and ensure that deficiencies are not likely to recur. As mentioned later in this section, organizations that have had recurrent compliance issues may be subject to a higher level of compliance action. For example, a PACE organization that failed to provide transportation for a period of time to participants one year ago may have received a NONC at that time. If the organization fails to correct this deficiency after first being cited with a NONC for the deficiency regarding the PACE organization's previous failure to provide transportation, we may escalate this continued failure to comply with CMS requirements by issuing a WL, based on the PACE organization's history and continued failure to correct the deficiency.

As proposed, § 460.19(b)(5) would provide that CMS considers whether an organization self-reported a compliance

failure. A PACE organization that self-reports that the organization has found the deficiency, such as through an internal audit, generally indicates that the organization is actively engaged in identifying and correcting compliance issues, and likely has initiated the corrective action to address the deficiency prior to CMS being made aware of the matter. We do not consider issues to be self-reported if they are identified through specific requests made by CMS, the review of data CMS either has or has requested, complaints that have come into CMS through sources such as 1-800-Medicare, or complaints that CMS has asked the PACE organization to provide. If an organization has self-reported a compliance issue, we may decide to lower the level of non-compliance (for example, issuing a NONC instead of a WL) because of the organization's transparency with respect to the non-compliant behavior, since it is possible CMS would not have found the deficiency if not for the self-reporting. However, even if the organization did self-report the issue, CMS may decide against lowering the level of compliance action if, based on the factors identified previously, CMS determines that a higher-level compliance action is warranted.

Finally, we proposed to add § 460.19(b)(6) to provide that CMS considers the PACE organization's failure to adequately oversee its operations. For example, if an organization fails to properly pay claims, is aware of the issue, and fails to correct it (for example, by processing the claims accurately), or if the organization fails to do any monitoring or auditing of its own systems to ensure proper claims payment is occurring, CMS could take that into account in determining whether to issue a compliance action and, if so, the level of compliance action.

As previously mentioned, we proposed to establish at § 460.18(c)(1)(i)(D) that CMS would have authority to deny a new application or an expansion application if a PACE organization accumulates 13 or more compliance action points during the applicable proposed 12-month look-back period. This would be the equivalent of just over two CAPs. We believe an organization whose performance results in issuance of two CAPs and a NONC, or whose performance results in any combination of compliance actions that adds up to 13 points, should not be permitted to expand.

We proposed to specify at § 460.18(c)(1)(ii) that CMS could also

deny an application from an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the same parent organization meets the past performance criteria for denial proposed in § 460.18(c)(1)(i). Specifically, if an initial applicant is a legal entity under a parent organization that has a PACE program agreement, or if there are other organizations under the same parent that have a PACE program agreement, and the parent's PACE application or the other related organizations' PACE applications would be denied based on any of the factors proposed in § 460.18(c)(1)(i), we would also deny the new entity's application based on the past performance of other members of its corporate family. It is likely that similar structures, policies, and procedures are used across legal entities that are part of the same parent organization, increasing the likelihood that any part of a parent organization that has at least one poorly performing legal entity may be at increased risk of poor performance. In addition, using other legal entities' performance when the new applicant has no history would also prevent organizations from manipulating our past performance methodology by establishing new legal entities and using those to submit PACE applications to avoid having CMS consider the troubled performance history of the parent organization or its subsidiaries when reviewing the new legal entity's PACE application.

It would be especially important, when we review a new application from a legal entity that does not have activity that would constitute the past performance of that legal entity, as a PACE organization, to consider information from the current or prior PACE program agreement(s) of the parent organization of the applicant, and from members of the same parent organization as the applicant. As noted in the proposed rule, we are seeing initial PACE applications more frequently that represent unique and distinct legal entities that are part of a broader parent organization. In the December 2022 proposed rule at page 79642, we described an instance in which we reviewed an initial PACE application for a new legal entity under a parent organization that already had created a number of separate and unique legal sub-entities. In that case, in accordance with § 460.18(a) and (b), we considered the known adverse audit findings of other legal entities that were under the same parent organization, and which resulted in formal enrollment

sanctions for the other legal entities. In the review of the new legal entity's application, we determined that the new legal entity was under the same "umbrella" as the legal entities that had been sanctioned because many of the key members of the executive leadership team were served in similar roles for both the sanctioned entities and the new applicant. We denied the application due to the nature of the deficiencies that led to formal sanctions for the related organizations.

We also proposed one exception to this policy. Specifically, we proposed that a PACE organization that acquires an organization that would have an application denied based on any of the factors in § 460.18(c)(i) would have a 24 month "grace" period that would extend only to the acquiring parent organization. This means that the acquiring organization would still be able to enter into new agreements or expand its programs under other agreements for which there are no performance issues for 24 months following the acquisition. It is in the best interest of the PACE program to allow PACE organizations that are meeting our requirements to acquire poorly performing PACE organizations without being penalized based solely on that acquisition. As stated in § 460.18(c)(ii), this "grace" period would be limited to 24 months from the date of acquisition. We believe this 24-month grace period would give an acquiring PACE organization sufficient time to "turn around" a poorly performing organization.

Finally, we proposed to add a new paragraph § 460.18(d) to provide CMS the explicit authority to consider prior termination history as part of the evaluation of an initial PACE or expansion application. Specifically, we proposed that if CMS has terminated a PACE organization's program agreement under § 460.50(a), or did not renew the program agreement, and that termination or non-renewal took effect within the 38 months prior to the submission of an application by the PACE organization, we would be able to deny the PACE organization's application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant satisfies all other application requirements. The 38-month period is consistent with the Part D regulations at 42 CFR part 423. Because PACE organizations that offer Part D are subject to 42 CFR part 423, we believe a 38-month period is appropriate. This ensures PACE applicants are not unduly burdened by having two different sets of past performance requirements,

resulting in two different timeframes. CMS does not unilaterally terminate PACE organizations' program agreements without significant failures, which are often failures affecting the furnishing or quality of care provided to PACE participants. Furthermore, a PACE organization whose program agreement has been terminated may appeal. If the PACE organization chooses to appeal and the termination is subsequently upheld through the appeals process, the organization has been found to have committed an action or actions that are egregious enough to warrant a termination. If the organization does not appeal, then the organization is acknowledging our ability to terminate its PACE program agreement. Allowing organizations to re-enter the PACE program when they have failed to adequately implement a prior agreement would be contrary to ensuring that high-quality care is provided to PACE participants. However, we believe that an organization, after a 38-month period, may have improved its operations sufficiently for us to consider its submission of an initial application.

We solicited comments on these proposals. We appreciate stakeholders' input on the proposed changes and have provided comment summaries and our responses later in this section.

Comment: Several commenters supported the evaluation of PACE organizations' past performance in CMS's application review process. Commenters also supported our proposed 24-month grace period and expressed appreciation for CMS's transparency in publicly sharing the past performance methodology.

Response: We thank those supporting the evaluation of past performance during application reviews.

Comment: A few commenters questioned whether the corrective actions resulting from CMS's audits are included in the calculation of compliance points. Commenters were concerned that issues identified in audits would unfairly disadvantage those organizations that have been audited by CMS within the past twelve months as compared to organizations that were not audited by CMS.

Response: We clarify that the compliance action plans identified in § 460.19(c)(3) are separate from the corrective action requests resulting from audits, as identified in § 460.194, and are not considered as part of the past performance methodology. We explained in the proposed rule that the corrective action requests resulting from audits are considered routine and result from a process which CMS considers

separate and distinct from past performance. We updated the language § 460.18(c)(1)(D)(1)(i) to state that these corrective action requests resulting from audits, as identified in § 460.194, are not issued points used for past performance evaluation purposes.

Comment: A few commenters were concerned that the 13-point compliance point threshold would disproportionately affect larger organizations. They expressed concern that organizations that had many center sites, especially in different States, could incur a disproportionate number of points due to the size or geographic spread of the organization.

Response: We do not believe that the compliance point threshold would disproportionately affect larger organizations because past performance is determined at the legal entity level, not the parent organization level. PACE organizations are generally licensed under different legal entities in each State. The compliance action taken against a contract only impacts that contract's legal entity and does not impact any other legal entity held by that parent organization. This eliminates the concern of the commenters that compliance actions will disproportionately affect larger organizations. Moreover, regardless of the size of the PACE organization, CMS expects all PACE organizations to comply with established requirements. Therefore, we decline to adjust the proposed 13-point calculation to account for the size of an organization.

Comment: A commenter requested that CMS outline the process, protocols, and compliance thresholds that rise to the levels of a Notice of Non-Compliance, a Warning Letter, or a Request for a Corrective Action Plan.

Response: In the December 2022 proposed rule starting on page 79640, we outlined the factors CMS uses to determine whether to take a compliance action against a Medicare Advantage Organization and the level of compliance that is appropriate. The process CMS uses to determine whether to issue and how CMS issues a Notice of Non-Compliance, a Warning Letter, or a Request for a Corrective Action Plan to an organization is the same for regardless of the type of compliance taken. CMS considers the following list of factors when determining the level of compliance action to take as described in this list, and we note that we may consider additional factors not specifically listed here that address the impact of the non-compliance or the organization's inadequate oversight that contributed to the non-compliance: the nature of the conduct, the degree of

culpability of the organization, the actual or potential adverse effect on enrollees which resulted or could have resulted from the conduct of the organization, the history of prior offenses by the organization, the organization's contractors or subcontractors, whether the non-compliance was self-reported, and other factors which relate to the impact of the underlying non-compliance or the organization's inadequate oversight of the operations that contributed to the non-compliance. Once we determine the level of compliance action to issue based on our criteria, we issue the action to the organization through a letter. As for compliance review protocols, as discussed in the December 2022 proposed rule, we base the review protocols on the specific issue being reviewed in accordance with the approach detailed therein, for example, the standard protocol for fiscal soundness is such that the organization either has a positive or negative net worth. However, the protocols for other issues such as, for example, the failure to ensure enrollment packets are provided timely to participants are subject to review and consideration in accordance with the factors set forth at § 460.19, such as how many participants are affected and the lack of timeliness with respect to when the enrollment packets were actually received by an enrollee. Compliance thresholds may also be dependent upon specific circumstances. As identified above, compliance actions are taken for fiscal soundness if the organization has a negative net worth. The level of compliance taken for untimely delivery of an enrollment packet would depend on the application of the factors outlined in our final regulation. We believe these criteria and processes are well-documented in the December 2022 proposed rule and do not believe additional elaboration is needed here.

Comment: One commenter disagreed with our proposal to have the authority to deny an application based on past performance when an organization was under sanction, even though the sanction was ultimately lifted prior to CMS receiving the application. The commenter suggested that denying an application after a sanction is lifted would inhibit the expansion of PACE into new States.

Response: We believe sanctions, even if lifted, should be a basis for denial if that sanction was in place at any time during the twelve-month look-back period. A sanction is issued for serious non-compliance and is in place until such time the issue is corrected and not likely to reoccur. Sanctions issued for

these reasons, indicate the organization should continue to focus on compliance rather than expansion, even after the sanction is lifted. We believe the inclusion of sanctions that have been lifted within the twelve-month look-back period is an important protection for the PACE program and the participants of the PACE organization that was under sanction as well as being consistent with Part C and Part D Past Performance regulations. For these reasons, we are finalizing our proposal to establish as a basis for denying a PACE application that an organization was under sanction within the twelve-month look-back period, without modification.

Comment: A commenter stated that CMS should not start the look-back period until 2025, noting that it would be unfair to use compliance letters issued prior to January 1, 2025. The commenter suggested that CMS exclude the time of performance during the COVID-19 pandemic and the associated public health emergency. This commenter also stated that CMS should provide PACE organizations time to train and educate employees on compliance.

Response: We understand the commenters concern regarding the time for consideration of compliance letters. By waiting, we could be providing PACE organizations additional time to correct any issues that might result in a compliance action. However, organizations should be vigilant about complying with program rules, regardless of the timing of the start of the past performance methodology. If a PACE organization is complying with CMS rules, the start of the period of past performance is immaterial. The timing is only a concern for those organizations whose current non-compliance would result in CMS denying an application based on past performance. It is exactly those organizations that should not expand and providing them with an additional year to come into compliance with existing rules is not in the best interest of the program or participants. This is particularly important should PACE organizations that are out of compliance attempt to expand during any period in which the start date of our consideration of past performance is delayed.

With respect to the commenter's contention that we should delay the implementation to avoid issues that may have resulted from the COVID-19 Public Health Emergency, we disagree. The federal COVID-19 Public Health Emergency declaration ended May 11, 2023, and sufficient time has passed allowing PACE organizations an

opportunity to address and cure any issues resulting from the Public Health Emergency and return to a normal state of operations.

Finally, the commenter suggested waiting so PACE organizations had time to train and educate their employees regarding past performance criteria. CMS's past performance measures do not require training or educating employees. Any training or educating would concern adhering to CMS regulations, which employees should already be trained on and educated about. Past performance only looks back at the actions of the organization and does not require the organization to do anything differently.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the rule as proposed.

Comment: A commenter suggested we use a six-month look-back instead of a 12-month look-back. The commenter stated that a 12-month look-back effectively prohibits an organization from expanding for 24 months.

Response: We do not believe a six-month look back is appropriate for a few reasons. The 12-month look-back period aligns with the look-back period used in the MA and Part D past performance methodology, which has proven effective over a number of years. In addition to aligning with the MA and Part D past performance methodology, we believe a 12-month look-back period allows for CMS to obtain sufficient data to determine whether an organization is operating in such a manner that we would deny an application. We believe a six-month look-back period is an insufficient amount of time for CMS to evaluate an organization's performance. We believe a 12-month look-back period is necessary to ensure an organization can provide the required services in a compliant manner over the long term, and not only in a shortened timeframe.

As mentioned previously, we are working towards consistency within programs and across programs where applicable. PACE organizations are already subject to Part D regulations. Establishing a 6-month look-back period for PACE would be inconsistent with the 12-month look-back period in the Part D regulations.

For these reasons, we are finalizing as proposed.

Comment: A few commenters stated that some PACE organizations may have high-quality programs but are not fiscally solvent and that applications from these organizations should be approved. A commenter stated that a PACE organization, to meet fiscal

soundness requirements for expansion, may decrease staff or services resulting in less care for participants.

Response: We do not agree with the commenter that CMS should look beyond an organization's negative net worth when reviewing past performance. While a PACE organization may be able to provide quality services in the absence of a positive net worth, such an entity should not expand its operations until it demonstrates it can meet our fiscal soundness requirements. If such an organization were to expand operations the organization would likely incur additional costs, possibly resulting in further deterioration of the organization's fiscal soundness. An organization with a decreasing net worth and potentially experiencing cash flow problems, may reduce services to participants or the number of providers to continue operating, neither of which would be a desired outcome. As previously noted, we believe an organization's past performance is an indicator of future performance. We believe a positive net worth is critical to ensuring the future success of a PACE organization.

Based on these reasons we are finalizing these requirements as proposed.

B. PACE Determining That a Substantially Incomplete Application Is a Nonapplication (§§ 460.12 and 460.20)

Sections 1894(e)(8) and 1934(e)(8) of the Act established CMS's authority regarding PACE provider application requirements. Based on this authority, we proposed to strengthen the PACE regulations at §§ 460.12(a) and (b) and 460.20(b), which pertain to application requirements, by further defining what constitutes a complete and valid application.

CMS accepts PACE applications from entities seeking to establish a PACE program (initial applicants) or to expand an existing PACE program's service area (including both expansion of a PACE program's geographic service area and/or the addition of a new PACE center), on designated quarterly submission dates.

To receive funds under Part D to provide prescription drug benefits, PACE organizations must qualify as Part D sponsors under § 423.502(c)(1) by submitting an application in the form and manner required by CMS. Therefore, as a matter of necessity, initial PACE applicants that provide the Part D benefit to eligible beneficiaries must submit a separate Part D application. Effective March 31, 2017,

CMS requires organizations to submit all applications electronically via the Health Plan Management System (HPMS). The PACE application includes attestations and certain required documents to ensure compliance with established PACE regulations, including, but not limited to: policies and procedures related to enrollment, disenrollment, grievances and appeals; information regarding the legal entity and organizational structure; and State-based documents, including a State assurance document. The State assurance document is a template that includes standard statements regarding the State's roles and responsibilities and includes the physical address of the proposed PACE center, geographic service area, or both, as applicable, depending on the type of application. This document must be signed by an official within the applicable State Administering Agency (SAA) and the designated agency for the PACE program in the State in which the program will be located. The document confirms the State's support for the PACE application. It is imperative that the applicant demonstrate the State's support of the application because the State is an equal party to the PACE program agreement, which, once approved and finalized, establishes the 3-way contract between CMS, the State, and the PACE organization.

Section 460.12 sets forth the application requirements for an organization that wishes to qualify as a PACE organization, and for an active PACE organization that seeks to expand its geographic service area and/or add a new PACE center site. Paragraph (a) of § 460.12 states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area and/or add a new center site must submit a complete application to CMS in the form and manner specified by CMS. Furthermore, § 460.12(b)(1) specifies that an entity's application to become a PACE organization must include an assurance from the SAA of the State in which the program is to be located indicating that the State considers the entity qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity. Similarly, an existing PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the SAA of the State in which the program is located, indicating that the State is willing to amend the signed PACE program agreement to

include the expanded service area and/or new center site (§ 460.12(b)(2)).

We indicated in the final rule titled “Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)”, which appeared in the June 3, 2019 issue of the **Federal Register** (84 FR 25610) (hereinafter referred to as the June 2019 final rule) that an application received without the required State assurance document would not be considered a complete application and would, therefore, not be reviewed (see 84 FR 25615 and 25671).

Section 460.20(a) provides that within 90 days, or 45 days in the case of an application to expand a service area or add a PACE center, after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS: (1) approves the application or (2) denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. An application is considered complete only when CMS receives all information necessary to determine whether to approve or deny the application (§ 460.20(b)).

As part of annual training sessions and resources available at: <https://www.cms.gov/Medicare/Health-Plans/PACE/Overview>, CMS acknowledges and has stated that the State readiness review (SRR) of a center site, as applicable, is the only required application document that may not be available and submitted at the time of the initial application submission to CMS on the designated quarterly application submission date. The SRR is conducted at the applicant’s PACE center by the State, and the accompanying report issued by the State certifies to the State and CMS that the PACE center satisfies all applicable local, State, and Federal requirements for operation. CMS has instructed PACE applicants to upload the SRR during the application process, including following the initial submission date if necessary, and when responding during the course of CMS’s review to a CMS-initiated request for additional information from the applicant.

The application is not considered complete and valid without the required documentation from the applicable SAA that provides clear evidence of the State’s support. However, in our experience, some PACE organizations submit a State assurance document that is not signed by the State, is provided after the designated submission date, or has changed the location of the proposed PACE center or included the corporate address as a placeholder.

Should any of these aforementioned scenarios occur, CMS will instruct the applicant to withdraw the application.

In the December 2022 issue of the **Federal Register** (87 FR 79637) (hereinafter referred to as the December 2022 proposed rule), we proposed to treat any PACE application that does not include a signed and dated State assurance document, meaning a document with accurate service area information and the accurate physical address of the PACE center, as an incomplete and invalid application and therefore not subject to CMS review or consideration. Further, an application submitted without a valid State assurance document must be withdrawn from HPMS. These applicants must wait until the next quarterly submission date to submit the application with the State assurance document included. We proposed to add paragraph § 460.12(b)(3) to specify that any PACE application that does not include the proper State assurance documentation is considered incomplete and invalid and will be removed from HPMS.

In the June 2019 final rule, we amended § 460.12(a) by adding the phrase “in the form and manner specified by CMS” to describe the submission to CMS of a complete application, to allow for submission of applications and supporting information in formats other than paper, which was the required format at the time the proposed rule (84 FR 25671) was issued. We proposed to amend § 460.12(a), which states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area (through a geographic service area expansion and/or addition of a new center site) must submit a complete application to CMS “in the form and manner specified by CMS” by adding a parenthetical with the words “including timeframes for submission” after “manner,” in order to make it clear that CMS will only accept applications that are submitted within the timeframes established by CMS.

In the December 2022 proposed rule, we proposed to establish at § 460.20(c) that any application that, upon submission, is determined to be incomplete under proposed § 460.12(b)(3) because it does not include a signed and dated State assurance document with accurate service area information and the physical address of the PACE center, as applicable, would be withdrawn by CMS, and the applicant would be notified accordingly. We proposed § 460.20(b)(1) to further specify that the applicant would not be entitled to a

hearing if the application is withdrawn based on that determination. Without the necessary evidence of support for the application by the SAA, the application would not be valid, and therefore not subject to reconsideration. This is consistent with how CMS addresses MA or Part D applicants that submit substantially incomplete applications. Such applications are considered invalid applications and applicant organizations are not entitled to a hearing per § 422.660 or § 423.650.

Finally, we proposed to establish at § 460.12(a)(2) that an individual authorized to act for an entity that seeks to become a PACE organization (initial PACE applicant) is required to submit a separate Part D application that complies with the applicable requirements under 42 CFR part 423 Subpart K. This is consistent with our current practice, under which initial PACE applicants must submit a Part D application. By contrast, existing PACE organizations seeking to expand their service area are not required to submit a Part D application. Therefore, consistent with current practice, we did not propose to establish Part D application requirements for PACE organizations seeking to expand their existing service area. As stated in the proposed rule, we will continue our current practice of following the timeframes for PACE applications, including submission deadlines and review periods, for Part D applications associated with PACE applications—that is, we will continue to accept Part D applications from initial PACE applicants on a quarterly basis. We believe it is important to continue to align application and review and submission deadlines for PACE applicants to the extent practicable to promote consistency.

Consistent with current practice, we proposed to treat an initial PACE application that does not include responsive materials for one or more sections of its Part D application as substantially incomplete, and those applications would not be reviewed or subject to reconsideration. If the Part D application associated with an initial PACE application is deemed substantially incomplete, that would render the PACE application incomplete and therefore not subject to review or reconsideration.

Comment: A few commenters were not in support of the State assurance form being a requirement for a PACE application submission. They requested that PACE applicants be afforded an opportunity to amend the State assurance document after application submission.

Response: We appreciate the comments and understand the request. The State assurance document is a necessary part of the application because the document demonstrates that the State is supportive of the PACE application. Since the State is a party to the 3-way agreement that is signed once the application is approved, it is important that the information provided on the State assurance form is correct at the time of application submission.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed requirements at §§ 460.12 and 460.20 to determine that a substantially incomplete PACE application without a State assurance document is a nonapplication. These provisions will strengthen the PACE regulations which pertain to application requirements, by further defining what constitutes a complete and valid application.

C. Personnel Medical Clearance (§§ 460.64 and 460.71)

Sections 1894(f)(4) and 1934(f)(4) of the Act grant CMS broad authority to issue regulations to ensure the health and safety of individuals enrolled in PACE. The PACE regulations at §§ 460.64 and 460.71 protect participants' health and safety by requiring PACE staff to be medically cleared of communicable diseases before engaging in direct participant contact.

In the 1999 PACE interim final rule (64 FR 66242), we added § 460.64, which sets forth certain personnel qualification requirements for PACE staff. When drafting these regulations, we reviewed the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (for example, home health agencies, nursing facilities, intermediate care facilities) (*Id.*). We also explained that in drafting these provisions we took a flexible approach that relied on State requirements as much as possible (*Id.*).

In the 2002 interim final rule, titled "Medicare and Medicaid Programs; Programs of All-inclusive Care for the Elderly (PACE); Program Revisions," which appeared in the **Federal Register** October 1, 2002 (67 FR 61496), we added § 460.71, which sets forth oversight requirements for PACE employees and contractors with direct patient care responsibilities. We noted the importance of adding this new section due to the vulnerable frail population served by the PACE program and the increased opportunity for a PACE organization to contract out

participant care services due to the amendment in the 2002 interim final rule which allowed PACE organizations to provide PACE center services through contractual arrangements (67 FR 61499). One of the new requirements that the 2002 interim final rule adopted was the requirement at § 460.71(b)(4) for PACE organizations to develop a program to ensure that all staff furnishing direct participant care services be "free of communicable diseases." In the rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions," which appeared in the **Federal Register** on December 8, 2006 (71 FR 71243), herein after referred to as the 2006 PACE final rule, we amended § 460.64 to align with § 460.71(b)(4) by adding the requirement at § 460.64(a)(5) that employees and contractors with direct participant contact "[b]e medically cleared for communicable diseases and have all vaccinations up-to-date before engaging in direct participant contact." In the June 2019 final rule, we amended the language in § 460.71(b)(4), which referred to staff being "free of communicable disease" so that it instead referred to staff being "medically cleared for communicable disease," which is the phrasing used in § 460.64(a)(5) (84 FR 25636) to reduce confusion across PACE organizations.

The proposed rule at 87 FR 79643 discussed how we have seen as part of our audit and oversight activities that PACE organizations have an inconsistent approach to medical clearance. We further discussed how the COVID-19 pandemic impacted the population served by PACE and "demonstrated a need for a more comprehensive approach to infectious disease management and prevention" (*Id.*). We believe that the inconsistent approach to medical clearance that has been noted on audit has led to insufficient medical clearance, which places PACE participants at risk of exposure to communicable diseases. Therefore, we proposed to amend §§ 460.64 and 460.71 to require all PACE organizations to develop and implement a comprehensive medical clearance process with minimum conditions that CMS deems acceptable to meet the requirement of medical clearance and to better protect the frail and vulnerable population served by PACE.

We proposed several modifications to the requirement at § 460.64(a)(5). Currently, the language states that staff must "be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact."

First, we proposed to separate the requirement to be medically cleared for communicable diseases from the requirement to have all immunizations up to date. We believe these are two separate and distinct requirements, and each serves a unique and important purpose. Specifically, we proposed to create a new paragraph (a)(6) that would specify that each member of the PACE organization's staff (employee or contractor) who has direct contact with participants must have all immunizations up to date before engaging in direct participant contact. We proposed to include in paragraph (a)(6) language specifying that, at a minimum, vaccinations identified in § 460.74 must be up to date. As we discussed in the proposed rule at 87 FR 79644, CMS does not currently define what immunizations are included in the requirement that "all immunizations are up to date." We considered defining all immunizations as including those recommended by the Advisory Committee on Immunizations Practices (ACIP) for health care workers, including when they are applicable based on individual criteria such as age or past infection. However, based on the PACE population we also considered limiting the required vaccinations for PACE staff with direct participant contact to the Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B. We solicited comment on whether any specific vaccinations other than the COVID-19 vaccination should be required for each member of a PACE organization's staff (employee or contractor) that has direct participant contact, with particular focus on commenters' views on vaccinations recommended by ACIP. We also solicited comment on whether we should use the ACIP list without modifications, or whether we should only require this subset of vaccines: Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.

At § 460.64(a)(5), we proposed to require that each member of a PACE organization's staff (employee or contractor) who has direct participant contact be medically cleared of communicable diseases both before engaging in direct participant contact and on an annual basis. Requiring staff to be medically cleared of communicable diseases annually will ensure that medical clearance is not a one-time requirement, but rather an ongoing responsibility. We solicited comment on adding this annual

requirement into the medical clearance provision.

We also proposed adding requirements to define what would constitute an acceptable medical clearance process. As discussed in the proposed rule at 87 FR 79644, we considered many different provider types, including hospital systems, and what different States require for medical clearance. We also considered the PACE population, and its vulnerability to communicable diseases. Based on these factors, we proposed at § 460.64(a)(5)(i) to require that staff who engage in direct participant contact must be medically cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of the practitioner's authority to practice. This exam could be done at the PACE center by the primary care provider already employed by the PACE organization; therefore, it would not be difficult to operationalize. We also proposed at § 460.64(a)(5)(ii) that as part of the initial physical examination, staff with direct participant contact must be determined to be free of active Tuberculosis (TB) disease. It is important for organizations to screen for TB because it is a deadly disease and baseline testing is recommended by the CDC for all health care professionals. We proposed to add "initial" into this regulation text, because annual TB testing is not recommended by the CDC unless a risk assessment is performed which indicates it is necessary.

However, we also understand that not all individuals who have direct participant contact have the same level of risk of having communicable diseases (through previous exposures) and requiring a physical examination may be overly burdensome. Therefore, we proposed that, as an alternative to medically clearing all staff with direct participant contact for communicable diseases based on a physical examination, the PACE organization could opt to conduct an individual risk assessment as allowed under proposed § 460.64(a)(5)(iii). If the results of the risk assessment indicate the individual does not require a physical examination in order to be medically cleared, then a physical examination would not be required.

We proposed at § 460.64(a)(5)(iii) to establish the minimum requirements that the PACE organization must satisfy if it chooses to conduct a risk assessment for medical clearance. First, we proposed to specify at § 460.64(a)(5)(iii)(A) that the PACE organization must develop and

implement policies and procedures for conducting a risk assessment on each individual with direct participant contact based on accepted professional standards of care, for example, standards of care for screening influenza. While each organization should have the operational latitude to develop its own policies and procedures, consistent with these proposed requirements, to assess if an individual needs a physical examination, when drafting and implementing these policies and procedures, organizations should consider any applicable professional standards of care and/or any applicable State guidelines on medical clearance.

We proposed at § 460.64(a)(5)(iii)(B) to specify that the purpose of the risk assessment is to determine if, based on the assessment, a physical examination is necessary for an individual. As we discussed in the proposed rule at 87 FR 79645, we believe that the best practice for medical clearance is a physical examination by a physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice. However, by allowing PACE organizations to conduct a risk assessment to determine if some individuals on a PACE organization's staff who engage in direct participant contact (employee or contractor) may not need a full physical exam would provide some administrative flexibility for organizations. We proposed at § 460.64(a)(5)(iii)(C) to establish a requirement that the results of the risk assessment be reviewed by a registered nurse, physician, nurse practitioner or physician assistant. We initially considered limiting these professions to primary care providers. However, we believe that because this risk assessment is used to screen staff to determine whether a physical exam is needed but is not itself a physical exam meant to diagnose an individual, it would be appropriate for a registered nurse to review those results and help triage staff that may need a more thorough exam. However, because registered nurses are not permitted to diagnose individuals, it would be inappropriate for a registered nurse to perform the physical examination.

Finally, we proposed to identify at § 460.64(a)(5)(iii)(D) the minimum requirements we would expect to be included in a PACE organization's risk assessment. First, we proposed to require that any risk assessment developed by a PACE organization would assess whether staff have been exposed to or have symptoms of the following diseases: COVID-19, Diphtheria, Influenza, Measles,

Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, and Varicella Zoster Virus. We proposed to include the aforementioned diseases in the risk assessment because they are commonly reportable and transmissible via air or through droplets. In addition to the aforementioned specific diseases, we also proposed to include any other infectious disease noted as a potential threat to public health by the CDC in order to allow for situations such as the recent COVID-19 pandemic where a new communicable disease creates a situation that poses a threat to public health and is significant enough that the CDC notes the threat or determines that a threat exists and communicates that threat via an official mechanism such as the CDC's Health Alert Network mentioned above. We would expect in those situations for a PACE organization to update its risk assessment to include that new public threat in the screening process. As we discussed in the proposed rule at 87 FR 79645, we considered CDC's Health Alert Network, the agency's primary method of sharing cleared information about urgent public health incidents with public information officers; Federal, State, territorial, Tribal, and local public health practitioners; clinicians; and public health laboratories. It is likely that any threat to public health related to communicable diseases would be shared through this mechanism, but we solicited comment on whether this would be an appropriate source to consider, or whether there are other sources that CMS and PACE organizations should use. Because we recognize these sources may change over time, we were not inclined to add a specific source into regulation, but we solicited comment on that as well. We also proposed to require that a PACE organization's initial risk assessment must determine whether staff are free of active TB disease. We considered adding TB into the list of diseases in § 460.64(a)(5)(iii)(D)(1); however, we believe screening for this disease through a series of questions about exposure or symptomatology would not be sufficient to rule out this condition when conducting an initial evaluation of an individual. Although we proposed an alternative to requiring a physical examination for every employee or contractor with direct participant contact (that is, by allowing PACE organizations to conduct a risk assessment), we solicited comment on whether we should eliminate the risk assessment from this proposal and

require all staff who engage in direct participant contact (employee or contractor) to undergo a physical examination by a physician in order to be medically cleared. We discussed and accounted for the burden of updating the policies and procedures in the collection of information requirements section of the proposed rule.

As we previously discussed, the requirement for medical clearance with respect to communicable diseases resides both in §§ 460.64(a)(5) and 460.71(b)(4). In section § 460.71(b)(4), we proposed to amend the current language to state that all employees and contracted staff furnishing care directly to participants must be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5). We also proposed to add language to a newly designated § 460.71(b)(5) to require all employees and contracted staff to have all immunizations up-to-date before engaging in direct participant contact. Under our proposal, current paragraphs (b)(5) and (b)(6) would be redesignated as paragraphs (b)(6) and (b)(7). As we stated in the proposed rule, we believe that modifying this provision as proposed would not increase the burden on PACE organizations as they are already required to ensure employees and contractors have all immunizations up-to-date (87 FR 79646).

We received the following comments related to this proposal:

Comment: Several commenters expressed concerns with the solicitation for comment related to vaccinations. These same commenters noted that requiring an expansive list of required immunizations would create a new federal floor for PACE that was unlike what any other Medicare provider was required to adhere to. These commenters were concerned that requiring specific vaccinations would impair PACE organizations' ability to hire and retain staff. A commenter stated that a PACE organization had lost 30 percent of its staff after the COVID-19 vaccination rule went into effect. Another commenter requested that CMS clarify if religious and medical exemptions would apply to the new vaccination requirements. Multiple commenters requested that, if CMS finalized a list of required vaccinations, CMS finalize the more targeted subset of vaccinations for which CMS solicited comment, specifically Hepatitis B virus, influenza, measles, rubella, and varicella. Lastly, a commenter asked CMS to clarify whether the up-to-date COVID-19 requirement referred to the

primary series or if booster shots would be required.

Response: When we issued the proposed rule (87 FR 79452) on December 27, 2022, many Medicare and Medicaid providers and suppliers (including PACE organizations) were required to have policies and procedures in place for staff vaccination against COVID-19. However, on June 5, 2023, we issued a final rule "Medicare and Medicaid Programs: Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements" (88 FR 36485), hereinafter referred to as the "LTC 2023 final rule." In that final rule, we cited, among other considerations, "increased vaccine uptake, declining infection and death rates, decreasing severity of disease, increased instances of infection-induced immunity" as reasons for withdrawing the provisions of the COVID-19 staff vaccination rule (88 FR 36488). Taking these considerations into account, we removed the requirement at § 460.74(d) for PACE employees and contractors to be up-to-date with COVID-19 vaccinations. In our proposed rule, we had proposed referencing the COVID-19 vaccination rule at § 460.74(d) as part of our new paragraph § 460.64(a)(6). Following the withdrawal of that rule, we are not finalizing the proposed reference to § 460.74(d) in §§ 460.64(a)(6) and 460.71(b)(5).

We thank commenters for their concerns regarding PACE organizations' ability to staff due to the COVID-19 vaccination rule as well as our solicitation for comment relating to requiring a specific set of immunizations in the proposed rule. As we stated in the LTC 2023 final rule, "[S]taffing shortages peaked nationally during the Omicron wave, with nearly one in three facilities reporting a shortage in January 2022. Staffing shortage rates have fallen since then, and remained relatively stable through March 2022, even after the implementation of the staff vaccination IFC" (88 FR 36495). Based on the data available, we disagree with commenters that implementing additional vaccination requirements would adversely impact PACE organizations' ability to staff. However, we understand the concerns expressed by commenters

that requiring a specific list of vaccinations for PACE organizations would potentially hold PACE organizations to a different standard regarding vaccinations than other Medicare programs. While we are not finalizing a specific list of vaccination requirements, and instead will leave the language in § 460.64(a)(6) that "all immunizations must be up to date", we will continue to assess the need for vaccinations. We will consider moving forward with a vaccination requirement in the future if the need arises. We also encourage PACE organizations to consider resources such as the ACIP vaccination standards when determining which immunizations to require for their employees and/or contractors.

Comment: Several commenters expressed concerns with the proposed requirement that medical clearance be conducted on an annual basis, versus only being done at the time of hire. These commenters suggested that it was overly burdensome for PACE organizations, particularly smaller organizations, to have to re-clear staff on an annual basis. These commenters also indicated that this would place an undue burden on a PACE organizations' ability to contract with other health care providers who may not be currently required to medically clear staff on an annual basis.

Response: We agree with commenters that an annual physical screening requirement may be overly burdensome for some PACE organizations since the requirement could impact PACE organizations' ability to contract with other health care providers. Therefore, we are not finalizing the proposed requirement that the physical examination or risk assessment be conducted annually. Instead, we will maintain the current requirement that direct care personnel be medically cleared prior to having direct contact with participants.

Comment: Most commenters requested that CMS codify the risk assessment approach to medical clearance as an alternative to requiring a physical examination for every individual. Commenters indicated this alternative proposal would allow PACE organizations to retain some discretion to medically clear staff as well as to reduce burden on PACE organizations. A couple of commenters requested that CMS leave medical screening requirements up to individual States, while a couple of other commenters expressed concern that home health agencies in certain States are not required to undergo additional medical screenings. These commenters noted

that State medical screening requirements apply to all health care providers within each respective State, and that requiring only PACE organizations to follow stricter federal requirements by conducting a physical exam in all instances or requiring specific vaccinations would put PACE organizations at a disadvantage when competing for contracts with medical providers and/or facilities. Instead, most commenters wanted CMS to finalize the risk assessment approach without requiring the PACE organization to conduct a physical exam.

Response: We thank commenters for sharing their concerns. We understand why commenters requested that we finalize the risk assessment alternative to the proposal that a physical exam be completed on each individual that provides direct participant care. As we stated in the proposed rule, PACE organizations serve a vulnerable population, and we believe performing a physical exam prior to staff having direct contact with participants is a best practice to protect participants from infectious diseases (87 FR 79644). However, we understand that requiring a physical exam for every individual that a PACE organization may employ or contract with may be overly burdensome, and therefore we proposed the risk assessment as a way for PACE organizations to determine if a physical exam is necessary for all personnel (*Id.*).

We recognize the concern commenters expressed of additional medical screening requirements putting PACE organizations at a disadvantage in contract negotiations with medical providers and/or facilities, including home health agencies, and as we discussed in our earlier responses, we are not finalizing our proposed requirements for annual medical clearance or a specific list of required vaccinations. We believe our decision not to finalize the annual physical screening requirement or the specific vaccination list will alleviate contracting concerns; however, PACE organizations can also take into consideration the processes they already have in place to demonstrate compliance with individual State requirements when they develop the risk assessment tool. Therefore, we are finalizing the requirement for a physical examination of direct care personnel with the risk assessment as an alternative provided the risk assessment meets the minimum requirements set forth in the proposed rule.

Comment: Multiple commenters raised questions and concerns regarding whether allowing colleagues to conduct health screenings would violate HIPAA.

A commenter requested that PACE organizations be allowed to conduct physical exams or outsource them as needed. Another commenter asked that risk assessments without red flags be allowed to be reviewed by non-clinical staff to free up the time of clinical staff. A commenter supported CMS's approved list of clinical staff who can perform the risk assessment and/or physical exam.

Response: We appreciate the commenters' concerns over potential HIPAA Privacy Rule violations; however, we believe they are misplaced. The HIPAA Privacy Rule does not apply to employment records held by a covered entity in its role as an employer. In our experience, there are many medical organizations and hospital systems that perform medical clearance on personnel without violating the HIPAA Privacy Rule. However, it should be noted that the language allowing PACE organizations to perform their own physical exams or risk assessments was in no way meant to force PACE organizations to do so. Our intent was to allow PACE organizations the option to perform medical clearances in house; however, there is nothing in our proposal that would prohibit a PACE organization from requiring direct care personnel to seek a physical examination from their primary care physician or from contracting with a primary care provider for the specific purpose of conducting medical clearance reviews. As we stated in the proposed rule, we do not believe that assessments conducted by unlicensed staff or self-assessments are sufficient to meet the requirement for medical clearance (87 FR 79643). We also considered different clinical staff to determine the appropriate professions to perform the physical exam versus the risk assessment (87 FR 79645). We determined that while a physical exam required a primary care provider, a registered nurse could screen staff through the risk assessment because it is not "a physical exam meant to diagnose an individual" (*Id.*) We believe it is outside the scope of authority of nonclinical staff to perform a physical exam or risk assessment. Therefore, we are finalizing the clinical staff members approved to perform a physical exam or risk assessment, as proposed.

Comment: A commenter stated that the communicable disease clearance is a "snapshot in time" and is ineffective due to the transient nature of communicable disease. Another commenter stated that the proposal was not evidence-based, specifically the requirement to screen annually for

Tuberculosis, which is not recommended by the CDC.

Response: We thank commenters for their responses. While screening for medical clearance prior to individuals having direct participant contact does not ensure that participants will never be exposed to communicable diseases, we believe it is a minimum safeguard to ensure that PACE participants are protected to the extent possible. It is also a common practice in other health care settings to have a process to ensure new individuals coming into an organization have received some form of health screening to demonstrate that the individuals are free of communicable diseases. As we stated in an earlier response, we are not finalizing the requirement for a physical examination or risk assessment to be conducted on an annual basis.

After considering the comments, and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing the proposed changes to §§ 460.64(a) and 460.71(b)(4) in part, with a modification to remove the requirement to conduct medical clearance on an annual basis. We are finalizing the proposed changes to §§ 460.64(a)(6) and 460.71(b)(5) in part, with a modification to remove the reference to § 460.74.

D. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c))

As discussed in the December 2022 proposed rule, sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act specify that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE Protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24

hours per day, every day of the year. This includes the full range of services required under the PACE statute and regulations. Although the PACE regulations at 42 CFR part 460 have codified service delivery requirements established in the Act, they currently do not include specific timeframes for service delivery. Since the 1999 PACE interim final rule, in which CMS discussed the crucial role of timely comprehensive care and service delivery in maintaining participant functional status (64 FR 66251), we have continued to revisit the feasibility of implementing such timeframes in subsequent rulemaking (64 FR 66251, 71 FR 71292, 85 FR 9138, 86 FR 6034).

As discussed in the December 2022 proposed rule (87 FR 79648), previous rulemaking has highlighted the challenges of determining specific timeframes for delivering the varied and broad scope of services PACE organizations must provide to participants, which is further complicated by the many possible scenarios that are part of the multifaceted care needs of PACE participants. As required at the current § 460.98(b)(4), services must be provided as expeditiously as the participant's health condition requires. Determining how quickly a service must be provided would depend on more than the physical health of the participant, and PACE organizations must consider all aspects of the participant's condition, including their social, emotional, and medical needs when determining the provision of services. Although we continue to believe that a specific timeframe for service delivery would not be feasible, and that ultimately, a service delivery timeframe based on the needs of the participant's condition remains the best timeframe for service delivery, our monitoring and oversight efforts have demonstrated the need for additional participant protections regarding timely service delivery. For example, based on data collected through audits, in the past 4 years, over 80 percent of audited PACE organizations have been cited for a failure to provide services in a way that is necessary to meet participant needs.

In response to audit findings, in the December 2022 proposed rule (87 FR 79648), we proposed to strengthen participant protections and accountability for PACE organizations by amending the service delivery requirements at § 460.98 to establish maximum timeframes for arranging and scheduling IDT-approved services for PACE participants, allowing for certain exceptions. First, we proposed to amend

§ 460.98 by redesignating current paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively. Next, we proposed to add a new paragraph (c) with the heading "Timeframes for arranging and providing services" and add 4 new subparagraphs. In addition, we proposed to move the requirement in current paragraph § 460.98(b)(4) to new paragraph (c)(4). We also proposed to redesignate paragraph (b)(5) as (b)(4).

Our proposal at the new section § 460.98(c) included four subparagraphs related to the timeframes for arranging and providing services. A "service" as defined in § 460.6 means all services that could be required under § 460.92, including items and drugs. We proposed at new § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after the primary care provider orders the medication. We explained that we consider the use of the words "arrange and schedule" to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information that would enable the pharmacy to fill the medication order and provide the participant with timely access to the medication. We explained that this timeframe would not require the medication to be delivered to the participant within those 24 hours, unless the participant's condition required delivery within that timeframe.

Next, we proposed to establish at new § 460.98(c)(2) the requirement that PACE organizations arrange or schedule the delivery of IDT-approved services, other than medications, as identified in the proposed § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or a member of the IDT first approves the service, except as identified in § 460.98(c)(3). This requirement pertains to all IDT-approved services other than medications. We would expect PACE organizations to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within the proposed timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. As with the proposal at § 460.98(c)(1), we noted that the proposed maximum timeframe to arrange or schedule the delivery of IDT-approved services, as we proposed at § 460.98(c)(2), does not apply a specific timeframe to the provision of the service.

We solicited comment on alternative maximum timeframes for arranging or

scheduling IDT-approved services, particularly timeframes within 5 to 10 (that is, 5, 6, 7, 8, 9, or 10) calendar days after the date the IDT or a member of the IDT first approves the service.

Additionally, we invited comment on whether there are additional definitions of "arrange or schedule" that we should consider. We requested that such comments address how the alternative timeframes they recommended would ensure participant health and safety, especially if commenters advocate for a timeframe longer than 7 calendar days.

We proposed at § 460.98(c)(2)(i)(A) through (D) to define which services are included in the definition of IDT-approved services. We proposed to specify at § 460.98(c)(2)(i)(A) that IDT-approved services include services approved by the full IDT. These services would typically be the ones discussed and approved during IDT meetings. This would be any service other than a medication. We proposed to specify at § 460.98(c)(2)(i)(B) that IDT-approved services also include services approved by a member of the IDT. We believe this is important to emphasize to ensure that service determination requests that are immediately approved by a member of the IDT under § 460.121(e)(2) are subject to this new timeframe. We proposed at § 460.98(c)(2)(i)(C) that IDT-approved services include services ordered by a member of the IDT. We would consider an IDT member ordering a service as approving that service for purposes of proposed § 460.98(c)(2). We explained that, under our proposal at § 460.98(c)(2), the timeframe to arrange or schedule a service begins when the IDT or a member of the IDT first approves the service. Therefore, when any one of these approvals at § 460.98(c)(2)(i)(A) through (D) occurs, on that first instance, the timeframe would be initiated.

We proposed at new § 460.98(c)(3) to exclude routine or preventative services from the timeframe requirement in § 460.98(c)(2) when certain requirements are met. We understand that PACE organizations may not be able to schedule every service within 7 calendar days, especially when the service is a routine service and not needed until a much later time. To satisfy this exception, we proposed at § 460.98(c)(3)(i) through (iii) three requirements that would all need to be met in order for a PACE organization to be exempt from the timeframe in § 460.98(c)(2). First, we proposed at § 460.98(c)(3)(i) that the PACE organization must document that it was unable to schedule the appointment for the routine or preventative service due to circumstances beyond the control of

the PACE organization. Second, we proposed to establish at § 460.98(c)(3)(ii) that the PACE organization is exempt from the timeframe as long as the participant does not have a change in status that requires the service to be provided more quickly. Last, we proposed at § 460.98(c)(3)(iii) that the PACE organization may be excepted from the timeframes to arrange a service if the PACE organization provides the service as expeditiously as the participant's condition requires.

We proposed to redesignate § 460.98(b)(4) as § 460.98(c)(4) without further modification, except to add a new paragraph heading "Providing approved services". Thus, new § 460.98(c)(4) would maintain the requirement that PACE organizations provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical physical, emotional, and social needs. Under redesignated § 460.98(c)(4), PACE organizations would continue to make determinations on how quickly to provide a service on a case-by-case basis, and we would expect PACE organizations to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require during monitoring efforts by CMS.

We estimated a one-time burden for PACE organizations to update their policies and procedures to reflect the proposed timeframes for arranging and providing services. We discuss and account for the one-time burden for their policies and procedures to reflect these proposed timeframes for arranging and scheduling services in the Collection of Information Requirements section.

In the paragraphs that follow, we summarize the comments received on the proposal at § 460.98(b)(4) and (c) and respond to those comments.

Comment: A few commenters recommended that CMS address how PACE organizations would satisfy the proposed requirements at § 460.98(c) to "arrange and schedule" services. Specifically, two commenters recommended that CMS define "arrange and schedule" such that PACE organizations would demonstrate they have arranged and scheduled services when they can provide documentation that a service authorization was acted upon to initiate scheduling. Another commenter recommended that CMS add language to define "reasonable efforts", a term not included in the proposed provision, to arrange and schedule services with providers external to a PACE organization, particularly

specialty providers. The commenter expressed concern that PACE organizations may be unfairly penalized for providers' communication delays that impact when provider appointments can be scheduled.

Response: We explained and provided examples of the actions a PACE organization would have to take to arrange and schedule services within the maximum timeframes at § 460.98(c) in the December 2022 proposed rule (87 FR 79649). The proposed rule explained that, for purposes of the proposed requirement at § 460.98(c)(1), we consider "arrange and schedule" to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information for the pharmacy to fill the medication order and provide the participant with timely access to the medication (87 FR 79649). This timeframe would not require the medication to be delivered to the participant within those 24 hours, unless the participant's condition required delivery in that timeframe. For the proposed requirement at § 460.98(c)(2), we described the action that we would expect the PACE organization to take within the proposed 7-calendar day maximum timeframe to arrange or schedule IDT-approved services other than medication (87 FR 79649). Delivery of services would not need to occur within the proposed timeframe, unless the participant's condition required delivery within that timeframe. Instead, the PACE organization would be expected to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within this timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved (87 FR 79649). We also emphasized that, for our proposal at § 460.98(c)(2), the timeframe begins when the IDT or a member of the IDT first approves a service (87 FR 79650).

In the December 2022 proposed rule (87 FR 79649), we described some examples of how a PACE organization might comply with the requirement at § 460.98(c)(2). If the IDT approved increasing a participant's physical therapy frequency from two to three times per week, we would expect the PACE organization to conduct outreach to the participant's physical therapist or the physical therapist's administrative support to set up a third weekly appointment within the timeframe at § 460.98(c)(2). If the IDT determines that the participant should see an ophthalmologist, the PACE organization

would be required to reach out to the ophthalmologist office to schedule the appointment within the timeframe at § 460.98(c)(2). We would not expect the delivery of the service (in this example, the actual appointment) to occur within the proposed timeframe, only that the PACE organization scheduled the appointment within that timeframe. Following the ophthalmologist appointment, if the IDT determines that eyeglasses were necessary upon review of the provider's recommendation, the PACE organization would then be required to arrange for the provision of the eyeglasses within the timeframes proposed at § 460.98(c)(2), which may include a purchase order for eyeglasses. During an audit or review, we would expect the PACE organization to have documentation to support compliance with the requirements in § 460.98(c). For example, a note that the appointment was scheduled or documentation that eyeglasses were purchased.

We believe that these explanations sufficiently establish how PACE organizations would comply with the proposed requirements at § 460.98(c), and do not believe codifying documentation standards or "reasonable efforts" at § 460.98(c) would enhance the provision's effectiveness. As per the current requirement at § 460.98(b)(4) (which we proposed to redesignate to § 460.98(c)(4)), PACE organizations must already document, track, and monitor the provision of services across all care settings. Since arranging and scheduling services are components of service delivery, we expect PACE organizations to maintain documentation of efforts to arrange and schedule services.

After consideration of the comments we received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c) to establish timeframes for arranging and providing services without modification.

Comment: With respect to our proposal at § 460.98(c)(1) and regarding the required timeframes for arranging and scheduling the dispensing of medications, many commenters agreed that PACE organizations must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires and supported CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications. However, most commenters disagreed with CMS establishing one timeframe for all medications, and instead recommended establishing separate timeframes for arranging and scheduling

the dispensing of emergency medications and non-emergency medications. These commenters advocated for allowing a longer maximum timeframe for arranging and scheduling the dispensing of non-emergency medications, and a shorter timeframe for emergency medications. Most of these commenters supported allowing up to 24 hours to schedule and arrange the dispensing of emergency or urgently needed medications and recommended that PACE organizations be allowed up to 2 business days to schedule and arrange the dispensing of non-emergency medications. Many commenters expressed that a longer timeframe for arranging and scheduling the dispensing of non-emergency medications would allow better prioritization of arranging and scheduling the dispensing of emergency medications. A commenter proposed a 48-hour timeframe for the coordination of all medications without explaining the basis for their recommendation. Another commenter did not support CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications.

Response: PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year as established at § 460.98(a). As a result, PACE organizations must meet participant needs on evenings, weekends, and holidays as expeditiously as the participant's condition requires. Therefore, we are not persuaded to lengthen the proposed timeframe to arrange and schedule the dispensing of medications on the basis of standard business hours. Furthermore, we emphasize that the timeframe requirement at § 460.98(c)(1) does not pertain to the provision of medications, only to scheduling and arranging the dispensing of medications, which can typically be facilitated electronically. As explained in the December 2022 proposed rule (87 FR 79649), for the purposes of § 460.98(c)(1), we consider the use of the words "arrange and schedule" to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information for the pharmacy to fill the medication order and provide the participant with timely access to the medication. However, PACE organizations must still provide services, including medications, as expeditiously as the participant's

condition requires, as per the newly redesignated § 460.98(c)(4).

Additionally, we are not persuaded to implement two distinct maximum timeframes for arranging and scheduling the dispensing of emergency and non-emergency medications. We understand that PACE organizations prioritize the delivery of emergency and non-emergency provider medication orders differently, because participants must receive services as expeditiously as their condition requires, taking into account their medical, physical, social and emotional condition in accordance with § 460.98(c)(4). However, we disagree with creating a distinction in regulation for arranging and scheduling the dispensing of emergency versus non-emergency medications, because we believe doing so would be difficult and impractical. For example, a medication that may be emergent to one participant may not be emergent to another, depending on factors that may not be apparent without information specific to the individual participant's medical, physical, social, and emotional condition. We think it is a fair and reasonable expectation that all medications be arranged and scheduled with the pharmacy within 24 hours. As previously explained, the timeframe requirement at § 460.98(c)(1) pertains to arranging and scheduling the dispensing of medications, which is related to, but distinct from, the service delivery requirement at § 460.98(c)(4). Therefore, although PACE organizations must arrange and schedule the dispensing of a medication no later than 24 hours after a primary care provider orders the medication, PACE organizations may deliver or provide the medication to the participant at a later time, as long as the medication is provided to the participant as expeditiously as their condition requires. We also believe this requirement is more easily accomplished than commenters seem to think. The timeframe to arrange or schedule a medication begins when an IDT member first approves or orders the service. Therefore, when a primary care provider orders a medication, they can submit the order to the pharmacy at the same time and satisfy this requirement. Based on many of the electronic medical records we have seen during oversight efforts, we think many systems are set up to ensure this happens seamlessly.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's

condition requires, but no later than 24 hours after a primary care provider orders the medication, without modification.

Comment: A few commenters expressed concern and made recommendations in regard to establishing maximum timeframes for the provision of medications. A commenter opposed the proposal at § 460.98(c)(1) and expressed that providing all medications within 24 hours was likely to cause harm to participants. The commenter gave the example that some medications, especially medications meant to treat chronic conditions in the elderly, should be explained and delivered thoughtfully in order to avoid misuse. Other commenters expressed concern that factors outside of the PACE organization's control, for example, pharmacy benefit manager (PBM) issues and national medication shortages, may delay access to medications and impact the PACE organization's ability to provide medications within the proposed 24-hour timeframe for arranging and scheduling the dispensing of medications. Additionally, a commenter recommended a maximum timeframe of 48 hours for the delivery of all medications.

Response: We believe these commenters may have misunderstood that the proposed maximum timeframe at § 460.98(c)(1) would apply to scheduling and arranging the dispensing of medications, not the provision of the medications. As discussed in the preceding comment response, our intention with this proposal was not to impose a specific timeframe for the delivery of medication, but to establish a maximum timeframe for the PACE organization to arrange and schedule the dispensing of medications. Considering the wide range of medications provided in PACE and varying needs of participants, we do not believe a specific timeframe for the provision of services, including medications, is feasible at this time. We agree with commenters that the delivery of medication would be based on the needs of the participant. We expect PACE organizations to provide medications as expeditiously as the participant's condition requires, as per the redesignated § 460.98(c)(4). Additionally, if PBM issues like medication shortages could impact participant care, the PACE organization must have contingencies in place to ensure participants have timely access to all necessary medications.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to

comments, we are finalizing our proposal at § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication, without modification.

Comment: While most commenters agreed with the premise of a maximum timeframe to arrange and schedule services other than medications, most of these commenters disagreed with our proposal that 7 calendar days was the appropriate timeframe to apply. Most commenters recommended we allow a maximum timeframe of up to 10 calendar days for arranging or scheduling these services.

These commenters made their maximum timeframe recommendation for services at § 460.98(c)(2) in consideration of potential delays in communication with provider offices. While a commenter cited general delays in communication from provider offices as another potential consideration for extending the maximum timeframe at § 460.98(c)(2), another commenter suggested that more time may be needed to coordinate scheduling appointments with providers whose offices may be closed on weekends and holidays. A commenter preferred a 10-calendar day maximum timeframe, in part, due to the time needed to coordinate with both the provider and participant based on provider availability and in consideration of participant preference. Additionally, some commenters suggested that the participant might not need certain services arranged or scheduled within the proposed timeframe to meet their care needs. One commenter did not specify a particular alternative maximum timeframe to arrange or schedule the delivery of all IDT-approved services other than medications. Rather, the commenter expressed that establishing a 7-calendar day maximum timeframe for scheduling or arranging specialty items such as power mobility devices and stair lifts would be challenging for the PACE organization to meet.

A few commenters expressed concerns with arranging and scheduling services with external providers, particularly specialists. A commenter that expressed this concern, suggested that delays in scheduling or arranging specialty services may not be within the PACE organization's control, and that ensuring compliance with the proposed requirements would be administratively burdensome and would divert resources from participant services. Another commenter recommended an exception

to the proposed maximum timeframe and suggested up to 30 days for the PACE organization to schedule appointments with specialist providers.

Lastly, a commenter expressed that PACE organizations are unique with each participant requiring a personalized array of services, and that a single timeframe for service delivery could not meet all their needs.

Response: PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year as established at § 460.98(a). When we published the December 2022 proposed rule (87 FR 79650), we solicited comment on different maximum timeframes for arranging or scheduling the delivery of IDT-approved services, other than medications, and we specifically asked commenters that supported a longer timeframe than the proposed 7-calendar day maximum timeframe to include a rationale for how their alternative timeframe would ensure participant health and safety. While most commenters requested a longer timeframe, most commenters cited operational challenges for PACE organizations as the reason for a longer timeframe and did not address participant health and safety. However, during our oversight and monitoring efforts, we have not seen that the time and effort required to schedule services is a significant contributor to scheduling delays. Rather, we have observed that scheduling delays are often the result of a process breakdown after the primary care provider orders the service, which delays any attempts to schedule the service. For example, we have observed in numerous audits where a specialist service is ordered and the first documented attempt to schedule the appointment with the provider does not occur for weeks or months. We have not seen that PACE organizations expend significant effort making multiple unsuccessful attempts to schedule provider appointments to ensure the participant receives the service timely.

Since PACE organizations are required to provide services through employees or contractors (see § 460.70(a)), they should have mechanisms in place to ensure that they are able to quickly schedule or arrange services. As explained in the December 2022 proposed rule (87 FR 79649) and reiterated in this rule, to comply with the proposal at § 460.98(c)(2), PACE organizations must take affirmative steps to make sure the IDT-approved service was set up, scheduled, or arranged within the proposed timeframe, which may include

scheduling appointments and/or purchasing the item the IDT approved. This requirement does not pertain to the provision of services, only to scheduling and arranging the service. However, PACE organizations must continue to provide services as expeditiously as the participant's condition requires in accordance with the current requirement at § 460.98(b)(4), which we proposed to be redesignated as § 460.98(c)(4).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(2) to require PACE organizations to arrange or schedule the delivery of IDT-approved services, other than medications, as identified in paragraph § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or member of the IDT first approves the service without modification.

Comment: Many commenters fully supported the proposed exception at § 460.98(c)(3) for routine or preventative services being excluded from the requirement in paragraph (c)(2).

Response: We thank the commenters for their support of our proposed criteria to exempt a PACE organization from the requirements at § 460.98(c) when certain conditions are met as proposed at § 460.98(c)(3)(i) through (iii).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(3) to exclude routine or preventive services from the requirements in § 460.98(c)(2) when requirements in § 460.98(c)(3)(i) through (iii) are met without modification.

E. Care Coordination (§ 460.102)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require PACE organizations to provide comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and

1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. Additionally, sections 1894(b)(1)(C) and 1934(b)(1)(C) of the Act specify that PACE organizations must provide services to participants through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services in accordance to regulations, and specify the covered items and services that will not be provided directly by the entity, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations. We have codified requirements pertaining to the interdisciplinary team (IDT) at § 460.102.

As discussed in the December 2022 proposed rule, changes to § 460.102 are the result of years of assessing PACE organizations' compliance with care coordination requirements established by the Act and our conclusion that further specification of these care coordination requirements in regulation would benefit participants and improve PACE organizations' understanding of how to comply with these requirements. In the December 2022 proposed rule, we proposed strengthening § 460.102 to identify the IDT's specific care coordination responsibilities, introduced maximum timeframes for the IDT's review of all recommendations from hospitals, emergency departments, urgent care providers, other employees, and contractors, and reiterated the IDT's role in timely service delivery.

Although the PACE organization is ultimately responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, the IDT has a critical role in enabling the PACE organization to meet these responsibilities. As established in the 1999 PACE interim final rule (64 FR 66248), the IDT, then referred to as the multidisciplinary team, must comprehensively assess and meet the individual needs of each participant. In addition, the IDT is responsible for the initial assessment, periodic reassessments, the plan of care, and coordinating 24-hour care delivery (64 FR 66249). Through monitoring and oversight activities, CMS has

determined that further specification of IDT responsibilities is necessary to ensure appropriate compliance with the program requirements. While many IDTs appropriately apply the multidisciplinary approach to providing care, our monitoring efforts have shown that some organizations do not ensure the IDT is fully involved in coordination of care for participants across all care settings. We have also seen organizations interpret IDT responsibilities to coordinate care narrowly. For example, an IDT may order care, but then fail to ensure that the care has been provided in accordance with those orders and that the participant's needs were met.

In the December 2022 proposed rule we proposed several amendments to § 460.102(d)(1). First, we proposed to redesignate current paragraph (d)(1)(ii) as paragraph (d)(1)(iii), and to add a new paragraph (d)(1)(ii). We also proposed to add a new paragraph (d)(1)(iv). We proposed to modify § 460.102(d)(1) to specify that the IDT is responsible for all activities as described at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) for each participant. The addition of "for each participant" emphasizes that these responsibilities are not general requirements the IDT must fulfill, but rather specific responsibilities the IDT must fulfill for each participant. Since the inception of PACE, CMS has considered the IDT responsibilities to apply to all participants at the individual level. The 1999 PACE interim final rule (64 FR 66288) established basic requirements for the IDT at § 460.102(a), including that the IDT must comprehensively assess and meet the individual needs of each participant and that each participant be assigned an IDT at the PACE center that they attend.

We proposed to modify the requirement at § 460.102(d)(1)(i) to include only the IDT's responsibility for the initial assessment, periodic assessment, and plan of care and to relocate the requirement pertaining to the IDT's responsibility to coordinate 24-hour care delivery to new § 460.102(d)(ii). We believe the responsibility to coordinate 24-hour care delivery is a separate and distinct requirement from the requirements to conduct assessments and create or revise a plan of care. Additionally, we proposed to add a paragraph heading at § 460.102(d)(1)(i) to read "Assessments and plan of care" in order to reflect the proposed modified content of the paragraph. We proposed to move IDT coordination of care requirements from § 460.102(d)(1)(i) to new § 460.102(d)(1)(ii), because separating

IDT coordination of care responsibilities at § 460.102(d)(1)(ii) from the assessment and care planning responsibilities at § 460.102(d)(1)(i) improves the provision's readability. We also proposed to modify the language of § 460.102(d)(1)(ii) and to add 5 paragraphs at § 460.102(d)(1)(ii)(A) through (E) to further specify what coordination of 24-hour care delivery involves by defining what actions we consider care coordination to include.

We proposed at new § 460.102(d)(1)(ii) to require that the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings. We added language into this requirement about meeting the participant's needs across all care settings in order to clarify the scope of the IDT's care coordination for all participants, including, but not limited to, participants residing in long-term care facilities. We also added "implementation" into the requirement at § 460.102(d)(1)(ii) because we have seen through audits and monitoring efforts that PACE organizations are interpreting "coordination" narrowly, and they do not consider it to include all necessary components of care coordination, such as ensuring the implementation of care. For example, we have seen problems with medication orders being implemented inappropriately, wound care not being done in accordance with orders, and other necessary services not being provided to the participant.

We have received requests to explain the difference between the PACE organization's responsibility to furnish care, and the IDT's responsibility to coordinate care. As we discussed in the January 2021 final rule, PACE organizations are responsible for furnishing comprehensive services to PACE participants across all care settings, 24 hours a day, every day of the year (86 FR 6034, 86 FR 6036). The IDT, which consists of a subset of PACE organization's employees or contractors, is responsible for certain activities, such as coordinating care, which includes services that are furnished by the IDT as well as services furnished by other employees and contractors of the PACE organization. The proposed requirement at § 460.102(d)(1)(ii) for the IDT to coordinate and implement 24-hour care delivery that meets participant needs across all care settings aligns with this interpretation, as the IDT is not always responsible for directly furnishing or providing the care to participants, but it always maintains responsibility for coordinating care for participants.

As previously noted, we proposed adding 5 subparagraphs at

§ 460.102(d)(1)(ii)(A) through (E) that further specify IDT coordination responsibilities across all care settings. We proposed at § 460.102(d)(1)(ii)(A) that the IDT is responsible for ordering, approving, or authorizing all necessary care in order to clarify CMS expectations regarding one aspect of the IDT care coordination responsibilities. PACE is a program designed around the IDT being responsible for authorizing and ordering all care that is needed for PACE participants. In fact, contractors, including medical specialty providers, must agree to furnish only those services authorized by the PACE IDT at § 460.70(d)(5)(i). We believe the responsibilities at § 460.102(d)(1)(ii)(A) are important aspects of coordinating care that are inherent to the IDT's established and central role in care coordination.

We proposed at § 460.102(d)(1)(ii)(B) to establish that the IDT is responsible for communicating all necessary care and relevant instructions for care. As discussed in connection with proposed § 460.102(d)(1)(ii)(A), the IDT is already responsible for authorizing all care the participant receives; however, in order for the participant to actually receive the care, the IDT must communicate the orders and relevant instructions to the appropriate individuals. For example, while a PCP may order a specialist consult, it is often scheduling or administrative staff that are responsible for arranging the appointment. As a part of coordinating care, the IDT must ensure that it communicates the necessary care and instructions to those individuals that need to know, for example, the individuals who will schedule, arrange, or provide the care and services. In the December 2022 proposed rule (87 FR 79652), we contemplated adding further specificity in regulation about who those individuals may be, but we believe that it would encompass too many individuals for us to identify. For example, for a participant residing in a nursing facility, the IDT would need to ensure it communicated orders and instructions for care to the facility staff. For scheduling appointments, the IDT may need to communicate orders to administrative staff. We believe the IDT would be in the best position to identify the staff that need to know the information, and therefore we are leaving this regulatory provision broad.

We proposed to specify at § 460.102(d)(1)(ii)(C) that the IDT is responsible for ensuring care is implemented as it was ordered, approved, or authorized by the IDT. We have seen through oversight and monitoring efforts that while the IDT

will order or authorize care, the team does not always follow through on ensuring that the care is provided in accordance with those orders. For example, a PCP may order wound care 3 times a week, but then the IDT will not follow through on ensuring that the wound care is done in accordance with those orders. As previously discussed, the 1999 PACE interim final rule (64 FR 66279) established the IDT as instrumental in controlling the delivery, quality, and continuity of care. Part of controlling the delivery and quality of care is ensuring that the care that is ordered, approved or authorized is actually provided.

We proposed at § 460.102(d)(1)(ii)(D) to establish that the IDT is responsible for monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs. The IDT cannot appropriately coordinate 24-hour care delivery without also ensuring that it remains alert to the participant's condition by monitoring and evaluating the participant's condition. While the IDT is responsible for making sure that care is implemented in accordance with the approved or authorized orders, the IDT also remains responsible for ensuring the participant's needs are met through that care. For example, if the PCP orders wound care 2 times a week but the wound continues to worsen, the PCP should consider whether a new order is necessary in order to meet the participant's needs.

We proposed to specify at § 460.102(d)(1)(ii)(E) that the IDT is responsible for promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant. The IDT's responsibilities for a participant do not end when care is authorized or ordered. As we stated in the 2006 PACE final rule (71 FR 71289), it is important for the IDT to monitor and respond to any changes in a participant's condition. Also, it is essential that the IDT respond promptly and modify care when it is determined that the participant's needs are not currently being met. For example, if the PCP writes an order for blood pressure medication but then notes during a later assessment that the medication is not working, we would expect the PCP and the IDT to consider alternative medications or treatments that might better meet the participant's needs.

We proposed to redesignate current § 460.102(d)(1)(ii) as § 460.102(d)(1)(iii) and add the title "Documenting recommended services" for improved readability. No further modifications

were proposed for this provision. Then, we proposed to add § 460.102(d)(1)(iv) to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists, within maximum timeframes, as proposed in at § 460.102(d)(1)(iv)(A) through (C). As discussed earlier, the IDT is responsible for authorizing, approving and ordering all care, including care recommended from contracted providers. Through monitoring and oversight activities, we had identified instances where the IDT is not promptly reviewing recommendations from urgent and emergency care providers, as well as employees and contractors. Based on data collected during the 2021 audits, approximately 75 percent of audited PACE organizations were cited based on a failure to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Delayed review of recommendations and action on recommendations can delay the provision of necessary care and services and can jeopardize participant health and safety. To address these concerns, we proposed timeframes for the IDT to review and act on recommendations from urgent and emergency care providers, as well as employees and contractors.

As we stated in the January 2021 final rule (86 FR 6132), we do not believe we could implement a specific timeframe for the provision of services, given the vast array of services that PACE organizations provide and variation in individual participant needs. However, we believe requiring the IDT to promptly act on recommendations from urgent and emergency care providers, as well as employees and contractors, creates accountability for expeditious service delivery while offering flexibility for wide ranges of services and variation in urgency. The timeframes we proposed at § 460.102(d)(1)(iv)(A) through (C) would be maximum timeframes within which the IDT must review, assess and determine whether service recommendations from urgent and emergency care providers, as well as employees and contractors, are necessary to meet the participant's medical, physical, social, or emotional needs, and if so, promptly arrange and furnish the service in accordance with the timeframes at § 460.98(c).

Per § 460.98(b)(4) (which we proposed to redesignate as § 460.98(c)(4)), PACE organizations must continue to provide services as expeditiously as the

participant's condition requires, taking into account the participant's medical, physical, social, and emotional needs. To meet the participant's needs, the IDT may need to review and act on recommendations sooner than the timeframes proposed in § 460.102(d)(1)(iv). Nothing in § 460.102(d)(1)(iv) would require the IDT to approve all recommendations; however, we would expect that the IDT review, assess, and act on the recommendation. That action would either be to make a determination to approve or provide the recommended service or make a determination to not approve or provide the recommended service. If the IDT makes a determination to approve or provide a service, it must arrange and schedule the service in accordance with § 460.98(c). If the IDT makes a determination not to approve or provide a service, we would expect the IDT to document the reason(s) for not approving or providing the recommended care or services in accordance with current § 460.102(d)(1)(ii), which, as previously noted, we proposed to redesignate as § 460.102(d)(1)(iii) and § 460.210(b).

We proposed at § 460.102(d)(1)(iv)(A) to establish that the appropriate member(s) of the IDT must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge. We considered multiple factors when proposing a 24-hour timeframe and expressed that we believed the 24-hour timeframe was necessary and reasonable due to the following considerations. First, the 24-hour timeframe would be limited to only those recommendations made by hospitals, emergency departments and urgent care providers, and it would not apply to recommendations made by other providers or more routine appointments. Second, we considered that PACE is responsible for the needs of the participant 24 hours a day, every day of the year. When a participant is discharged from one of these settings there may be recommendations made or care needed that cannot wait until the next business day. For example, a participant who is discharged from the hospital on a Saturday with a recommendation for antibiotics should not have to wait until Monday to have their prescription ordered or approved by the IDT. Third, we proposed to not require that the full IDT be involved in

assessing and acting on these recommendations, but rather the appropriate member(s) of the team as determined by the IDT. We invited comment on alternative maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers and to make a determination on the recommendation's necessity. We requested commenters' perspectives on timeframes of 12 hours, 24 hours, 48 hours, and 72 hours from the time of the participant's discharge. We requested that such comments address how the commenter's preferred/recommended timeframe would ensure participant health and safety.

We proposed to require at § 460.102(d)(1)(iv)(B) that the appropriate member(s) of the IDT must review all recommendations from other employees and contractors and make a determination with respect to whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made. As discussed in the December 2022 proposed rule (87 FR 79653), we have seen through monitoring and audits where recommendations have not been considered or acted upon for significant periods of time, which has contributed to delays in the provision of necessary care. While we do not believe that all recommendations made by all types of employees and contractors need to be responded to as quickly as recommendations from hospitals, urgent care providers, or emergency departments, we do believe the IDT must act promptly to consider the recommendations made, and, when the IDT deems the recommended care necessary, it must authorize the recommended care. We explained that the proposed 5-day timeframe would represent the maximum amount of time a PACE organization would have to determine whether a recommended service is necessary, and that we would expect the IDT to consider the participant's condition in determining whether it is necessary to make a determination sooner than 5 calendar days after the recommendation is made.

Additionally, we proposed that the timeframe would begin when the recommendation is made, not when the recommendation is received by the IDT. We have seen through monitoring instances of PACE organizations not making initial requests for consult notes from a participant's appointment with a specialist until months after the

appointment has taken place, and only learning at that time that a recommendation was made during the appointment. It is important that the PACE organization promptly act on recommendations, and it is our expectation that they develop processes with their employees and contractors to ensure the IDT is receiving recommendations in a manner that allows the IDT to determine the necessity of the recommended services within the proposed timeframe. We invited comment on alternative maximum timeframes for IDT review of all recommendations from other employees and contractors and to make a determination on the recommendation's necessity. We asked about commenters' perspectives on whether we should adopt a 3-calendar day timeframe, a 5-calendar day timeframe, a 7-calendar day timeframe, or a 10-calendar day timeframe. We requested that commenters address how the alternative timeframes would ensure participant health and safety.

In the December 2022 proposed rule (87 FR 79654), we emphasized that these recommendation review and necessity determination timeframes are maximum timeframes that the IDT and PACE organization should consider when reviewing recommendations. For some recommendations, such as an MRI to be done in 3 months, these timeframes would be sufficient to ensure that the service is approved and arranged before the service is needed. However, there are other recommendations made where it would not be appropriate for the IDT to take a full the full maximum timeframe to assess and act on a recommendation, and then arrange and schedule it. For example, if a cardiologist indicated that the participant needed an urgent coronary artery bypass graft, we would expect that the IDT and PACE organization act upon that information in a more expeditious manner.

Finally, we proposed to establish at § 460.102(d)(1)(iv)(C) that, if recommendations are authorized or approved by the IDT or a member of the IDT, the services must be promptly arranged and furnished in accordance with the timeframes at § 460.98(c).

As discussed in the December 2022 proposed rule, we are not scoring this provision in the Regulatory Impact Analysis section because the IDT is already required to comprehensively assess and meet the individual needs of each participant, including ensuring the participant's access to all necessary covered items and services 24 hours per day, every day of the year. We reiterate our belief that, by modifying this

provision, we would not be increasing burden on PACE organizations, as they already consider these items on a routine basis. We are also not scoring this provision in the Collection of Information section since all information impacts of this provision have already been accounted for under OMB control number 0938–0790 (CMS–R–244).

We summarize the comments received on the proposal at § 460.102 and provide our responses to those comments in this section of this rule.

Response to Comments

Comment: Some commenters expressed concern with the implementation of IDT care coordination responsibilities across all care settings as proposed in § 460.102(d)(1)(ii), and particularly in reference to IDT care coordination when participants reside in acute and long-term care facilities. Although most of the commenters that provided recommendations pertaining to § 460.102(d)(1)(ii) acknowledged that PACE organizations are responsible for overseeing participants' care at these facilities, they considered IDT involvement in daily care coordination activities for participants residing in care facilities to be functionally impractical and potentially harmful to participants. A few commenters thought that having the IDT order all necessary care for participants residing in care facilities could delay the provision of necessary care. In order to prevent delays in necessary care, a couple commenters recommended that the PACE organization delegate ordering care to care facility providers operating within their scope of practice. Another commenter suggested that the IDT does not have purview to order services provided by care facilities and recommended that the IDT take a consultative approach to overseeing care of participants staying in care facilities.

Another commenter noted different challenges with IDT involvement in daily care coordination at care facilities. These commenters remarked on the difficulty of ensuring daily communication between the IDT and the care facilities when care facilities experience operational issues, like staffing shortages, that may diminish their ability to promptly communicate with the IDT. The commenter asked CMS to provide guidance on how PACE organizations could strengthen care coordination with external healthcare facilities and suggested care coordination with the IDT be added into the contractual agreement between the PACE organization and care facility.

This commenter also requested that CMS provide guidance on the types of documentation that would be needed to demonstrate that the IDT is meeting the care coordination requirements proposed at § 460.102(d)(1)(ii).

Response: The PACE program design is based on the IDT being responsible for authorizing and approving all care that is needed for PACE participants. Contractors, including medical specialty providers and contracted facilities, must agree to furnish only those services authorized by the IDT per § 460.70(d)(5)(i). Therefore, the IDT is currently required to authorize all participant care, regardless of the participant's care setting. PACE organizations may need to establish different coordination procedures and/or contract terms to ensure adequate communication with inpatient care facilities that meets the needs of participants. This does not mean that the PACE organization, or the PCP, needs to directly order all services for the participant that resides in acute and long-term care settings. While we know that some PACE organizations ensure that their PCP has privileges at contracted facilities (and therefore can order services directly), this is not always an option. While the PCP may not directly order all care, it does not absolve the IDT from ensuring that only approved or authorized care is provided. For example, even if a skilled nursing facility (SNF) PCP orders the participant's care, the IDT must authorize or approve the participant's care at the SNF.

As for documentation that demonstrates IDT compliance with the care coordination requirements proposed at § 460.102(d)(1)(ii) when a participant resides in a care facility, CMS expects to see documentation of communications with the facility that demonstrate the IDT's active monitoring and management of the participant's condition. This may include documentation from the admission of the participant, which includes all approved or ordered services (including medication) and ongoing documentation addressing any changes to the participant's care.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(ii) to require coordination and implementation of 24-hour care delivery that meets participant needs across all care settings without modification.

Comment: A commenter requested that CMS clarify the specific actions the IDT should take to “act on”

recommendations as proposed in § 460.102(d)(1)(iv), which states that the interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists.

Response: In the December 2022 proposed rule (87 FR 79653), after introducing at § 460.102(d)(1)(iv) the requirement that the IDT review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists, we explained the specific components of the requirement in § 460.102(d)(1)(iv)(A) through (C). In addition to the IDT reviewing all recommendations from emergency or urgent care providers, employees, and contractors, we proposed that the IDT would determine whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs and arrange and furnish necessary care in accordance with § 460.98(c). Therefore, for the purposes of § 460.102(d)(1)(iv), “act on” means, in addition to reviewing and assessing these recommendations, the IDT would decide whether it is appropriate to approve the service and ensure the provision of any approved services. If the IDT determines a recommended service is not necessary, they must document their rationale for not approving or providing the service in accordance with the redesignated § 460.102(d)(1)(iii) and § 460.210(b).

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: A few commenters had concerns regarding the proposed requirement at § 460.102(d)(1)(iv) that the IDT review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists, specifically with respect to the involvement of the full IDT in recommendation reviews. They believed that CMS was proposing to require that the full IDT be involved in reviewing and approving these recommendations, which they considered administratively burdensome without added benefit to participant outcomes, particularly in emergency situations.

Response: We disagree with the commenters' interpretation of this requirement. The proposed regulatory text supports flexibility in determining which IDT disciplines review, assess and act on recommendations. Although § 460.102(d)(1)(iv) proposed to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, § 460.102(d)(1)(iv) further specifies that, in the cases of § 460.102(d)(1)(iv)(A) and (B), "The appropriate member(s) of the interdisciplinary team must review all recommendations." The proposed language at § 460.102(d)(1)(iv) is similar to the language in § 460.121(h)(1), which allows the IDT to determine the appropriate IDT member or members to conduct a reassessment in response to a service determination request. For the proposed § 460.102(d)(1)(iv)(C), the IDT or a member of the IDT may authorize and approve the recommended service, which then must be promptly arranged and furnished.

Additionally, as discussed in the December 2022 proposed rule (87 FR 79653), we reiterate that the IDT can determine the appropriate IDT disciplines for reviewing recommendations. We do not anticipate that the full IDT would need to be involved in all decisions relating to recommendations made by hospitals, emergency departments, or urgent care centers. More likely, 1 or 2 IDT members would be responsible for these recommendations, and we believe typically this would be the PCP. The PCP in PACE is typically the only individual that can order care given a state's scope of practice laws, and the PCP has the additional responsibility of ensuring they manage the participant's condition, including the use of specialists and inpatient care, as required per § 460.102(c)(2). The example we provided in the December 2022 proposed rule involved a post discharge recommendation for antibiotics. In this instance, the PCP may be the only IDT discipline needed in order to appropriately review, assess, and act on the medication request, since the PCP is responsible for ordering care and medications. We clarify that the IDT has flexibility to determine which IDT disciplines should review, assess, and act on employee and contractor recommendations as well, which may not involve the full IDT. However, we emphasize that PACE organizations are responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant, and that the IDT should review

recommendations with a multidisciplinary approach, as appropriate.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: Most commenters recommended that CMS modify the proposed § 460.102(d)(1)(iv)(A) to extend the maximum timeframe for the IDT review of all recommendations from hospitals, emergency departments, and urgent care providers from 24 to 72 hours from the time of the participant's discharge. A few commenters recommended other maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers: 2 business days, 3 calendar days from the time the IDT was notified of the discharge, and 96 hours after documentation is included in the participant's medical record. One commenter did not recommend a maximum timeframe for IDT review of these recommendations but believed the proposed maximum timeframe to be unreasonable and shared the experience that it may be several days or weeks before the PACE organization receives emergency department recommendations. Another commenter was against imposing any timeframe for IDT review of recommendations from hospitals, emergency departments, and urgent care providers. These commenters advocated for more time to process these recommendations primarily due to concerns that hospitals, emergency departments, and urgent care providers tend to be providers external to the PACE organization for which the PACE organization has no purview. Additionally, some commenters noted that participants may not notify the PACE organization when they receive emergency or urgent care services. Thus, commenters expressed concern that PACE organizations may not be made aware of a participant's discharge or receive the recommendation from the external provider promptly enough for review of the recommendation within 24 hours from the time of the participant's discharge. The commenter that recommended a 2-business day maximum timeframe for the IDT review of these recommendations also recommended we keep long holiday weekends in mind when setting

timeframes for recommendation reviews and that codifying a business day instead of a calendar day approach to the IDT recommendation review timeframe would give the PCP an opportunity to consider the information in the recommendation and develop a plan of care.

Several commenters interpreted the proposed maximum timeframe at § 460.102(d)(1)(iv)(A) to require the full IDT to be on-call to review all recommendations from hospitals, emergency departments, and urgent care providers on weekends. They expressed that having the full IDT present to review recommendations on weekends would impose unreasonable cost increases on the PACE organization, reduce IDT availability for participant care, and impact staff retention. Another commenter expressed general concern for requiring the IDT to review these recommendations within the proposed timeframe when the participant's discharge occurs on weekends.

Response: We carefully considered commenters' recommendations on lengthening the maximum timeframe to act on recommendations from hospitals, emergency rooms and urgent care providers. When we solicited comment on potentially lengthening the proposed timeframe of 24 hours, we asked commenters to indicate in their response how a longer timeframe would ensure participant health and safety. While commenters overwhelmingly requested a longer timeframe than 24 hours, all commenters indicated operational challenges as the basis for their recommendation and did not discuss how these longer timeframes would ensure participant health and safety. While we think there needs to be some consideration to operational challenges, our primary focus is on the participant and their needs. We are not persuaded to lengthen the timeframe to 72 hours or greater without some consideration of how the participants' needs would be addressed. However, we understand that sometimes, despite the PACE organizations' best efforts, 24 hours to act on recommendations may not be enough time. Therefore, we have modified the timeframe in which the appropriate member(s) of the IDT must review and determine the necessity of all recommended services from hospitals, emergency departments, and urgent care providers from our proposed 24 hours to 48 hours from the time of the participant's discharge as a compromise to the majority of commenters' preference for a 72-hour timeframe. We consider 48 hours to be a maximum timeframe, and therefore have also added language to take into

account the participant's condition, such that the finalized timeframe requirement is "as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge." We believe the 48-hour timeframe would not negatively impact participant well-being, as we reiterate that the 48-hour timeframe is a maximum timeframe, and PACE organizations ultimately must both review the recommendation and provide any necessary services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs, which may require the IDT to act sooner than the maximum 48-hour timeframe. Since PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, which includes weekends and holidays, we believe the 48-hour maximum timeframe provides an appropriate level of protection for participants and accountability for PACE organizations regarding the types of services typically recommended after a participant receives urgent or emergency care. Additionally, as discussed in our earlier response to commenters regarding the IDT involvement in recommendation reviews, the IDT has flexibility to determine which IDT disciplines should review, assess, and act on recommendations. We do not expect the full IDT's involvement in every recommendation review. The recommendation review may be conducted by 1 IDT member. However, we continue to emphasize the importance of a multidisciplinary approach to participant care.

After consideration of the comments received, and for the reasons outlined in our response to comments, we are modifying and finalizing our proposal at 460.102(d)(1)(iv)(A) to require that the appropriate member(s) of the interdisciplinary team review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

Comment: A commenter requested clarification regarding how the IDT's recommendation review, as proposed at § 460.102(d)(1)(iv) should be documented, and more specifically asked whether the IDT review of recommendations could be conducted

verbally, or whether the reviewing provider should document their review of the order.

Response: We interpret this commenter's question as asking about documentation expectations for recommendations the IDT receives and reviews orally. At a minimum, the IDT is responsible for documenting recommendations from employees and contractors into the medical record per § 460.210(b)(4). Once the recommendation is documented, the IDT may have oral conversations regarding the necessity of that recommendation. Not all of those discussions would need to be documented. However, we expect to see the result of that discussion documented to demonstrate that the IDT assessed and considered the recommendations. If a recommendation was approved, we expect to see some evidence or documentation that the service was approved/authorized or ordered. If the recommendation was not considered necessary (and therefore not approved), the IDT is responsible for documenting the rationale for that decision per redesignated §§ 460.102(d)(1)(iii) and 460.210(b)(5). Additionally, if the IDT approves or orders the recommended service, the PACE organization must document, track, and monitor the provision of the service as per the redesignated § 460.98(b)(4).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: Most commenters recommended that we modify § 460.102(d)(1)(iv)(B) to extend the maximum timeframe for the IDT to review and make determinations on all recommendations from other employees and contractors. We had initially proposed 5 calendar days from the date the recommendation was made as the maximum timeframe, and most commenters recommended a maximum timeframe of 10 calendar days. Commenters' primary justification for extending the timeframe centered on the concern that providers external to the PACE organization might not cooperate in providing all necessary information to the IDT in a timely manner, which they considered beyond the control of the PACE organization, and potentially a situation that may unfairly penalize

PACE organizations. Many commenters mentioned that PACE organizations may experience delays in follow-ups from specialist providers, since provider offices are often closed on weekends and holidays. A commenter did not recommend a specific alternative maximum timeframe for IDT review of other employee and contractor recommendations but expressed that the proposed 5-calendar day maximum timeframe was unreasonable based on their experience that PACE organization may not receive specialist recommendations for up to 2 weeks after the date the provider made the recommendation. Another commenter recommended that CMS not impose any timeframe for IDT reviews of contractor recommendations. This commenter considered any review timeframe for contractor recommendations unreasonable and echoed other commenters' concerns that PACE organizations may be penalized for situations outside of their control, such as when contracted providers do not communicate or provide necessary documentation timely to the PACE organization. This commenter also suggested that IDT review of all contractor recommendations would increase IDT responsibilities to the point of negatively impacting the time they can devote to participant care. A commenter asked that we clarify what the starting point for the review timeframe would be and recommended that we base the timeframe on when the PACE organization receives the recommendation rather than the date the recommendation was made.

Response: After careful consideration of the comments, we have decided to modify the proposed § 460.102(d)(1)(iv)(B). Specifically, we have modified the maximum timeframe in which the appropriate member(s) of the IDT must review and make necessity determinations for all recommended services from other employees and contractors from the proposed 5 calendar days to 7 calendar days from the date the recommendation was made. As previously mentioned in the December 2022 proposed rule (87 FR 79653), most PACE organizations audited in 2021 received citations of non-compliance for failing to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Most PACE organizations audited in 2022 and 2023 also received citations in this area. During our oversight and monitoring efforts, we have not observed that PACE organizations are routinely making multiple good faith attempts to receive

documentation, including recommendations, from specialist providers. Instead, we have seen numerous situations where PACE organizations make no attempt to obtain recommendations from specialists, and therefore are not aware of their recommendations until months later. The delayed receipt of specialist recommendations jeopardizes participant wellbeing by delaying necessary follow-up care and services. In consideration of our oversight and monitoring observations and commenter concerns, we believe the 7-calendar day timeframe is an appropriate compromise between the 5-calendar day timeframe we originally proposed and the 10-calendar day timeframe that the majority of commenters on this proposal preferred. We believe the 7-calendar day maximum timeframe offers additional flexibility to the IDT in terms of coordination with external providers, while continuing to prioritize participant wellbeing.

We continue to emphasize that the 7-calendar day timeframe is a maximum timeframe, and that the IDT must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, which may require action sooner than 7 calendar days. Although we recognize there may be logistical challenges involved with external provider communications, PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and we decline to implement a timeframe that may result in a lower standard of care on the basis of communication delays by the contracted providers, as we expect PACE organizations to initiate communication and follow-up with external providers to ensure participants receive any necessary follow-on care and services. We also understand that some specialists may not provide written consult notes immediately following an appointment, but nothing would prevent the IDT from calling the specialist and documenting recommendations prior to receiving the complete consultation documentation. Additionally, as discussed in the December 2022 proposed rule, we reiterate that the § 460.102(d)(1)(iv)(B) timeframe begins the date the recommendation was made (87 FR 79654), not the date that the PACE organization or IDT receives the

recommendation. In order to ensure participants receive the care they need, in the timeframe they need it, it is important that the timeframe begins when the recommendation is made, and that the PACE organization puts processes into place to get information relating to the recommendations quickly from providers.

After consideration of the comments received, and for the reasons outlined in our response to comments, we are modifying and finalizing our proposal at § 460.102(d)(1)(iv)(B) to require the appropriate member(s) of the interdisciplinary team to review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 7 calendar days from the date the recommendation was made.

Comment: A commenter suggested that we may have made an error when proposing at § 460.102(d)(1)(iv)(C) that services must be promptly arranged and furnished under § 460.98(c). The commenter did not believe the use of "arrange and furnish" was consistent with other sections in the proposed amendments to § 460.98, which specify maximum timeframes for arranging and scheduling services, but also that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

Response: Although the proposed and now finalized § 460.98 addresses timeframes for arranging and scheduling services, the redesignated § 460.98(c)(4) also states that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs. As discussed in the December 2022 proposed rule, the IDT must arrange (or schedule) the IDT-approved service within the maximum timeframes established at § 460.98(c)(1) and (2) and furnish the service as required by § 460.98(c)(4). (87 FR 79654).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv)(C) to require that, if recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c) without modification.

F. Plan of Care (§ 460.106)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities.

In the 1999 PACE interim final rule (64 FR 66251), CMS developed requirements for participant plans of care based on the requirements in Part IV, section B of the original PACE Protocol. Those requirements were finalized in the 2006 PACE final rule (71 FR 71292).

In 2010, in response to questions from PACE organizations, CMS issued a subregulatory document titled, "Care Planning Guidance for PACE Organizations." This care planning document provided detailed guidance for developing, implementing, monitoring, reevaluating, and revising plans of care. While this document stressed that care plans should be comprehensive and include the participants medical, physical, social, and emotional needs, it also noted that not all care received by the participant would need to be included in the care plan, and instead, could be tracked and documented through discipline specific progress notes.

Since that time, CMS has seen through oversight and monitoring efforts that participant care plans are often sparse and may not fully detail the care received by a participant. We have noted that organizations are relying heavily on providing and documenting care through discipline-specific progress notes, rather than through incorporation into a more comprehensive and formal plan of care.

In the June 2019 final rule (84 FR 25675), CMS added additional requirements around the development

of a comprehensive plan of care which included: a consolidation of discipline-specific initial assessments into a single plan of care for each participant within 30 days of the date of enrollment; documentation in the plan of care of the reasoning behind any IDT determination that certain services are not necessary to the care of a participant; and documentation in the plan of care that the participant was assessed for all services, even where a determination was made that certain services were unnecessary at the time.

In addition to the modifications at § 460.104(b), in the June 2019 final rule, CMS also amended § 460.106 in order to provide additional clarity with respect to the development and content of the plan of care process (84 FR 25646). Among other changes, CMS added requirements for PACE organizations to utilize the most appropriate interventions for each care need that advance the participant toward a measurable goal and outcome (§ 460.106(b)(3)); identify each intervention and how it will be implemented (§ 460.106(b)(4)); and identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes (§ 460.106(b)(5)).

Despite the addition of these requirements in the June 2019 final rule, we continue to find that PACE organizations are struggling with developing, implementing, monitoring, reevaluating, and revising plans of care. As we discussed in the proposed rule, we have seen through our oversight and monitoring process that robust initial care plans become more sparse over time due to the omission of care originally included in the plan of care which is instead handled through discipline-specific progress notes as the participant's enrollment continues (87 FR 79655). In the proposed rule, we acknowledged that documenting detailed information about participant care and services in discipline-specific progress notes is necessary and an accepted standard practice, but argued that practice should not be done in lieu of a comprehensive plan of care that addresses the participant's needs because it results in individual IDT members providing care in an isolated and individualized approach (*Id.*).

Since the June 2019 final rule became effective, CMS has completed 40 PACE audits and we have identified a failure to provide services or delays in providing services in 37 of the 40 audits conducted. Although this noncompliance cannot be directly attributed to a failure to consolidate information into a comprehensive plan

of care, our audit findings suggests that the coordination and delivery of necessary services is a challenge for PACE organizations.

Finally, we discussed in the proposed rule how we have also seen on audit that participant and caregiver involvement in the care planning process tends to be minimal and primarily occurs after the development and/or revisions to the plan of care have been finalized and implemented by the IDT (*Id.*). In the 1999 PACE interim final rule (64 FR 66252), CMS specifically stated that plans of care must be developed, reviewed, and reevaluated in collaboration with the participants or caregivers. In the proposed rule, we stated that the purpose of participant/caregiver involvement is to ensure that they approve of the care plan and that participant concerns are addressed (87 FR 79656). Furthermore, in the 2006 PACE final rule (71 FR 71293), CMS reiterated that it is our expectation that the IDT will include the participant in the plan of care development when possible and include the participant's representative when it is not appropriate to include the participant or at the instruction of the participant.

As we discussed in the proposed rule, we believe it is prudent to implement additional requirements related to the minimum requirements for a participant's plan of care (*Id.*). The proposed rule included a discussion of our attempt to adopt language and requirements that are consistent with the long-term care facility regulation at § 483.21(b) when possible because these regulations require nursing homes to develop comprehensive and person-centered care plans that meet residents' needs. Since individuals who enroll in PACE must be deemed nursing home eligible, they have similar needs as those who receive services from nursing facilities (*Id.*).

First, we proposed to modify the requirement in § 460.106(a) to require that the members of the IDT specified in § 460.102(b) must develop, evaluate, and if necessary, revise a person-centered plan of care for each participant. As we discussed in the proposed rule, this is consistent with the requirement at § 460.104(b) that states that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT (87 FR 79656). Additionally, the IDT is required to reevaluate the plan of care on a semiannual basis at the current § 460.106(d); however, we proposed to remove that requirement as our proposal

at § 460.106(a) would cover the role of the IDT in both the initial care plan development and also the subsequent reviews and reevaluations of the care plan. We also proposed to add language into § 460.106(a) that would require each plan of care to take into consideration the most current assessment findings and identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being. The nursing home regulations require that care plans must describe "the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being" (§ 483.21(b)(1)(i)). This language should also apply to PACE care plans, since they serve the same nursing home eligible population.

Next, we proposed to add a new section, § 460.106(b), which would define the specific timeframes for developing, evaluating, and revising care plans. For initial care plans, we intend to maintain the requirement for the IDT to finalize the development of the initial plan of care within 30 calendar days of the participant's enrollment that is located at current § 460.106(a), but we propose to move this requirement to new section § 460.106(b)(1).

The regulation at § 460.106(d) currently requires the IDT to reevaluate the plan of care, including defined outcomes, and make changes as necessary on at least a semi-annual basis. The interpretation of the semiannual timeframe has posed issues for PACE organizations. We therefore proposed at § 460.106(b)(2) to require that the IDT must complete a reevaluation of, and if necessary, revisions to each participant's plan of care at least once every 180 calendar days. We believe that creating a strict timeframe of 180 days would be less ambiguous and easier for organizations to track.

We proposed at § 460.106(b)(3)(i) that the IDT must complete a reevaluation, and if necessary, revisions of the plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status or more expeditiously if the participant's condition requires. As we discussed in the proposed rule, the current requirement is that the IDT must conduct reassessments when a participant experiences a change in participant status and the IDT must also reevaluate the participant's plan of care (87 FR 79656). However, there is no timeframe for how quickly the IDT

members must conduct those reassessments or reevaluate the plan of care to determine if changes are needed. In the proposed rule, we argued that we believe that a 14-calendar day timeframe is appropriate since it will ensure the IDT is promptly acting on changes to the participant's status (*Id.*). We reviewed the long-term care requirements which state that a resident must receive a comprehensive assessment within 14 calendar days after the date the facility determines, or should have determined there was a significant change in status in the resident's condition and the facility must use the results of the assessments to develop, review, and revise the resident's plan of care (*Id.*). In the proposed rule, we argued this is an appropriate standard to apply in PACE as well due to the similarities between the populations (*Id.*). As discussed later in this section of this proposed rule, we also proposed to modify § 460.104(e) to emphasize that all required assessments must be completed prior to the plan of care being revised. Therefore, this 14-calendar day timeframe would include both the required assessments under § 460.104(d)(1) and the process of revising the plan of care under § 460.106.

We proposed to specify at § 460.106(b)(3)(i) that the 14-calendar day timeframe starts when the PACE organization determines, or should have determined, that a change in the participant's condition occurs. As we discussed in the proposed rule, if a participant experiences a change in status that triggers this reassessment and reevaluation of the care plan, the PACE organization should not be able to delay the timeframe by not recognizing the change in status for a period of time (87 FR 79657). We also proposed to define at § 460.106(b)(3)(i) what constitutes a change in status. As we discussed in the proposed rule, what constitutes a change in status has not been previously defined and we proposed to adopt in PACE the requirement applicable to nursing homes at § 483.20(b)(2)(ii), but with language tailored to be specific to PACE (*Id.*). Therefore, the proposed requirement would state that for purposes of this section, a "change in participant status" means a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires IDT review or revision of the care plan, or both.

In conjunction with the proposed requirement that a PACE organization

must reevaluate and, if necessary, revise the plan of care within 14 calendar days after a change in the participant's condition occurs, we proposed at § 460.106(b)(3)(ii) that if a participant is hospitalized within 14 calendar days of the change in participant status, the IDT must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital. In the proposed rule, we recognized that when a participant is hospitalized, it is difficult for the IDT to assess the participant, and revise a plan of care, during the course of that hospitalization (87 FR 79657). We proposed that the timeframe for reevaluating the plan of care starts when the participant is discharged from the hospital. Despite this proposed exception, we reminded PACE organizations in the proposed rule that their responsibilities toward the participant do not end or stop when a participant is hospitalized, and the IDT should remain alert to pertinent information in all care settings under § 460.102(d)(2)(ii) (*Id.*).

We solicited comment on whether 14 calendar days is an appropriate timeframe to use or if 21 or 30 days would be more appropriate.

We proposed at § 460.106(c) to make certain modifications related to the content of a plan of care. As we discussed in the proposed rule, the current content of a plan of care is specified at § 460.106(b), which requires the care plan to include the care needed to meet the participant's medical, physical, emotional and social needs; identify measurable outcomes to be achieved; utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal; identify each intervention and how it will be implemented; and identify how each intervention will be evaluated to determine progress (87 FR 79657). We discussed in the proposed rule that we have seen as part of our audit and oversight activities where treatments for participants' medical conditions are included in discipline-specific notes, but not in the comprehensive care plan which has caused members of the IDT to be unaware of the treatments and recommendations the participant has received from other members of the IDT or outside contracted specialists (*Id.*). Additionally, we discussed how we have seen participants experience delays in receiving the recommended treatment or service, the treatment or service not being provided at all, and in some situations, duplicate orders for a

service or treatment due to the IDT being unaware the service or treatment was previously provided (*Id.*). Therefore, in addition to proposing to move the content of plan of care requirements from § 460.106(b) to § 460.106(c), we proposed to add language to the section to create minimum requirements for what each plan of care must include. As we discussed in the proposed rule, we considered the regulations at § 483.21(b) which specify the requirements for a comprehensive plan of care (*Id.*). Additionally, § 483.21(b) references § 483.24 (Quality of Life), § 483.25 (Quality of Care), and § 483.40 (Behavior Health), so we considered those sections as well. Therefore, at § 460.106(c), we proposed modifying the language to state at a minimum, each plan of care must meet certain requirements, which would be set forth in the regulations at proposed § 460.106(c)(1)(i) through (xiii). At § 460.106(c)(1), we proposed to add language that requires PACE organizations to identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring, and that at a minimum, the care plan must address specific factors we will discuss in the next paragraph. As we discussed in the proposed rule, care plans are currently required at § 460.106(b)(1) to include the care needed to meet the participant's medical, physical, emotional and social needs, as identified in the initial comprehensive assessment (*Id.*). However, we proposed to further specify that the plan of care should address all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring which is consistent with nursing home requirements. As explained in the proposed rule, our proposal related to chronic behavioral and psychiatric disorders is consistent with long-term care requirements in § 483.40, which require that each resident must receive and the facility must provide the necessary behavioral health care and services (87 FR 79657). We observed that the nursing home care plan requirements at § 483.21(b) reference the behavior health requirements at § 483.40. Therefore, we proposed that chronic behavioral and psychiatric disorders that require treatment or routine monitoring also be included in PACE plans of care.

We proposed to limit what diseases must be included in the plan of care to

those that are chronic and require treatment or routine monitoring. As we discussed in the proposed rule, when considering how organizations would define “chronic” we believe that most organizations would consider the guidance issued by the CDC, which defines chronic diseases as conditions that last 1 year or more, and require ongoing medical attention or limit activities of daily living or both (87 FR 79658). We also solicited comment on whether acute conditions should be included in the minimum content that a care plan must address.

We proposed to specify at § 460.106(c)(1)(i) that the PACE participant’s plan of care must address the participant’s vision needs. This is consistent with the long-term care provisions at §§ 483.20(b)(1)(v) and 483.25(a). As we discussed in the proposed rule, the age of the PACE population and the co-morbidities that may impact the population makes addressing a participant’s vision an important part of the care plan (87 FR 79658). We similarly proposed at § 460.106(c)(1)(ii) that a PACE participant’s plan of care must address the participant’s hearing needs. This is consistent with the long-term care regulations at § 483.25(a). We proposed at § 460.106(c)(1)(iii) that a participant’s plan of care must address the participant’s dentition. This is consistent with the requirement at § 483.20(b)(1)(xi). We proposed at § 460.106(c)(1)(iv) that a plan of care must address the participant’s skin integrity. This is consistent with the requirements at §§ 483.20(b)(1)(xii) and 483.25(b). We proposed at § 460.106(c)(1)(v) that the participant’s plan of care must address the participant’s mobility. This is consistent with the requirement at § 483.25(c). We proposed at § 460.106(c)(1)(vi) that the participant’s plan of care must address the participant’s physical functioning (including activities of daily living). This is consistent with the requirements at §§ 483.20(b)(1)(viii) and 483.24(b). We proposed at § 460.106(c)(1)(vii) that the plan of care must address the participant’s pain management needs. This is consistent with the requirement at § 483.25(k).

As we discussed in the proposed rule, the next few proposed requirements deviate from the nursing home requirements and are tailored specifically to the PACE program (87 FR 79658). We proposed to require at § 460.106(c)(1)(viii) that the plan of care address the participant’s nutrition, including access to meals that meet the participant’s daily nutritional and special dietary needs. The proposed

language is based on the long-term care regulations at §§ 483.20(b)(1)(xi), 483.24(b)(4), and 483.25(g), but it is tailored to be more specific to PACE. As we discussed in the proposed rule, PACE participants live in a variety of settings and the exact manner in which the organization meets the requirement may be different for each participant (*Id.*). For this reason, we proposed to include in § 460.106(c)(1)(viii) language that would specify that the plan of care address not only nutrition, but also how a participant accesses meals that meet their nutritional and special dietary needs.

We proposed at § 460.106(c)(1)(ix) to establish the requirement that the plan of care address the participant’s ability to live safely in the community, including the safety of their home environment. As we discussed in the proposed rule, the proposal also deviates from the nursing home requirements, as the goal of PACE is to keep nursing home eligible individuals out of a facility and living in the community, and the IDT must assess the participant’s environment and living situation for potential factors that may make it unsafe for the participant (87 FR 79658). As we noted in the 2006 PACE final rule (71 FR 71275), PACE organizations are at risk for all health care services the participant receives and, therefore, we expect PACE organizations will be involved in assuring the health and safety of participants at all times, including when they are at home. We proposed at § 460.106(c)(1)(x) that the plan of care must address the participant’s home care needs. As we discussed in the proposed rule, this proposal would also deviate from nursing home guidance because, while nursing homes provide 24-hour care to residents living at the facility, PACE provides similar care through home care services (87 FR 79653). Therefore, we believe a participant’s home care needs must be addressed through the plan of care. We proposed to establish at § 460.106(c)(1)(xi) that the participant’s center attendance must be included in the plan of care. As we discussed in the proposed rule, center attendance is an integral part of the PACE program, and we believe it is appropriate to include it in a participant’s plan of care (*Id.*). We proposed at § 460.106(c)(1)(xii) to require that a participant’s transportation needs be incorporated into the plan of care. As we discussed in the proposed rule, transportation is an essential part of the PACE benefit, as often it is the PACE transportation that ensures participants have access to their

necessary medical appointments and specialist visits (*Id.*). In addition, we proposed to require at § 460.106(c)(1)(xiii) that a participant’s communication needs (including any identified language barriers) be incorporated into the plan of care. As we discussed in the proposed rule, for participants who are not English speaking, or have some other difficulty communicating, addressing and resolving these needs preemptively can mean the difference between quality of care and participants not receiving the care they need (*Id.*).

We solicited comment on all items identified in proposed § 460.106(c)(1) and whether they should be required content in a plan of care for PACE participants. We specifically requested comment on whether to include acute diseases and/or acute behavioral and psychiatric disorders in the plan of care as part of the minimum criteria. We also solicited comment on whether there is other content that is required to be in a nursing home care plan that should also be included in a PACE plan of care.

We proposed at § 460.106(c)(2) to require that the plan of care must identify each intervention (the care or service) needed to meet the participant’s medical, physical, emotional, and social needs. As we discussed in the proposed rule, the PACE organization must also identify any service that will be provided to meet the participant’s medical, physical, social, or emotional needs (87 FR 79659). We proposed to include at § 460.106(c)(2) an exception to the interventions that need to be included in the plan of care; specifically, proposed § 460.106(c)(2) would provide that the plan of care does not need to identify the medications needed to meet a participant’s needs if a comprehensive list of medications is already documented elsewhere in the medical record. As we discussed in the proposed rule, we define services at § 460.6 to include medications because we strongly believe that medications are an important part of the PACE benefit and may be the most applicable service for a particular diagnosis or condition (*Id.*). However, we also understand that medications may change frequently, and are typically documented in the medical record in way that would allow the IDT to understand all current, pending and discontinued medications. While we did not propose to require that all medications be identified in the plan of care, we solicited comment on whether the plan of care should include a comprehensive list of active medications.

We proposed to redesignate current § 460.106(b)(3), which requires the care

plan to utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome, as § 460.106(c)(3).

We proposed at § 460.106(c)(4) to specify that the plan of care must identify how each service will be implemented, including a timeframe for implementation. The proposed rule noted that the IDT is already required to identify how each intervention will be implemented in § 460.106(b)(4); we proposed to modify the language to specify that as part of identifying how the intervention will be implemented, the PACE organization should specify a timeframe for that implementation (*Id.*). As part of the plan of care process, the IDT should determine the parameters of a service—specifically, how it will be provided to the participant in order to meet their needs.

We proposed at § 460.106(c)(5) to require that the plan of care must identify a measurable goal for each intervention. As we discussed in the proposed rule, the current care plan regulations require that the plan identify measurable outcomes (§ 460.106(b)(2)) and utilize appropriate interventions that advance the participant toward a measurable goal (§ 460.106(b)(3)) (87 FR 79659). We explained in the proposed rule that our proposal at § 460.106(c)(5) is consistent with the intention of the current requirement; however, we believe that it is important when identifying a service to also identify the measurable goal for that service (*Id.*).

We proposed at § 460.106(c)(6) to require that the care plan identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified. As we discussed in the proposed rule, the IDT is currently required at § 460.106(b)(5) to identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes (87 FR 79659). We explained in the proposed rule that our proposal is similar in intent, but would reduce ambiguity by specifying that the evaluation by the IDT should focus on determining whether the goal was met before deciding if the intervention needs to be continued, discontinued or modified (*Id.*). We further explained that if the participant met the goal, the IDT may decide to discontinue the service; however if the participant didn't meet the goal, the IDT may decide to modify or continue the intervention, and at that time, the IDT will need to determine both a new measurable goal and how that goal will be evaluated (*Id.*).

Finally, we proposed at § 460.106(c)(7) to require that the plan of care must identify the participant's preferences and goals of care. As we discussed in the proposed rule, it is important for the PACE organization to document the participant's goals and wishes for treatment and to consider them not only when developing and reevaluating the plan of care, but during implementation of the services that were added to the plan of care (87 FR 79659).

We proposed to move the requirements in § 460.106(c) to § 460.106(d) and make modifications to the existing requirements. We proposed to move the language in § 460.106(c)(1) to § 460.106(d)(1) and modify it to read that the IDT must continuously implement, coordinate, and monitor the plan of care, regardless of whether the services are furnished by PACE employees or contractors, across all care settings. As we discussed in the proposed rule, we have seen where PACE organizations met the minimum requirement of reassessing participants semiannually and updating the plan of care accordingly, but then took no further action with respect to the plan of care until the next semiannual assessment period (87 FR 79660). In the proposed rule, we reemphasized that the intent of the plan of care is to create a comprehensive, living document that is updated per the participant's current status at any given point (*Id.*). We proposed to include the language "across all care settings," to reiterate the responsibilities of the IDT in ensuring that care is appropriately coordinated and furnished, regardless of where a participant resides.

We proposed to move the current requirements at § 460.106(c)(2) to § 460.106(d)(2) and to modify § 460.106(d)(2) to specify that the IDT must continuously evaluate and monitor the participant's medical, physical, emotional, and social needs, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT and other employees or contractors. As we discussed in the proposed rule, the modification to change the language from "participant's health and psychosocial status" to "participant's medical, physical, emotional, and social needs" is intended to align more closely with the regulation on required services at § 460.92(b) (87 FR 79660).

We proposed to add § 460.106(d)(3) to state that all services must be arranged and provided in accordance with § 460.98(c). As we discussed in section

VI.G. of the proposed rule, we have proposed additional criteria concerning the arranging and provision of services that are determined necessary by the IDT (87 FR 79648). We explained in the proposed rule that when a service is care planned, the IDT has determined that the service is necessary for the participant, and we would expect it to be arranged and provided in accordance with the rules governing other approved or necessary services (87 FR 79660).

As we discussed in the December 2022 proposed rule, although § 460.106(e) currently requires that the team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, we have seen as part of our audit and oversight activities where participants and/or caregivers are unaware of the contents of their plan of care or what services they should be receiving (87 FR 79660). We further discussed how we often see that the plan of care is finalized by the team and then provided or reviewed with the participant after the fact as a means of "collaboration." (*Id.*) Therefore, we proposed to split the existing language into two new paragraphs § 460.106(e)(1) and (e)(2). We proposed at § 460.106(e)(1) that the IDT must develop, evaluate, and revise each plan of care in collaboration with the participant or caregiver, or both. We proposed to amend the language to refer to "each" plan of care in order to emphasize that this collaboration must be performed for every new plan of care, including the initial, semi-annual, and a revised plan of care as a result of a change in status. We also proposed at § 460.106(e)(2) that the IDT must review and discuss each plan of care with the participant and/or caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and the participant's concerns are addressed.

As we discussed in the December 2022 proposed rule, we have seen organizations have insufficient documentation related to participant plans of care despite the current requirement that the team document the plan of care, and any changes made to it, in the participant's medical record (87 FR 79660). We further explained how we often see minimum documentation related to whether a participant has met the goals set at the last assessment and any changes in the participant's status, but no documentation of the conversations with the participant in the plan of care, including whether the participant disagreed with any part of the plan of care and whether those concerns were

addressed (*Id.*). Therefore, we proposed to modify the language in § 460.106(f) to state that the team must establish and implement a process to document and maintain records related to all requirements for the plan of care in the participant's medical record, and ensure that the most recent care plan is available to all employees and contractors within the organization as needed. As we discussed in the proposed rule, our proposal is consistent with the current requirement, but ensures that the PACE organization understands that it must document all care planning requirements (*Id.*). Therefore, we would expect to see documentation that the appropriate members of the IDT were involved in care planning in accordance with § 460.106(a), the IDT met the timeframes for finalizing care plans in § 460.106(b), that the care plans included all required content in § 460.106(c), that the IDT implemented and monitored the plan of care in accordance with § 460.106(d), and that the participant and caregiver were appropriately involved in the care planning process in accordance with § 460.106(e).

We also proposed certain modifications to § 460.104 to align with our proposed amendments to § 460.106. We proposed to remove most of the language currently in § 460.104(e) and add the requirement that when the IDT conducts semiannual or unscheduled reassessments, the IDT must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments. As we discussed in the proposed rule, we believe this will eliminate any unnecessary duplication and ensure there is no confusion as it relates to care plans (87 FR 79661).

As both the development of and updates to the care plan are a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with the development of and updates to the care plan are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a usual and customary business practice.

We solicited comment on these proposals. A summary of the comments received and our responses follow.

Comment: Most commenters appreciated CMS's clarification of semi-annual by modifying the requirement to 180 days. Several commenters expressed concern over the change in

requirement from a semi-annual re-evaluation of the plan of care to a re-evaluation at least every 180 days. Those commenters stated the requirement is overly burdensome because it will require PACE organizations to monitor and track the care plan precisely and notify the IDT when the next care plan is due. A commenter requested clarification of whether the 180-day timeline restarts every time the plan of care is reevaluated or if it is predicated on the participant's enrollment date. A commenter requested that the requirement be modified from 180 days to the last day of the 6th month following the last reevaluation of the plan of care because it would provide PACE organizations an entire month to focus on care planning rather than having to calculate the 180 days exactly. Another commenter pointed out that 180 days is just short of six months, and that CMS should change the requirement to 185 days to allow for a full six months between reevaluations for plans of care.

Response: We thank commenters for sharing their concerns regarding the 180-day timeline being overly burdensome. We believe that providing a clear standard will reduce the ambiguity of the semi-annual care plan requirement currently in regulation. We are not persuaded by the argument that tracking the care plan by 180 days is overly burdensome as PACE organizations are already required to track care plans semi-annually. We have also consistently heard from both PACE organizations and advocacy groups that PACE requirements are overly vague and clarification of CMS's intent is appreciated whenever possible. For these reasons, we are not persuaded to extend the timeframe beyond the proposed 180-days or leave the requirement as it currently is written. Additionally, we clarify that we intend the 180-day timeline to restart every time a new care plan is finalized. We believe this is consistent with other parts of the regulation that contemplate care plans being developed within specific timeframes (for example, §§ 460.104(b) and 460.106(a)) and also the service determination request language which discusses requests made "prior to completing the development" of the initial plan of care (see § 460.121(b)(2)). For example, if a participant experiences a change in health status, the participant must be assessed, and a new care plan must be developed and implemented. The participant's next care plan would then be due 180 days from the date the latest

care plan was finalized. To ensure there is no ambiguity on when the timeframe begins, we are finalizing the proposed requirement with a modification to the regulation text to state that the 180-day timeline starts from the date when the last care plan was finalized at § 460.106(b)(2).

Comment: Multiple commenters requested that CMS extend the timeframe to conduct unscheduled assessments following a change of status from the 14-day timeline that was proposed to a 30-day timeline to allow PACE organizations more flexibility in complex cases and more time to coordinate with providers outside of the PACE organization's network. A commenter questioned CMS's decision to hold PACE organizations to the same standard as long-term care facilities when it is not clear whether the 14-day timeline used by these facilities improves care. A few commenters requested that CMS add a participant being discharged from a SNF as an exception to the 14-day timeframe, similar to the exception proposed for participants who are hospitalized. These commenters argued that it is beneficial for the participant to be as stable as possible before conducting assessments and developing a care plan. These commenters suggested that if a participant is placed in a SNF for a short-term stay, or another similar environment, the IDT should delay the reassessment timeframe until discharge, similar to the hospital exception. A commenter requested CMS consider providing an exception process to the timeline to allow PACE organizations an exemption when needed, but to limit abuse by requiring 85 percent of care plans to meet the regulatory timeframes to be considered compliant. Another commenter requested that CMS clarify when the timeline would begin for care planning purposes if a PACE organization failed to determine, but should have determined, that there had been a change in the participant's health or psychosocial status.

Response: We thank the commenters for their suggestions to extend the timeline to conduct an unscheduled re-evaluation of the care plan following a change in status. We understand the concerns expressed by commenters about the ability of PACE organizations to obtain necessary information from outside sources, such as hospitals, to complete assessments of the participants after a change in status. We had solicited comment on whether the timeline should be 14, 21, or 30 days and, if commenters believed a different timeline was more appropriate for PACE, why PACE should be held to a

different standard than long term care facilities. While most commenters requested 30 days, we were not persuaded by the commenters' arguments for why this longer timeframe was justified. PACE organizations must have processes in place to ensure their contracted providers are promptly communicating information relating to the participant's condition. Incidents that prompt a change in status reassessment are not minor events, but situations that have a direct impact to a participant's ability to function, and therefore, they need to be considered and addressed as expeditiously as the participant's health requires. As we have stated previously, because PACE and long-term care facilities serve the same vulnerable population, we feel aligning the requirements ensures participants receive the same quality of care they would receive in a nursing home or other SNF. We are also not persuaded to add an exception to the timeframe for conducting a re-evaluation of the care plan to include a participant's discharge from a SNF. SNFs are contracted with the PACE organization, and the PACE organization should already have processes in place to conduct assessments of participants when they are at those facilities as needed. Additionally, while commenters requested exceptions for "short term" stays in a SNF, "short term" is an undefined period of time which will change for every participant in every situation. While some participants may experience a short term stay of a week, other participants may be admitted for a "short term" stay and end up residing in the SNF for a month or even longer. Delaying those participants' re-evaluations until after discharge would be inappropriate as the participant may end up residing for long periods in another care setting without a care plan that is appropriately tailored to their needs. We would note, nothing in our modification prohibits a PACE organization from conducting change in condition assessments and care plans on a more frequent basis. If the PACE organization determines that the participant should be re-assessed following the discharge from the SNF, it is encouraged to do so.

As for the language that the timeframe begins within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status; this language is meant to convey that the trigger for the timeframe is when the change in status event occurs, even if that event happens

prior to the PACE organization becoming aware of it. For example, if the participant has a stroke with hemiplegia on a Monday, and the PACE organization becomes aware of the stroke 2 days later, the 14-calendar day timeframe begins the date of the stroke, not the date the PACE organization becomes aware of the stroke. However, if the participant is hospitalized because of the stroke, the 14-calendar day timeframe would begin upon discharge from the hospital. We are finalizing the 14-calendar day timeframe as proposed.

Comment: Several commenters requested that CMS modify the proposal on the required content of plans of care to focus on what is most important and relevant to participants' needs as identified by the IDT in collaboration with the participant and/or designated representative. A few commenters also requested that CMS clarify that the proposed changes to the content of the care plan will not interfere with the participant's views and wishes, including the participant's desire to decline certain plan goals. A few commenters expressed concern that the minimum requirements for the content of care plans would include such a high level of detail that it would impact the IDT's time and resources and create administrative burden. A commenter stated that long-term care facilities and PACE organizations are different and should not be held to the same standards, and asked for clarification of how CMS would determine the validity of an assessment for a participant who has no needs in a specified area. A commenter requested that CMS clarify what the word "need" means in the context of the care plan, and whether that refers to an assessed medical need or a need the participant believes they have. Another commenter stated that it was impractical and duplicative for IDT members to incorporate their individual notes and diagnoses from the medical record into a care plan for all participants.

Response: We thank commenters for sharing their concerns on the proposed required content to the plan of care. Our intent in proposing required content for the plan of care wasn't to override participant's wishes and desires for what is included in their individual plans of care, but instead to ensure that all participants are equally assessed for services that meet their needs, and to ensure the care plan is a comprehensive document that reflects an accurate picture of the care a participant receives. In the event a participant is assessed for a service that they do not wish to include in their plan of care, we would expect the PACE organization to

document that the participant was assessed for the service and requested it not to be included in their plan of care. Additionally, if the IDT determined the participant did not have any identified needs in a particular area, they would indicate that in the plan of care. For example, if the participant is assessed as having perfect vision, the care plan content for vision may include an optometry appointment once a year without any further goals or interventions. Or the IDT may note that there are no current needs in a particular area, such as skin integrity. When determining a participant's needs in a particular area the IDT should use all available information including recent assessments to ensure the care plan accurately reflects the participant's condition in a particular area. Per our changes to § 460.121(b)(2), as discussed in section IX.L of this final rule, when a participant believes they have a need, we would expect the IDT to assess the participant for that need to determine if the need is present. Then the IDT would assess what services or interventions are necessary to meet that need, just as the IDT determines whether any request for a specific service is necessary to improve and/or maintain a participant's medical, physical, emotional, or social wellbeing. Then we would expect the IDT to document the request for assistance with the stated need, the IDT's determination, and in the event the need was determined not to be present, the IDT's reasoning for that determination. We would review the available documentation in the medical record to determine if the participant's needs were appropriately assessed and addressed.

We understand that long-term care facilities and PACE organizations are not the same, but they share some important similarities. They are both direct care providers serving nursing home eligible participants. Therefore, we do not believe it is inappropriate to adopt long-term care standards in order to ensure equitable access to care among the vulnerable populations served.

We are not persuaded that requiring the IDT to record its diagnoses into the care plan as well as the medical record is duplicative. PACE was created to care for the individual as a whole, with the IDT and care planning being important components of the program's success. If the care plan does not include all current diagnoses from the different IDT disciplines, then the participant may not receive all the care for which they have been approved. As we stated in the proposed rule, we have seen as part of our oversight and monitoring activities that PACE organizations rely heavily on

discipline specific progress notes causing participant care plans to be sparse and not fully detailing the care received by the participant (87 FR 79655). If the IDT is not fully aware of all of a participant's comorbidities as well as any developments in the participant's medical, physical, emotional, and social status, the participant's planned treatment and services may not be adequate to meet the participant's needs. We are finalizing the required content of the care plan as proposed.

Comment: Multiple commenters agreed with CMS's decision not to include acute diseases or medications in the care plan requirements. A commenter supported CMS's inclusion of vision in the content requirements of the care plan and requested that CMS require PACE organizations to report the number of participants referred to a doctor of optometry for a comprehensive eye exam.

Response: We thank the commenters for their support of the proposed required content of the plan of care. We agree with commenters that the inclusion of acute diseases is not always appropriate in the plan of care and are finalizing the proposed required content without inclusion of acute diseases or medications; however, as we stated in the proposed rule, nothing prevents a PACE organization from including acute diseases or medications in the care plan if they so choose (87 FR 79659). Additionally, while we appreciate the support for including vision as required care plan content, the collection of data including optometry appointments is outside the scope of this rule.

Comment: A few commenters requested CMS refer to the National Consensus Project for Quality Palliative Care to include interventions such as palliative care, non-pain symptoms, caregiver burden, participant's cognitive status and decision-making ability, financial vulnerability, and spiritual concerns.

Response: While we agree with the commenters that interventions for other areas in a participant's life are an important consideration for treating a participant's medical, physical, emotional, and social needs, we are not persuaded to require additional content regarding non-pain symptoms, caregiver burden, participant's cognitive status and decision-making, financial vulnerability, or spiritual concerns. While we agree that these specific areas may be relevant to some participants, we believe it is such a personal matter that we are not adding them to the minimum criteria. However, we encourage PACE organizations to

consider whether other interventions would be appropriate when developing the care plan based on the participant's needs and other regulatory requirements, including requirements related to participant rights. We may consider proposing additional minimum content for the plan of care in the future. We would note that nothing in our proposal would prevent PACE organizations from including additional content in the care plan if they so desired. We also extensively discussed the proposed palliative care requirements in section IX.G, Specific Rights to Which a Participant is Entitled, where we proposed to require PACE organizations to define comfort care, palliative care, and end-of-life care, and obtain consent from participants and/or their designated representatives prior to implementing comfort, palliative or end-of-life care. We believe our proposal in that section to require PACE organizations to explain the different treatment options, provide written information of those treatment options, and obtain written consent prior to initiating palliative, comfort or end-of-life care services is the appropriate avenue for addressing palliative care interventions. To the extent that a participant's services change as a result of their designation of palliative care, comfort care or end-of-life care, the IDT should consider how those changes impact the care plan and whether modifications to the care plan are necessary. Therefore, we are finalizing the required content of the plan of care as proposed.

Comment: Multiple commenters requested CMS to modify the proposed participant and/or caregiver participation requirement to allow PACE organizations to document attempts to engage the participant and/or their caregiver. These commenters stated that often participants and/or caregivers are averse to participating in the care planning process. Alternatively, a few commenters suggested CMS grant the IDT a grace period of 15 days to accommodate the participant's and/or caregiver's availability and willingness to review the care plan prior to finalization or to allow PACE organizations to finalize care plans prior to obtaining participant and/or caregiver approval. With respect to the latter alternative, a commenter stated that if the caregiver and/or participant do not approve of the care plan after it has been finalized by the PACE organization, the care plan can be reviewed and revised at that point. Another commenter requested CMS modify the proposed requirement to clarify how PACE

organizations can prove compliance when participants and/or their caregivers do not participate in the care planning process.

Response: We thank commenters for sharing their concerns regarding the proposed requirement to include participants and/or caregivers in the plan of care development and implementation process. We recognize that some participants and/or caregivers may be averse to participating in the care planning process. However, we would point out that there are different methods the IDT may use to involve the participant. Some participants may want to participate in the IDT meeting where the care plan is discussed and developed. Other participants may want to participate less in the care planning process. In those cases, we would expect, at a minimum, documentation to demonstrate that the care plan was fully reviewed with the participant, and that any concerns were addressed, prior to the care plan being finalized. It is important that participants and/or caregivers are active in discussions regarding the participant's needs. A collaborative approach to care planning allows participants and/or caregivers to be actively engaged in the care participants receive. As we stated in the proposed rule, often we see through our oversight and monitoring process that participants and/or caregivers are only informed of the new care plan after it has been completed by the IDT (87 FR 79660). We also believe this requirement addresses commenters' concerns, discussed in an earlier comment summary, regarding ensuring the participant's views and wishes are taken into consideration during the development of the plan of care. The best way to ensure that the care plan satisfies the participant's goals for care is to include the participant in the care plan discussion. Therefore, we are finalizing the participant and/or caregiver participation requirements as proposed.

We are also not persuaded by the argument to extend the timeframe beyond 180 days to allow a grace period for finalizing the care plan to accommodate participants' and/or their caregivers' availability and willingness to review the care plan. However, nothing prevents a PACE organization from factoring in their own grace period when calculating the 180-day timeframe to ensure the PACE organization has enough time to meet with the participant before the deadline. For example, if the participant is historically difficult to reach, the IDT may decide to start the care planning discussions a few weeks prior to the

180-day deadline in order to allow ample time to finalize the plan of care.

Our intent in proposing the participant and/or caregiver participation requirement was to reduce the instances of participants and/or caregivers being presented with a finalized care plan after the IDT has completed its assessments and recommendations. As we stated in the proposed rule, we “want to ensure the participant and/or caregiver has an opportunity to voice concerns and ensure that any concerns are addressed in the proposed plan of care” (87 FR 79660). While we understand that participants and/or caregivers may not wish to participate in the care planning process, they should at least be given the opportunity prior to the care plan being finalized. We would expect a PACE organization to document attempts to engage the participant and/or caregiver in the care planning process and would consider those attempts in our review of a PACE organization’s compliance with this requirement.

After considering the comments, we are finalizing the proposed changes to § 460.106 in part, with a modification to the language at § 460.106(b)(2) to clarify that the required timeline for the care plan reevaluation is 180 days from the date when the previous care plan was finalized.

G. Specific Rights to Which a Participant Is Entitled (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant’s right to considerate, respectful care and the right not to be discriminated against (§ 460.112(a)); the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions (§ 460.112(b)); the right to access emergency services without prior authorization (§ 460.112(d)); and the right to participate fully in decisions related to his or her treatment (§ 460.112(e)).

In the proposed rule, CMS proposed to amend § 460.112 to incorporate the following participant rights: the right to appropriate and timely treatment for health conditions including the right to receive all care and services needed to improve or maintain the participant’s health condition and to attain the highest practicable physical, emotional and social well-being; the right to have

the PACE organization explain all treatment options; the right to be fully informed, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services; the right to fully understand the PACE organization’s palliative care, comfort care, and end-of-life care services; and the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121.

Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act establish that PACE organizations shall provide participants access to necessary covered items and services 24 hours per day, every day of the year. We codified these required services at § 460.92, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered services, all Medicaid covered services as specified in the State’s approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant’s overall health status. At § 460.98(a), we established the requirement for PACE organizations to provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. However, as we discussed in the proposed rule, we have identified some PACE organizations that do not provide care meant to improve or maintain the participant’s condition, and instead provide a palliative-like benefit, where the services provided to participants are geared more toward ensuring the participant’s comfort even when that is not in line with the participant’s wishes or needs (87 FR 79661). We also stated in the proposed rule that we have seen organizations use terms such as palliative care and comfort care without clearly defining those terms for the participants and/or their designated representatives, leaving participants and families confused as to what level of care they are receiving (*Id.*). As we stated in the January 2021 final rule (86 FR 6041), enrollment in the PACE program continues until the participant’s death, regardless of changes in health status, unless the participant voluntarily disenrolls or is involuntarily disenrolled. We argued in the proposed rule that it is reasonable that a PACE participant may transition from receiving treatment meant to cure or maintain health conditions at the time of enrollment, to receiving end-of-life care by the time they approach their death (*Id.*). We further stated that it is essential that PACE participants understand their right to receive all

treatments in the PACE benefit package that are necessary and appropriate, and that they clearly understand their rights as their health transitions throughout their time in the PACE program (*Id.*).

For the foregoing reasons, we proposed certain modifications to § 460.112. First, we proposed to redesignate current paragraphs (a) through (c) as paragraphs (b) through (d) to allow for the addition of proposed new paragraph (a). Proposed new paragraph (a)(1) would state that participants have a right to appropriate and timely treatment for their health conditions, which includes the right to receive all care and services needed to improve or maintain the participant’s health condition and attain the highest practicable physical, emotional, and social well-being. As we discussed in the proposed rule, we considered the language in § 460.92 related to services meant to improve or maintain the participant’s health condition as well as nursing home regulations at § 483.21(b)(1)(i), which require care plans to describe “the services that are to be furnished to attain or maintain the resident’s highest practicable physical, mental, and psychosocial well-being” (87 FR 79661).

In addition, we proposed to add to § 460.112 a new paragraph (a)(2), which would state that participants have the right to appropriate and timely treatment for their health conditions, including the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team. As we discussed in the proposed rule, although the right to access emergency care services currently appears at § 460.112(d), we believe that it relates to the right to treatment, and therefore, we proposed to move the text of current § 460.112(d) to new § 460.112(a)(2) (87 FR 79662).

In the 1999 PACE interim final rule, we codified at § 460.112(a) (which we proposed to redesignate as § 460.112(b)) that all participants have the right to considerate respectful care, and each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment (64 FR 66253). We also codified at § 460.112(e) the right of participants to participate fully in all treatment decisions. As we discussed in the proposed rule, § 460.112(e)(1) has two specific parts; the right to have all treatment options explained in a culturally competent manner, and the right to make health care decisions (87 FR 79662). We stated in the proposed

rule that we believe the first right, the right to have all treatment options explained in a culturally competent manner, relates more to the rights under redesignated § 460.112(b) (“Respect and nondiscrimination”) (*Id.*). Therefore, we proposed to add a new paragraph at § 460.112(b)(8) which states that participants have the right to have all information regarding PACE services and treatment options explained in a culturally competent manner. As we stated in the proposed rule, culturally competent care respects diversity in the patient population and cultural factors that can affect health and health care, and can contribute to the elimination of racial and ethnic health disparities (*Id.*).

In the 1999 PACE interim final rule (64 FR 66254), we codified the participant’s rights to receive accurate and easily understood information at current § 460.112(b) (which we proposed to redesignate as § 460.112(c)). In the 2006 PACE final rule, we further stated that this information was necessary for participants to “comprehensively assess differences in their health care options” (71 FR 71295). We also codified at § 460.112(e) that “a participant who is unable to participate fully in treatment decisions has the right to designate a representative” (64 FR 66290). We argued in the proposed rule that a participant’s designated representative should receive the same accurate, easily understood information the participant receives in order to make informed decisions on behalf of the participant (87 FR 79662). We proposed to add language to the newly designated § 460.112(c) that would provide that a participant has the right to have all information in this section shared with their designated representative.

The proposed rule at 87 FR 79662 discussed how we have seen as part of our audit and oversight activities that PACE organizations used the terms palliative care, comfort care, and end-of-life care, without providing participants with clear information on how the PACE organization is defining those terms or offering clear explanations of whether participants who opt to receive those forms of treatment will also continue to receive curative treatments. Although we did not propose to define these terms, we believe it is important for PACE organizations to define the terms within their respective programs, and provide clear information to participants and their designated representatives on what the terms mean. Therefore, we proposed to add language to newly designated § 460.112(c)(5) that would provide that participants have the right to be fully informed, in

writing, of several factors before the PACE organization implements palliative care, comfort care, or end-of-life care. We proposed that the written notification to participants must explain four different aspects of the treatment options, which we outlined in proposed § 460.112(c)(5)(i) through (iv).

First, we proposed at § 460.112(c)(5)(i) that the written notification must include a description of the palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving to meet their individual needs. As we discussed in the proposed rule, a participant should have the right to fully understand the care they are agreeing to receive prior to that care being initiated (87 FR 79662).

As proposed, § 460.112(c)(5)(ii) would require PACE organizations to explain, in writing, to participants or their designated representative whether palliative care, comfort care, or end-of-life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving. As we discussed in the proposed rule, we have seen through audit that some PACE participants receive palliative care and/or comfort care in addition to curative treatment; however, we have also seen participants receive palliative care and/or comfort care instead of treatment meant to improve or maintain the participant’s health condition when the participant was unaware that in choosing palliative care, they were also choosing to forego curative treatments (*Id.*). We stated that providing palliative care only services may be appropriate in some instances, but we believe it is important that participants fully understand what they are agreeing to when they enter into palliative or comfort care status (*Id.*).

As proposed, § 460.112(c)(5)(iii) would require PACE organizations to identify all services that would be impacted if the participant and/or their designated representative elects to initiate palliative care, comfort care, or end-of-life care. As discussed in the proposed rule, PACE organizations would be required to provide a detailed explanation of how specific services would be impacted by the addition of or transition to palliative care, comfort care, or end-of-life care (87 FR 79663). We further explained that PACE organizations that provide palliative care services in conjunction with curative treatment may not have to provide a detailed analysis and could instead include language in their explanation that palliative or comfort care will not impact existing services (*Id.*).

As proposed, § 460.112(c)(5)(iv) would state that the participant has the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason either verbally or in writing. We also proposed to require PACE organizations to explain this right to participants both orally and in writing. A participant has the right to fully participate in treatment decisions, as established at current § 460.112(e). That includes the right to participate in the decision-making process of what care to receive, and a participant must not only understand what the proposed care or treatment decisions mean, but also that they can change their mind with regards to treatment decisions previously made. As we discussed in the proposed rule, we have seen situations where participants or their designated representatives want to stop palliative care or comfort care when they realize this means they will no longer receive other services, and they do not know they have the right to revisit prior treatment decisions (87 FR 79663). As we discussed in the proposed rule, participants should be clearly informed, in writing, that they have the ability to change their mind on these important treatment decisions (*Id.*).

In the 1999 PACE interim final rule (64 FR 66255), we established at § 460.112(e) the right for each participant to fully participate in all decisions related to his or her care. Paragraph (e)(1) specifies that this includes the right “[t]o have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.” In the proposed rule, we proposed to amend § 460.112(e)(1) by removing the language regarding the participant’s right to have all treatment options explained in a culturally competent manner. As we explained in the discussion around our proposed amendments to § 460.112(b), the right to have treatment options explained in a culturally competent manner is better suited for inclusion in that paragraph, which, as amended, sets forth participant rights related to respect and non-discrimination. We also proposed to restructure and modify § 460.112(e)(1) by separating the requirements into three subparts at § 460.112(e)(1)(i), (ii) and (iii). We proposed at § 460.112(e)(1)(i) to establish that a participant’s right to make health care decisions includes the right to have all treatment options fully explained to them. As we discussed in

the proposed rule, a participant cannot make an informed health care decision without fully understanding the options available (87 FR 79663).

As proposed, § 460.112(e)(1)(ii) would provide that participants have the right to refuse any and all care and services. As we explained in the 2006 PACE final rule (71 FR 71298), the right to refuse treatment is a type of health care decision, and participants have the right to make those decisions. We proposed at § 460.112(e)(1)(iii) to specify that participants have the right to be informed of the consequences their decisions may have on their health and/or psychosocial status. The language at current § 460.112(e)(1) refers to the participant's right to "be informed of the consequences of the decisions," but we proposed to add additional specificity around that right and the obligation it creates for PACE organizations by modifying the regulatory language to refer to the participant's right to "be informed of the consequences their decisions may have on their health and/or psychosocial status." As we discussed in the proposed rule, we believe this proposed revision would emphasize that the participant should be made aware of how their decision to refuse care may impact their health and/or psychosocial status (87 FR 79663).

We proposed to further amend § 460.112(e) by redesignating current paragraphs (e)(2) through (e)(6) as (e)(3) through (e)(7), and by adding a new paragraph (e)(2), which would state that participants have a right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Proposed paragraph (e)(2) would further require that PACE organizations take several steps, outlined at proposed § 460.112(e)(2)(i) through (iii), in order to ensure that participants understand this right.

At § 460.112(e)(2)(i), we proposed to establish that the PACE organization must fully explain the applicable treatment options to the participant prior to initiating palliative care, comfort care, or end-of-life care services. We proposed at § 460.112(e)(2)(ii) to require that the PACE organization provide the participant with written information about their treatment options in accordance with § 460.112(c)(5). As we discussed in the proposed rule for § 460.112(c)(5), we believe providing written information on these terms is important for the participant, and that the information must include details regarding the treatment and how the participant's current services may be impacted (87 FR 79662). We proposed to add paragraphs (e)(2)(i) and (e)(2)(ii) as separate

provisions because the organization should be responsible both for providing the written notification outlined in § 460.112(c)(5), and explaining the treatment options in a way that is understandable to the participant so that the participant has a full understanding of their options. Finally, we proposed at § 460.112(e)(2)(iii) that the PACE organization obtain written consent from the participant or their designated representative to change a treatment plan to include palliative care, comfort care, or end-of-life care. As we discussed in the proposed rule, we have seen that some organizations stop treatments to improve or maintain a participant's condition when a participant enters palliative care or comfort care, and therefore, we believe it is especially important that participants or their designated representatives are in agreement with these treatment options, and consent to receiving this care (87 FR 79664). We proposed to redesignate current paragraphs (e)(2) through (e)(6) of § 460.112 as (e)(3) through (e)(7) to allow for the addition of a new paragraph (e)(2) as discussed in this section. As we emphasized in the proposed rule, this proposed requirement would not take the place of any advanced directives a participant may have and would not eliminate the requirement in current § 460.112(e)(2) (which would be redesignated as (e)(3) under our proposal) that requires a PACE organization to explain advance directives and to establish them, if the participant so desires (*Id.*). That directive is distinct from the notification proposed at new § 460.112(e)(2), which would explain the services under the PACE benefit that may be provided or not provided to the participant as a part of their care decisions.

In the 1999 PACE interim final rule (64 FR 66256, 66290), we codified at § 460.112(g) the participant's right to "a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review." In the January 2021 final rule (86 FR 5864), we added § 460.121 to clearly define service determination requests and specify the requirements for how those requests would be processed. As we explained in that rule, the service determination request process serves as an important participant protection, as it allows a participant to advocate for services (86 FR 6008). We also explained that the service determination request process is the first step of the

appeals process (*Id.*). At § 460.112(g)(1), the participant is provided the right to be encouraged and assisted to voice complaints to PACE staff and outside representatives; and § 460.112(g)(2) provides participants the right to appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122. As we discussed in the proposed rule, we believe that § 460.112(g) should also reference the right to request a service determination request, which is the first step in the appeals process. Therefore, we proposed to add a new § 460.112(g)(2) to provide that a participant has the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121. We proposed to redesignate current paragraph (g)(2) as (g)(3) to allow for the addition of a new paragraph (g)(2) as discussed in this section. We believe the burden associated with this provision is related to developing written templates regarding the PACE organization's palliative, comfort, and end-of-life care services and tailoring those templates to the participants. We discuss this burden in the collection of information section of this final rule.

We solicited comments on these proposals and a summary of the comments received and our responses follow.

Comment: A majority of commenters requested that CMS proactively define the terms palliative care and end-of-life care in the final rule, rather than leaving the definition up to each PACE organization. Several commenters referenced CMS's current definition of palliative care in the hospice regulations at § 418.3. A commenter requested that palliative care be defined as care that focuses on improving the quality of life and easing suffering. Most commenters requested CMS to stop using the term "comfort care" as they stated that it is not a medically defined term and is more a term of art. Additionally, a majority of commenters requested that CMS stop using the terms interchangeably to avoid furthering the misconceptions around the different terms. A few commenters requested that CMS clarify that end-of-life care is a comprehensive set of services to provide for the physical, psychosocial, spiritual, and emotional needs of terminally ill patients and their family members.

Response: We thank commenters for their feedback. Commenters are correct that the hospice regulations define palliative care at § 418.3 as "patient and family-centered care that optimizes the quality of life by anticipating, preventing, and treating suffering." We

agree that the palliative care definition in the hospice regulations is a national standard and we encourage PACE organizations to consider this definition for use in their own program. We do not intend to define these terms for purposes of the PACE regulations as a part of this rule; however, we will consider defining these terms in future rulemaking. Our intent with this proposal is to ensure that PACE participants have notice of how the terms are defined by the PACE organization and how the definition impacts the care they receive. As we stated in the proposed rule, we have seen through our oversight and monitoring process that PACE organizations are using these terms interchangeably without providing participants with clear definitions or an explanation of how the different terms impact the treatment options available to participants (87 FR 79661). While we do not want to add to the misconceptions around the terms, we routinely see these three terms in PACE organization medical records, without clear definitions applied to them. This provision is intended to provide clarity for participants when PACE organizations use any of these terms in their explanation of benefits. Therefore, we will be finalizing the requirement that PACE organizations provide participants with clear, written definitions to increase transparency and understanding of what services participants can expect to receive in lieu of or in addition to the services they were receiving prior to opting for palliative, comfort, or end-of-life care without modification.

Comment: Several commenters objected to the proposed requirement that the PACE organization obtain written consent from the participant and/or their caregiver prior to implementing palliative care on the grounds that it would be administratively burdensome and unnecessary, as it was their understanding that palliative care is intended to be provided concurrently with curative care. A commenter requested that the proposed regulation language be altered to require consent only when the PACE organization implements a plan of care no longer considered curative or life-prolonging, and instead is focused on only palliative care or end-of-life care.

Response: We thank the commenters for sharing their concerns regarding the proposed requirement for written consent prior to implementation of palliative care. While we understand that palliative care may be provided in addition to all other services at some

organizations, that is not always the case. As we stated in the proposed rule, we have seen as part of our oversight and monitoring efforts that some PACE organizations are not continuing to provide curative treatment once a participant has elected to receive palliative care (87 FR 79661). In these situations, some participants are not aware that by consenting to receive palliative care, they are consenting to stop curative treatment in favor of palliative only care. In some cases, the participant may believe they are consenting to receive palliative care in conjunction with continuing to receive curative treatment. We disagree that requiring consent from participants prior to implementing palliative care would be overly burdensome. If a PACE organization offers palliative care in addition to or in conjunction with curative treatment, then the notice required in this provision is minimal. The PACE organization would need to provide a description of the term or benefit and would need to indicate that this is done in addition to all other services received by the participant. This notification could be provided to the participant early on in their enrollment through either enrollment materials or the care plan. However, if palliative or end-of-life care is offered in lieu of curative treatment, participants need to be informed that choosing palliative or end-of-life care will result in a cessation of curative treatment and participants need to consent to the change in treatment. It is only when a participant's services will change as a result of moving to palliative care, comfort care, or end-of-life care that the notification must become more tailored and include a detailed description of how the services being received by a participant will be impacted. We are finalizing the consent requirement as proposed because we believe it will protect participants from agreeing to forego curative treatment when that is not their intent.

Comment: A few commenters expressed support for our proposal to require PACE organizations to fully inform participants about applicable treatment options, including any policies that would limit participants' ability to receive curative treatment. These commenters also supported our proposed requirement that PACE organizations obtain consent from participants before making changes to the treatment plan, as well as our proposal that participants have the right to revoke consent at any time. A commenter expressed concern that in some cases participants have decided to

reinstate disease-directed care, but the care was not effectuated until the first of the month following the participant's request. The commenter requested that we clarify that if participants revoke or withdraw their consent to palliative care-only services, that decision to reinstate curative care should be effectuated immediately.

Response: We thank the commenters for their support for our proposal. We share the commenter's concerns about the need to effectuate a return to curative treatment immediately if the participant revokes their agreement for palliative only care. When a participant decides to return to curative treatment and/or forego palliative only care, the PACE organization must act on that information immediately. We would consider this a change in participant status, and per the changes to the plan of care that we are finalizing in section IX.F of this rule, the PACE organization would be required to reassess the participant and re-evaluate the participant's plan of care.

Comment: Several commenters expressed a desire that PACE organizations have the ability to continue to provide and/or coordinate hospice care through a Medicare Advantage or other hospice program to allow participants to remain enrolled in PACE. A couple of commenters requested that the proposed regulation language be altered to require PACE organizations to inform participants of their rights regarding hospice care both within and outside of the PACE program. Specifically, these commenters requested that PACE staff be required to explain to participants about the Medicare hospice benefit and the participants' right to enroll, including an explanation that participants must disenroll from PACE to enroll in the Medicare hospice benefit. A commenter also requested that CMS require PACE staff to disclose any contractual relationship the PACE organization has with hospices in the community. Finally, a few commenters requested that CMS should strengthen requirements regarding the IDT's capabilities to ensure they have sufficient expertise in pain and symptom management for participants with serious illness or who require end-of-life care.

Response: We thank commenters for their concerns. Although we have proposed to require PACE organizations to inform participants of all treatment options, including palliative and end-of-life care, and how those options may impact curative treatment, nothing we have proposed would remove the ability of PACE organizations to continue

providing hospice-like services or contracting with community hospice programs to provide hospice services to participants. The enrollment agreement that PACE participants enter into with the PACE organization is required to provide information regarding disenrollment, including the requirement to disenroll from PACE in order to receive and enroll in the Medicare hospice benefit per § 460.154(i). The PACE organization is also already required to disclose contractual relationships to participants upon enrollment and throughout the time the participant is enrolled in the PACE program. Therefore, we are not persuaded that an additional requirement is needed in regulation regarding hospice care.

As for ensuring that the IDT includes the expertise to provide meaningful end-of-life care to participants, in the April 12, 2023 final rule, we modified the proposed regulation for contracted services to include palliative medicine. Effective January 1, 2024, PACE organizations are required to staff and/or contract with palliative medicine specialists. At this time, we do not believe it is necessary to include a palliative care specialist on the IDT as a routine role. The disciplines that participate in the IDT are the minimum required, but the IDT may always include additional personnel or specialists as it sees fit. To the extent an IDT wants to bring in a palliative care specialist to assist with developing an end-of-life plan of care, it is allowed and encouraged to do so.

Comment: A commenter requested that the language in the regulation be altered to require written notification only when a participant is moving to palliative only care or end-of-life care as it will not be beneficial to the participant and may be overly burdensome to PACE organizations.

Response: As we have stated previously, through our oversight and monitoring efforts, we have seen instances of participants transitioned to palliative-only care or end-of-life care without the PACE organization explaining to the participant that this transition means the participant will no longer receive curative treatment. We believe that requiring written notification to the participant regarding the implementation of palliative, comfort, or end-of-life care will reduce confusion among participants of what care they expect to receive. As we stated in response to a previous comment, if a PACE organization provides palliative care in addition to curative treatment, then inclusion of that additional benefit in the enrollment materials provided to

the participant at the time of enrollment or the inclusion of information regarding the palliative care benefit in the participant's care plan would likely be sufficient to meet this requirement.

Comment: A commenter supported the proposed requirement that participants have a right to request services via a service determination request in addition to their right to file a grievance or appeal.

Response: We thank the commenter for their support and are finalizing this provision as proposed.

After considering the comments, and for the reasons set forth in the proposed rule and in the previous responses, we are finalizing the changes to § 460.112 as proposed.

H. Grievance Process (§ 460.120)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We have codified requirements around the processing of grievances at § 460.120. The grievance process serves as an important participant protection as it allows for participants and their family members to express complaints related to the quality of care a participant receives, or the delivery of services. We have discovered through audits that the current grievance process, which allows PACE organizations latitude to define their own grievance resolution timeframes and develop their own procedures for processing grievances, has created confusion and inconsistency in how grievances are handled from organization to organization. In the December 2022 proposed rule (87 FR 79452), we proposed certain modifications to the grievance requirements at § 460.120 to strengthen participant protections and provide more detailed processing requirements for grievances from PACE participants and their family members. We also proposed certain adjustments that would align the requirements with the service determination process in § 460.121 for consistency.

First, we proposed to amend § 460.120(a) by removing the current paragraph header, which reads "Process to resolve grievances," and added in its place a new paragraph header "Written procedures." Specifically, we proposed to modify the requirement to state that each PACE organization must have formal written procedures to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the

requirements in this part. In addition, we proposed to further amend § 460.120(a) by removing the list of individuals who can file a grievance, as we proposed to create a new paragraph that outlines who may submit a grievance at § 460.120(d). We proposed to add to § 460.120 a new paragraph (b), which would define a grievance in PACE as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested; and further that a grievance may be between a participant and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant. We have heard from PACE organizations over the years that they would prefer that the term grievance be better defined in the regulations, and we have received requests from PACE organizations for the grievance definition to be narrowed to exclude complaints that may not rise to the level of a grievance. Based on this feedback, we considered how we might refine the definition of grievance for the purposes of PACE. Specifically, in the December 2022 proposed rule, we discussed how the grievance definitions in other managed care programs and care settings, specifically in MA and in nursing homes, could inform and enhance the grievance definition for PACE.

When considering these other approaches to defining what constitutes a grievance, we concluded that the definition used in PACE is already tailored more narrowly than the MA or nursing home requirements. That being the case, we do not believe it would be appropriate to narrow the definition even more, and potentially limit a PACE participant's ability to complain about their care and have their complaints resolved through a formal process. We noted that the MA regulations specify that a grievance is any complaint that meets the definition at § 422.561 regardless of whether remedial action is requested. We have seen on audit where PACE organizations will not recognize or process complaints that fit within the definition of a grievance, because remedial action was not requested. However, we want to stress that a grievance must be identified and processed if it satisfies the definition, regardless of whether remedial action is requested. This is an important participant safeguard because grievances are required under the current § 460.120(f) to be maintained, aggregated, and analyzed as part of the PACE organization's quality

improvement program. Regardless of whether remedial action is requested, it is important for organizations to analyze all complaints received in order to ensure they are making necessary improvements in their quality program. For these reasons, we proposed to include in our definition of a grievance that a request for remedial action is not required.

We also proposed that the definition of a grievance would provide that a grievance may be between a participant and the PACE organization, but it may also be between any other entity or individual through which the PACE organization provides services to the participant. This proposed change to the PACE grievance definition is based on the MA grievance definition, which provides at the current § 422.564(a) that each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers. PACE provides a wide array of services through different home care agencies, medical specialists, and facilities such as nursing homes. It is important that a participant or their family have the ability to voice complaints related to any care they receive, even if that care is provided through a contracted entity or individual.

We solicited comment on whether we should modify the PACE grievance definition to more closely resemble the definition of grievances in MA at § 422.561. Specifically, we solicited comment on whether we should consider adopting the following definition of grievance for purposes of the PACE regulations: A grievance means any complaint or dispute expressing dissatisfaction with any aspect of the PACE organization's or its contractors' operations, activities, or behavior, regardless of whether remedial action is requested.

We proposed to redesignate current § 460.120(b) as § 460.120(c), change the title, and amend the regulation text. Specifically, we proposed to change the title from "Notification to participants." to "Grievance process notification to participants.", to differentiate from notifications related to grievance resolutions, and to add the requirement that the grievance process notification be written in understandable language. We proposed to add new paragraphs (c)(1), (c)(2), and (c)(3) to § 460.120, which would set forth requirements for the grievance process notification. We solicited comment on whether the other

individuals should receive the grievance process notification, in addition to the participant, upon the participant's enrollment and annually thereafter. Specifically, we solicited comment on whether the other individuals specified in § 460.120(d) should receive the grievance process notification, or at a minimum, whether the participant's designated representative should receive the notification in addition to the participant.

First, we proposed at § 460.120(c)(1) that the grievance process notification must include information on the right of the participant or other individual specified in § 460.120(d) to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal. When we have conducted interviews of PACE participants and their family members as part of our audit process, we have heard that some participants are afraid to voice grievances for fear that the PACE organization will take some punitive action against them. For example, some participants have expressed fears that the PACE organization will eliminate their center attendance, or discontinue other necessary services, if the participant complains about the care they receive. We believe it is important for the grievance process notification to participants to emphasize that a participant or other individual specified in § 460.120(d) has the right to voice grievances without the fear of reprisal or discrimination.

We proposed at § 460.120(c)(2) that the grievance process notification must inform participants that a Medicare participant as defined in § 460.6 or other individual specified in § 460.120(d) acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services, consistent with section 1154(a)(14) of the Act. Since most PACE participants are Medicare beneficiaries, they are also eligible to submit quality of care grievances to a QIO. This right has not been formally provided to PACE participants before, and we are proposing to require it now in order to ensure that Medicare beneficiaries enrolled in PACE understand this additional right. We proposed at § 460.120(c)(3) to require that the grievance process notification include the grievance definition at § 460.120(b) and provide information on all grievance processing requirements in paragraphs (d) through (k) of § 460.120. In order for the grievance process to serve as a fair and efficient avenue for

participants to express their dissatisfaction with service delivery or the quality of care furnished, and to resolve their differences with the PACE organization or any other entity or individual through which the PACE organization provides services to the participant, participants must understand how to submit a grievance to the organization, and how that grievance will be processed once submitted.

We proposed to move the language regarding who can submit a grievance from current § 460.120(a) to a new paragraph at § 460.120(d), as we believe the details regarding who is eligible to submit a grievance will be more easily understood if they are placed in a new paragraph and separated from the remainder of § 460.120(a), which, under the amendments we proposed, would require PACE organizations to have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances. We proposed to amend the list of individuals who can submit a grievance to include the participant's caregiver. We believe the addition of the participant's caregiver would be in alignment with the service determination process requirements in § 460.121, which allow a participant's caregiver to request services (§ 460.121(c)(3)), and with the plan of care requirements at § 460.106, which allow the caregiver to be involved in the development and reevaluation of the care plan (§ 460.106(e)).

As we stated in the January 2021 final rule (86 FR 6018), given the fact that caregivers may provide some care to the participants, it is important that caregivers are able to advocate for services on the participant's behalf. Similarly, if caregivers are providing some care to the participant, they should be able to make complaints related to any aspect of the care that the participant receives from the PACE organization.

As we explained in the January 2021 final (86 FR 6018), we have not historically considered "caregivers" to include employees or contractors of the PACE organization. We know some organizations may use the term "caregiver" to describe an aide at a nursing home, but CMS would not generally consider these individuals to fall within this category. We also explained in that rule (86 FR 6018) that employees and contractors of the PACE organizations enter into a contractual relationship with the PACE organization and generally have a predominately financial incentive to provide care; and we have not considered these

individuals to be “caregivers” under the regulations. While these paid individuals may have pertinent information related to the participant’s care, their feedback is captured under the requirements for the IDT to remain alert to pertinent information under current § 460.102(d)(2)(ii). We do not believe that these paid individuals would generally be entitled to submit a grievance under § 460.120. In the December 2022 proposed rule (87 FR 79667), we solicited comment on our proposal to amend the list of individuals who can submit a grievance to include a participant’s caregiver.

We proposed to add these rules around the submission of grievances in new paragraph § 460.120(e). We proposed § 460.120(e)(1) would provide that any individual permitted to file a grievance with a PACE organization under § 460.120(d) may do so either orally or in writing. We proposed § 460.120(e)(2) would establish that the PACE organization may not require a written grievance to be submitted on a specific form. While we understand that some organizations may use forms to help them process and investigate the grievance, we do not believe that a PACE participant should be restricted in how they can submit the complaint. We have seen participants detail their complaints to PACE organizations in letters and email correspondence. Receipt of these written complaints should be considered grievances and accepted in their original form. If a PACE organization decides to create a grievance form on its own and summarize the original grievance, that would continue to be permitted under our proposal, as long as the PACE organization maintains the written communication in its original form as required by § 460.200(d)(2). Proposed § 460.120(e)(3) would provide that a grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant’s residence, the PACE center, or while transporting participants. This language is similar to the method for filing a service determination request at § 460.121(d)(2). As we indicated in the January 2021 final rule (86 FR 6019), these are the settings where participants have the most frequent contact with employees or contractors of the PACE organization, and therefore are logical settings for service determination requests to occur. We believe the same logic can be applied to grievances, and as a result, we limited our proposal to employees and contractors working in these settings.

We proposed at new § 460.120(f) to establish the requirement that the PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known. Investigating why the situation occurred is an important part of ensuring that appropriate action will be taken in response to a grievance. However, we also recognize there may be some situations where the cause for the complaint or a specific issue is already known and therefore an investigation is not needed. For example, if the PACE bus has a flat tire, and as a result is late to pick up a participant for their center attendance, the participant may complain to the PACE organization about the late pick-up. While this would constitute a grievance and would need to be identified and processed, an investigation would not be necessary because the PACE organization was already aware of the cause of the complaint (that is, the flat tire). If there are multiple issues within a grievance that require investigation, proposed § 460.120(f) would require the PACE organization to conduct a thorough investigation into each distinct issue when the cause of an issue is not known. We have seen on audit that some complaints may contain different issues within the one grievance. For example, a participant may call to complain that their home care aide is routinely late and does not clean the kitchen as is care planned for that participant. These are two different issues, and both may need to be investigated in order to appropriately resolve the grievance. The PACE organization may determine through its investigation that while the aide was late due to poor time management skills, the kitchen was not being cleaned because the home care company did not have the most recent care plan for the participant. The results of the investigation would directly impact how the PACE organization would resolve these concerns.

We proposed at § 460.120(g)(1) that the PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance. In our proposal for the PACE grievance regulation, we proposed to adopt a modified version of the requirement in the MA regulations, which would specify that the 30-day timeframe is the maximum amount of time the PACE organization has to resolve the

grievance, as opposed to the maximum amount of time to notify the participant. Proposed § 460.120(g) would maintain the language regarding ensuring that this timeframe is a maximum length of time, and that organizations may need to resolve grievances more quickly if the participant’s case requires. We proposed at § 460.120(g)(2) that the PACE organization must notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1).

We proposed § 460.120(h) would establish requirements for the processing of expedited grievances. Specifically, we proposed to require that the PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant. We proposed at new § 460.120(i) to create grievance resolution notification requirements for how the PACE organization must inform the individual who submitted the grievance of the resolution of that grievance. We proposed at § 460.120(i)(1) that the PACE organization may inform the individual either orally or in writing, based on the individual’s preference for notification, except for grievances identified in § 460.120(i)(3). We contemplated following the MA rule around notification in § 422.564(e)(3), which allows for oral grievances to be responded to orally or in writing but requires written grievances to be responded to in writing. However, we understand that because PACE organizations are not only an insurer, but also a provider, they often have calls or other remote communications with participants, and likely talk with them more often than an MA organization would talk with one of their enrollees. We also understand that some PACE participants would prefer oral notification, even if their grievance was submitted in writing. Likewise, some PACE participants may call with a grievance, but may want a formal written notice explaining the resolution. Therefore, we believe that PACE organizations should tailor the notification of the grievance resolution to what a PACE participant prefers.

We proposed to establish at § 460.120(i)(2) that oral or written notification of grievance resolutions

must include a minimum of three requirements. First, we proposed at § 460.120(i)(2)(i) that the notification must include a summary statement of the participant's grievance including all distinct issues. Second, we proposed at § 460.120(i)(2)(ii) that for each distinct issue that requires an investigation, the notification must include the steps taken to investigate the issue and a summary of the pertinent findings or conclusions regarding the concerns for each issue. Third, we proposed at § 460.120(i)(2)(iii) that for a grievance that requires corrective action, the grievance resolution notification must include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. In the example we used earlier, we noted that during the investigation into the home care aide not cleaning the kitchen, the PACE organization discovered that the home care agency did not have the most current care plan for that participant. The correction that would likely result from that investigation would be to provide the updated care plan to the home care agency and ensure they have received and understand it. This action should be communicated to the participant in order for them to understand how their grievance has been handled and resolved. Proposed § 460.120(i)(3) proposed requirements related to how PACE organizations must provide notification when the complaint relates to a Medicare quality of care issue. Specifically, we proposed that for Medicare participants, any grievance related to quality of care, regardless of how the grievance is filed, must be responded to in writing. This is consistent with the MA requirement in § 422.564(e)(3)(iii). As previously discussed, Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act.

We proposed to establish at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. The only exception to this requirement to provide a written resolution notice would be when the submitter specifically requests not to receive

notification as specified in proposed § 460.120(i)(4), which is discussed in more detail in this section of this final rule. We also proposed to specify that for any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint. This language is consistent with the language used in the MA program, and therefore we are proposing it be added to the PACE regulation as well. Because the QIO's statutory function related to review of quality of care concerns and responses to beneficiary complaints is only applicable to Medicare services and only available to Medicare beneficiaries, and because PACE organizations may have some participants who are not Medicare beneficiaries and may cover non-Medicare services, we expect PACE organizations to work with participants to help them understand whether their grievance relates to a Medicare quality of care issue.

We proposed to establish at new § 460.120(i)(4) that the PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive notification of the grievance resolution, and the PACE organization has documented this request in writing. In order to balance the need for an organization to track and process grievances, with respect for the preferences of participants who wish to not receive communications related to the resolution of a grievance after submitting the initial complaint, we proposed to specify in new § 460.120(i)(4) that PACE participants must have an option to request not to receive any further communication or notification of the grievance resolution following their initial complaint submission. In order for a PACE organization to withhold notification of the grievance resolution for participants who request to exercise this option, the PACE organization would be required to document the participant's request in writing.

We proposed to include in a new § 460.120(i)(4) language that provides the PACE organization would still be responsible for all other parts of this section. Section § 460.120(d) specifies the PACE organization must continue to furnish all required services to the participant during the grievance process. We proposed to redesignate current § 460.120(d) as 460.120(j) to account for our other proposals.

We proposed to add a new paragraph § 460.120(k) that would redesignate and modify the requirement that is currently included at § 460.120(c)(4). Specifically,

we proposed that the PACE organization must develop and implement procedures to ensure that they maintain the confidentiality of a grievance, including protecting the identity of any individuals involved in the grievance from other employees and contractors when appropriate. As we stated when discussing the proposed notification requirements at § 460.120(i)(4), we understand that some grievances may be sensitive, and some participants or other submitters may wish for their complaint to be kept confidential. For example, if a participant has a complaint related to their physical therapist, that participant may not want the physical therapist to be aware of the complaint. We expect that PACE organizations consider these situations and have a method for participants that may want certain information to be kept confidential. There may be instances where a person submitting the complaint may want their identity to be protected, or where the complaint involves a sensitive matter where the identity of all individuals may need to be protected, and we would expect the PACE organization to have a process for ensuring that there is a way to maintain the confidentiality of the identity of any individual involved in the grievance from other employees or contractors when it is appropriate. However, we reiterate that accepting and processing a confidential grievance would not negate the PACE organization's responsibilities to investigate and resolve the grievance. It also would not negate the responsibilities to document, aggregate and analyze the grievance, as required under current § 460.120(f). Additionally, as we discussed earlier, we have heard from multiple PACE participants that sometimes participants or their family members are afraid to complain to the PACE organization for fear of reprisal. While we require a PACE organization to ensure that confidentiality of a grievance is maintained, we also want to remind PACE organizations that participants have the right to submit grievances without fear of reprisal. We have heard through oversight and monitoring activities that participants are afraid that they will lose necessary services, or not be approved for services, if they complain regarding the care received by an organization. PACE organizations should ensure that all participants understand that they are free to complain without any fear of reprisal, regardless of what their grievance is about.

We proposed to add a new paragraph at § 460.120(l) that aligns with the record keeping requirements for service

determination requests, which are set forth at § 460.121(m). Specifically, proposed § 460.120(l) would require that a PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. We believe that proposed § 460.120(k), similar to the § 460.121(m) service determination request, would ensure that all relevant parts of the grievance process are documented, including details of the investigation, the findings, any corrective action that was taken, and the notification (oral and/or written) that was provided to the participant in the resolution.

Finally, current § 460.120(f) requires PACE organizations to maintain, aggregate, and analyze information on grievance proceedings. We proposed to redesignate this as paragraph (m) to account for our other proposals. We also proposed to remove the word “maintain” that appears in the current regulation text, since the requirement to maintain records has been added to the proposed paragraph (l). Redesignated § 460.120(m), as revised under our proposal, would state that the PACE organization must aggregate and analyze the information collected under the proposed paragraph (l) of this section for purposes of its internal quality improvement program. We noted that this requirement applies to all grievances; oral or written, including anonymous grievances.

We estimated a one-time burden for PACE organizations to update their grievance materials to meet these proposed requirements. We do not believe there will be a change in annual burden as a PACE organization is already required to provide notification to participants regarding their grievance resolution and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this proposal. We discuss and account for the one-time burden for PACE organizations to update their grievance materials to meet the proposed new requirements in the Collection of Information Requirements section. We solicited comment on this proposal regarding burden.

We summarize the comments received on the proposal at § 460.120 and provide our responses to those comments in this section of this rule.

Comment: Most commenters expressed their general support for CMS’s proposal to clarify the grievance process at § 460.120. A commenter preferred that CMS not formalize the grievance process in regulation, because they believed that establishing specific

grievance process requirements in regulation would add to PACE organizations’ administrative burden and would divert resources from participant care. Another commenter agreed with formalizing certain aspects of the grievance process but did not want to formalize the grievance process for all complaints, particularly for what the commenter referred to as “lower-level concerns.”

Response: We thank commenters for their support of formalizing the grievance process at § 460.120. Throughout the years, PACE organizations have expressed interest in a more clearly defined grievance definition, among other process clarifications in the regulation. We do not believe formalizing the grievance process in regulation will be overly burdensome for PACE organizations, as PACE organizations already must process grievances, including evaluating, resolving, responding to, and documenting grievances in a timely manner. Additionally, we included flexibilities in the proposed regulation at § 460.120 when certain conditions are met. For example, PACE organizations may provide oral or written resolution of the grievance, depending on the participant’s preference, as specified at the redesignated § 460.120(h)(1). Another flexibility at the redesignated § 460.120(h)(4) allows PACE organizations to withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. We disagree with the commenter’s suggestion to categorically exclude certain types of complaints from the formal grievance process at § 460.120. As established at § 460.112(g), each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, it is a participant’s right to be encouraged and assisted to voice complaints to PACE staff and outside representatives of their choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the proposed amendments to § 460.120 without modification.

Comment: Most commenters supported CMS’s proposed definition of grievance at § 460.120(b), and

specifically mentioned their agreement with the part of the proposed definition that describes complaints as grievances regardless of whether remedial action is requested. Many of these commenters, while agreeing with this aspect of the proposed grievance definition at § 460.120(b), generally rejected CMS’s consideration of the MA grievance regulations at §§ 422.561 and § 422.564 in the development of PACE grievance requirements. These commenters emphasized the uniqueness of PACE, as an insurer and provider, and recommended that PACE grievance requirements consider the program’s uniqueness, rather than repurposing MA grievance regulations for the PACE regulation.

A few commenters disagreed with including complaints for which no remedial action is requested as part of the proposed grievance definition at § 460.120(b). These commenters generally considered the proposed grievance definition at § 460.120(b) to be broader and more administratively burdensome than the current grievance definition at § 460.120, and either did not want to process these complaints as grievances or recommended a separate administrative process for such complaints. A commenter suggested that including complaints for which no remedial action is requested in the grievance definition would increase the number of complaints that would be considered grievances, which the commenter believed would increase the administrative burden of processing grievances without improving participant care and outcomes. The commenter recommended that CMS amend the proposed grievance definition to give PACE organizations the flexibility to not have to document complaints as grievances when the participant declines remediation. The commenter emphasized the uniqueness of the PACE care model and how it requires frequent communication and interaction between staff and participants, which they believed made documenting all complaints as grievances unreasonable and unnecessary. Another commenter indicated CMS’s proposed grievance definition emphasized process compliance over staff judgment to the detriment of quality care, participant outcomes, and organizational culture.

Response: We appreciate the commenters’ support for the grievance definition proposed at § 460.120(b), including where we specified that complaints can be grievances regardless of whether remedial action is requested. We acknowledge the commenters’ general concerns regarding developing

PACE requirements based on MA requirements and agree that there are significant differences between these programs in terms of design and function. We carefully considered the relevance of the MA grievance regulations at §§ 422.561 and § 422.564 as we developed the PACE grievance definition for the December 2022 proposed rule (87 FR 79665). Based on our review of MA grievance regulations, we proposed a PACE grievance definition that includes complaints as grievances regardless of whether remedial action is requested and provides that grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant (87 FR 79665). We have considered commenters' specific feedback on the proposed grievance definition at § 460.120(b) in the responses to comments that follow.

We disagree with the commenters that described the proposed definition of grievance at § 460.120(b) as overly broad, unnecessary, and burdensome with potentially negative consequences for participant care and PACE organizations' workplace culture. As explained in the December 2022 proposed rule, we believe the proposed grievance definition at § 460.120(b) clarifies how we expect PACE organizations to identify grievances. The proposed grievance definition was the result of requests from PACE organizations over the years for CMS to better define grievances in the PACE regulation. We believe the proposed grievance definition clarifies our expectations for grievances and would not necessitate major changes to PACE organizations' existing grievance processes if they are already compliant with the current requirements at § 460.120.

Additionally, we have determined that categorically excluding complaints that do not require remedial action would be counter to compliance with other requirements within the PACE statute and regulation. As established at § 460.112(g), each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, it is a participant right to be encouraged and assisted to voice complaints to PACE staff and outside representatives of their choice, free of any restraint, interference, coercion, discrimination, or reprisal by PACE staff. Therefore, amending the regulation to clarify that

the definition of grievance includes complaints regardless of whether remedial action was requested provides important guidance to PACE organizations on how to achieve program compliance with current program requirements. Also, PACE organizations are required to aggregate and analyze grievances as part of their quality improvement organization (see §§ 460.120(l) and 460.134(a)(5)). A participant may feel that remedial action is not necessary in a particular situation, but that does not mean the PACE organization should not consider, analyze, and aggregate that information as part of its quality improvement efforts as a whole. If multiple participants have the same complaint, and none of them request remedial action, it may still be indicative of a larger, systemic breakdown that needs to be considered by the PACE organization.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the grievance definition at § 460.120(b) as proposed, which includes complaints regardless of whether remedial action was requested.

Comment: Most commenters disagreed with our proposed inclusion of "caregiver" among the list of individuals who can submit a grievance at § 460.120(d). Mostly these commenters expressed concern that the term "caregiver" is not defined in the PACE regulation at 42 CFR 460, and recommended that we define, clarify, or provide guidance regarding the term "caregiver" so that PACE organizations are not required to include individuals in the grievance process who may not have formal legal authority to act on behalf of the participant. Several of these commenters expressed that allowing a caregiver without formal legal authority to submit grievances on behalf of the participant could influence the participant's care in a way that would not align with the participant's goals, could pose risks to HIPAA Privacy Rule compliance, or may cause confusion when coordinating care for participants with support networks made of many individuals with complex dynamics. Many commenters questioned why it would be necessary for caregivers to have the ability to submit grievances when the participant, participant's family, and participant's designated representatives can already submit grievances per the current requirement at § 460.120(a). One commenter suggested that adding caregivers to the list of individuals who may submit grievances on behalf of

participants creates more administrative burden for PACE organizations, because PACE organizations would have to provide and document an increased number of grievance resolution notifications.

Response: We believe that the guidance provided in the December 2022 proposed rule (87 FR 79666) and this response offers adequate clarification of CMS's expectations for PACE organizations regarding how caregivers may participate in the grievance process. As we originally discussed in the January 2021 final rule (86 FR 6018) and reiterated in the December 2022 proposed rule (87 FR 79666), caregivers are typically aware of the participant's situation and are involved in care planning activities, as required at the current § 460.106(e), which states that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. Because caregivers are involved in the care planning process and are presumably providing at least some care to the participant, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant and voice complaints about participant care, regardless of whether these service determination requests or complaints result in changes to the plan of care. Additionally, since caregivers are often the participant's family member and/or designated representative, we do not believe that allowing caregivers to submit grievances on behalf of participants will meaningfully increase burden for PACE organizations, as PACE organizations already must receive, process, and provide notification for grievances submitted by participant family members and/or designated representatives. Also, we reiterate that, as we explained in the January 2021 final rule (86 FR 6018), we have not historically considered "caregivers" to include employees or contractors of the PACE organization, though their feedback is captured under the requirements for the IDT to remain alert to pertinent information under current § 460.102(d)(2)(ii). We do not believe that these paid individuals would generally be entitled to file a grievance under § 460.120. Lastly, we believe that caregiver involvement in the grievance process would benefit, rather than negatively impact, participant care, even when PACE organizations must coordinate within the complexities of participants' support systems. The PACE organization remains responsible for resolving a grievance based on the

facts of the situation and not based on who may have initiated the complaint.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.120(d) to require that PACE organizations accept grievances from participants' caregivers without modification.

Comment: A commenter requested that we clarify whether the proposed maximum timeframe requirement for notification of a grievance resolution at § 460.120(g)(2) could be satisfied with attempts to notify the individual who submitted the grievance of the resolution within the 3-calendar day maximum timeframe, or whether the individual who submitted the grievance must receive the notification within that timeframe.

Response: We clarify that we would consider the individual who submitted the grievance resolution to be notified for the purposes of § 460.120(g)(2) when the PACE organization furnishes them with the resolution notification within the 3-calendar day maximum timeframe, but as expeditiously as the case requires. However, during a review of PACE organizations' grievance notification documentation, CMS may consider mitigating circumstances based on outreach attempts and when they occurred.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.120(g)(2) to require that PACE organizations notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1) without modification.

Comment: Some commenters recommended a longer timeframe for processing expedited grievances than 24 hours after the time the PACE organization receives the oral or written grievance, as proposed at § 460.120(h). Most of the commenters recommended increasing the maximum timeframe for processing expedited grievances to 72 hours. A commenter recommended that we modify the maximum timeframe to process expedited grievances to require the PACE organization to initiate an investigation within 24 hours, rather than fully resolving the expedited grievance within that timeframe. Another commenter suggested lengthening the maximum timeframe for processing expedited grievances to 2 business days. These commenters all

expressed concerns with the possibility that the proposed timeframe at § 460.120(h) would require staff to be available to process grievances at all times, including evenings and weekends, which may burden staff and exacerbate workforce shortages. A commenter suggested that more time may be needed to investigate the grievances at issue to determine if it is imminent or significant and should be processed as an expedited grievance. Most of the commenters expressed their support for allowing PACE organizations the flexibility to determine which grievances could have an imminent and significant impact on the health or safety of participants and should be processed as expedited grievances as proposed at § 460.120(h).

Response: We thank the commenters for their input regarding the proposed expedited grievance requirements at § 460.120(h). After consideration of the concerns raised by commenters, we are declining to finalize our proposal to establish an expedited grievance process at § 460.120(h), and we are redesignating all of our proposed provisions in § 460.120(i) to instead appear at § 460.120(h). While we are not finalizing the expedited grievance process, we remind PACE organizations that they are still required, as part of their quality improvement program at § 460.136(a)(5), to immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant. Additionally, we emphasize that the IDT is responsible for triaging grievances to determine what needs to be processed more quickly in order to meet the participant's needs. Ultimately, as per § 460.98(a), PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and PACE organizations must continue to meet this requirement as they process grievances.

Comment: A commenter disagreed with the proposal to establish at § 460.120(i)(1) the requirement that the PACE organization must provide notification of the grievance resolution either orally or in writing based on the individual's preference for notification, with the exception of quality of care grievances as proposed at § 460.120(i)(3). The commenter recommended that all grievance resolution notifications be provided in writing, regardless of the nature of the grievance, as a participant safeguard. Another commenter expressed general support for the flexibility to provide oral

or written notice of the grievance resolution as proposed at § 460.120(i)(1).

Response: We thank the commenter for expressing their concern regarding the impact of this provision on participant wellbeing. As discussed in the December 2022 proposed rule (87 FR 79668), we believe that PACE organizations should tailor the grievance resolution notification to the preference of the PACE participant or individual submitting the grievance. Based on our monitoring experience, we believe that requiring all grievance resolutions to be communicated in writing would be unnecessarily burdensome to PACE organizations and would not always be desired by the family members or participants filing the grievance. Therefore, we decline to modify the proposal.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to require that PACE organizations must provide notification of the grievance resolution either orally or in writing, based on the individual's preference for notification, without modification, except we are redesignating proposed § 460.120(i)(1) as § 460.120(h)(1).

Comment: A few commenters disagreed with the proposal at § 460.120(i)(2)(ii) to require PACE organizations to provide the steps taken to investigate the grievance in the grievance resolution notification. The commenters expressed concern that providing the steps taken to investigate the grievance in the notification adds burden to PACE organizations with no additional value to the participant, because detailing the investigation steps is not the same as providing a resolution.

Response: As we stated in the December 2022 proposed rule (87 FR 79668), we do not believe that every grievance, or every issue within a grievance, will require an investigation, and some issues may require minimal investigation; however, when an investigation is appropriate, we believe it would be important for the individual who submitted the grievance to understand what the organization found during its investigation. We agree with commenters that the value to the participant is the summary of the findings for each distinct issue, and not the specific steps taken to investigate the grievance.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing this provision by redesignating

§ 460.120(i)(2)(ii) as § 460.120(h)(2)(ii) and modifying § 460.120(h)(2)(ii) to require a summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation, and not requiring that the specific steps taken to investigate the grievance be included in the grievance resolution notification.

Comment: A few commenters disagreed with the proposal at § 460.120(i)(2)(iii) to require that grievance resolution notifications include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. These commenters noted that PACE organizations do not always know when corrective action will be fully implemented, especially when the corrective action requires a system change to a process within the PACE organization, and they did not believe it would be reasonable for CMS to expect PACE organizations to have all improvements in place and all grievance issues fully resolved in 30 days. Another commenter expressed concern that including corrective actions in the grievance resolution notification could include administrative or human resources actions that are not appropriate to share with participants or their designated representatives and stated that the finalized provision should protect the rights and privacy of participants, clinicians, and staff.

Response: We believe the commenters misunderstood our expectations regarding the proposal at § 460.120(i)(2)(iii). The § 460.120(g) grievance resolution and notification timeframe requirements apply to taking action to resolve the grievance and notifying the individual who submitted the grievance of the grievance resolution. Taking action to resolve the grievance and providing notification does not necessarily require that all corrective actions be completely implemented within the grievance resolution and notification timeframes proposed at § 460.120(g) for all grievances issues.

Additionally, we do not specify the level of detail a PACE organization should provide in the grievance resolution notification to describe the corrective actions taken, or when the participant may expect the corrective action(s) to occur. As explained in the December 2022 proposed rule (87 FR 79668), the purpose of including information on corrective actions that have or will be taken by the PACE organization in response to a grievance is for the participant to understand how their grievance has been resolved or

how it will be resolved. PACE organizations may protect provider privacy and business confidentiality in how they disclose the details of their investigation and any corrective action when providing grievance resolution notification. An appropriate level of detail for the corrective action demonstrates that the PACE organization has addressed each specific grievance issue, has taken or will take action to resolve the issue(s), and that the individual submitting the grievance can understand what actions were taken or will be taken to resolve the grievance. For example, if the complaint relates to a participant always being picked up by the PACE driver late, the correction may be that a new driver will be assigned to pick up that participant and the new driver will start in a week.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to require the grievance notification to include, for grievances that require corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur without modification, except we are redesignating proposed § 460.120(i)(2)(iii) as § 460.120(h)(2)(iii).

Comment: A commenter disagreed with the proposed requirement to include Quality Improvement Organization (QIO) rights in grievance resolution letters as proposed at § 460.120(i)(3), because they believed modifying standardized grievance notification forms would be administratively burdensome for PACE organizations and they expressed that participants already have many other options available when filing complaints with Medicare.

Response: Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act. The fact that there are other ways for participants to file complaints with Medicare has no bearing on participants' right to file quality of care grievances with the QIO. Up to this point, the PACE regulations have been silent as to this right, and the proposed requirement at § 460.120(i)(3) meant to ensure that participants understand and can access this platform for complaints related to quality of care. We would expect PACE organizations to communicate this right to participants, as applicable.

After consideration of the comments received and for the reasons outlined in

the proposed rule and our response to comments, we are finalizing our proposal to include QIO rights in grievance resolution letters to Medicare participants with quality of care grievances about Medicare covered services without modification, except that we are redesignating § 460.120(i)(3) as § 460.120(h)(3) and paragraphs § 460.120(h)(3)(i) and § 460.120(h)(3)(ii).

Comment: A commenter expressed wanting to better understand CMS's expectations for PACE organizations' cooperation with QIOs regarding quality of care grievances, as well as whether the quality of care grievance requirements we originally proposed at § 460.120(i)(3) (which we redesignate and finalize as § 460.120(h)(3), as noted in the previous response), would apply to Medicaid-only participants.

Response: We appreciate the commenter's interest in learning more about how PACE organizations should participate in the QIO quality of care grievance process, as required by section 1154(a)(14) of the Act and as proposed in the December 2022 proposed rule at § 460.120(i)(3). We will consider future educational opportunities that may help PACE organizations better understand the QIO quality of care grievance process and their role within it.

In the December 2022 proposed rule (87 FR 79668), we explained that Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act. We proposed at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. We reiterate that the QIO quality of care grievance process applies to Medicare participants' quality of care grievances regarding Medicare covered services. Therefore, participants who are not enrolled in Medicare, including Medicaid-only participants, would not be eligible for the QIO quality of care grievance process.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to include QIO rights in grievance resolution letters to Medicare participants with quality of care grievances about Medicare covered

services without modification, except we are redesignating § 460.120(i)(3) as § 460.120(h)(3). Additionally, we are redesignating § 460.120(j) through § 460.120(m) as § 460.120(k) through § 460.120(l) and any redesignated provision citations therein, without further modification.

I. PACE Participant Notification Requirement for PACE Organizations With Performance Issues or Compliance Deficiencies (§ 460.198)

Sections 1894(f)(3) and 1934(f)(3) of the Act provide CMS the discretion to apply such requirements of Part C of title XVIII and sections 1903(m) and 1932 of the Act relating to protection of beneficiaries and program integrity as would apply to Medicare Advantage (MA) organizations under Part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m) of the Act. Some examples of where CMS has previously exercised this discretion include the development and implementation of requirements related to PACE compliance and oversight, PACE enforcement actions (CMPs, sanctions, and termination), and PACE participant rights and protections.

Under §§ 422.111(g) and 423.128(f), CMS may require an MA organization or Part D plan sponsor to disclose to its enrollees or potential enrollees, the MA organization or Part D sponsor's performance and contract compliance deficiencies in a manner specified by CMS. The purpose of these beneficiary protections is to provide beneficiaries with the information they need to assess the quality of care they are receiving and to make sponsoring organizations accountable for their performance deficiencies, which should improve compliance with the rules and requirements of the Medicare program. Further, in the final rule titled "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (75 FR 19677, hereinafter referred to as the April 2010 final rule), which appeared in the April 15, 2010 issue of the **Federal Register**, we explained that "our intent is to invoke this disclosure authority when we become aware that a sponsoring organization has serious compliance or performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified."

In contrast to the Part C and D regulations at 42 CFR parts 422 and 423, respectively, the PACE regulations at

Part 460 do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies. In addition, we note that although regulations at Part 423 generally apply to PACE organizations, § 423.128 was waived for PACE organizations in 2005 (see January Part D 2005 final rule (70 FR 4430, 4432–33)). However, as explained in the proposed rule, we believe the disclosure of this information would serve as an important protection for PACE participants as it would help to ensure current and potential PACE participants and their caregivers have adequate information to make informed decisions about whether to enroll in, or to continue their enrollment, with a PACE organization. We also believe it is important to ensure there is public transparency regarding a PACE organization that has, or has had, performance and contract compliance deficiencies.

Therefore, we proposed to amend the regulations at 42 CFR part 460 by adding § 460.198, which would require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS. As in the MA and Part D programs, we anticipate that we would invoke the disclosure requirement when we become aware that a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or requires immediate correction, and where we believe PACE participants and potential PACE participants should be specifically notified.

Consistent with § 423.128(d), CMS waives any provision of the Part D regulations to the extent that CMS determines that the provision is duplicative of, or conflicts with, a provision otherwise applicable to PACE organizations under sections 1894 or 1934 of the Act, or as necessary to promote coordination between Part D and PACE. Because sections 1894 and 1934 of the Act do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies, the regulation at § 423.128(f) does not duplicate, conflict with, or impede coordination between Part D and PACE. In addition, we note that at the time CMS announced the waiver of § 423.128 in the January Part D 2005 final rule (see 70 FR 4432–33), the disclosure requirement in paragraph

(f) did not appear in § 423.128.²⁵⁸ Therefore, we believe the 2005 waiver of the rest of § 423.128 does not apply to § 423.128(f), and the disclosure of information regarding performance and contract deficiencies concerning a PACE organization in its capacity as a Part D sponsor will serve as an important protection for PACE participants. This policy does not impact the waiver of the remainder of § 423.128 for PACE organizations, as applicable.

We received the following comments on this proposal, which are summarized later in this section:

Comment: Numerous commenters expressed support for this proposal.

Response: We thank the commenters for their support of our proposal, which would enable CMS to require PACE organizations to disclose to current and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS.

Comment: Several commenters suggested that we clarify the scope, mechanism, format, and timing in which we would require PACE organizations to disclose contract and compliance deficiencies to current and potential participants.

Response: We currently anticipate limiting this requirement to situations where we are imposing an intermediate sanction on a PACE organization, and we will follow a disclosure process that is similar to the process in MA and Part D. As in the MA and Part D programs, we would provide PACE organizations with a letter template, and the PACE organization would complete the required information in the template (for example, the bases for the intermediate sanction and participants' rights to a special election period if they have been impacted by the issues identified). We will then review and approve the notification and provide a date for the PACE organization to mail the notice to participants. We will also require the PACE organization to post the notice to its website.

Comment: Several commenters suggested that we clarify the types of contract and performance deficiencies that we might require PACE organizations to disclose to current and potential participants.

Response: As previously discussed, we intend to use these disclosures for instances where we are imposing an intermediate sanction on a PACE organization. We recognize, however, that there may be other instances where

²⁵⁸ The April 2010 final rule (75 FR 19677) amended § 423.128 to include paragraph (f).

a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or require immediate correction where we believe PACE participants and potential PACE participants should be specifically notified. We may also require disclosures in these instances.

We received a comment on the following topic which is outside the scope of our proposal and to which we are therefore not responding: A request for CMS to create public reporting of performance for PACE organizations similar to Nursing Home Compare and an updated PACE manual with interpretive guidance prior to instituting a disclosure requirement.

After consideration of the comments received, and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing our proposal to add § 460.198 to require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS, without modification.

J. PACE Participant Health Outcomes Data (§ 460.202)

Sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act require PACE organizations to collect, maintain, and report data necessary to monitor the operation, cost, and effectiveness of the PACE program to CMS and the State administering agency (SAA).

Following publication of the 1999 PACE interim final rule, CMS established a set of participant health outcomes data that PACE organizations were required to report to CMS. In subsequent years, we have modified the participant health outcomes data on a routine basis to ensure that we are collecting data that is relevant and useful to our efforts to monitor and oversee the PACE program. According to 5 CFR 1320.15, at least once every 3 years, to comply with the Paperwork Reduction Act of 1995 (Pub L. 104–13) (PRA), CMS is required to publish the proposed data collection and solicit public comment. The data collection requirements related to participant health outcomes data can be found in the information collection request currently approved under OMB control number 0938–1264 (CMS–10525). Section 460.202 currently requires participant health outcomes data reported to CMS and the SAA to be specified in the PACE program agreement; however, CMS does not routinely update program agreements

based on changes to the required participant health outcomes data. As a result, the quality data collection specified in the program agreement is often out of date and no longer applicable within a few years.

Since the participant health outcomes data that PACE organizations must report to CMS and the SAA are specified and routinely updated through the PRA process, we proposed to amend paragraph (b) of § 460.202 by striking the final sentence, which states, “The items collected are specified in the PACE program agreement.” As explained in the proposed rule, we believe this change would eliminate any confusion regarding where the data collection requirements may be found (87 FR 79673).

The PACE program agreement would still include a statement of the data collected, as required by § 460.32(a)(11), but it would not include the level of specificity regarding the data collection that is included in the CMS PRA information collection request approved under OMB control number 0938–1264. We believe modifying § 460.202 as proposed would not increase the burden on PACE organizations as they are currently required to furnish information to CMS and the SAA through the aforementioned information collection request.

We solicited comment on this proposal and a summary of the comments received and our response follows.

Comment: A few commenters expressed support of the proposal to amend § 460.202(b) by removing the requirement that the PACE program agreement specify the data to be collected.

Response: We thank commenters for their support. We are finalizing our proposal without modification.

K. Corrective Action (§ 460.194)

Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency (SAA), to conduct comprehensive reviews of PACE organizations’ compliance with all significant program requirements. Additionally, sections 1894(i)(6)(A)(i) and 1934(i)(6)(A)(i) of the Act condition the continuation of the PACE program agreement upon timely execution of a corrective action plan if the PACE provider fails to substantially comply with the program requirements as set forth in the Act and regulation. In the 1999 PACE interim final rule, we specified at § 460.194(a) and (c) that PACE organizations must take action to correct deficiencies identified by CMS or the SAA, or PACE

organizations may be subject to sanction or termination (84 FR 66296). The 2019 PACE final rule amended § 460.194(a) to expand the ways CMS or the SAA may identify deficiencies that the PACE organization must correct (84 FR 25677). These include ongoing monitoring, reviews, audits, or participant or caregiver complaints, and for any other instance in which CMS or SAA identifies programmatic deficiencies requiring correction (84 FR 25677).

The 1999 PACE interim final rule also specified at § 460.194(b) that CMS or the SAA monitors the effectiveness of PACE organizations’ corrective actions. The burden on CMS and SAAs to always monitor the effectiveness of every corrective action taken by the organization after an audit is high, and the number of audits, and thus the number of instances in which monitoring is required, increases each year because the PACE program continues to rapidly grow, and CMS is required to conduct audits in each year of the three-year trial period for new PACE contracts. However, as discussed in the November 2023 proposed rule, our experience overseeing this program has shown that it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited organization. We provided the example that a PACE organization may implement a corrective action that impacts its unscheduled reassessments due to a change in participant status, but historically, these types of assessments are not conducted frequently; thus, it may not be worthwhile for CMS or the states to spend resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor. Additionally, as PACE continues to grow, it will be increasingly important that CMS and the SAA have the flexibility to determine how to use their oversight resources most effectively. Therefore, in the November 2023 proposed rule, we proposed an amendment to § 460.194(b) that specified, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions (88 FR 78587).

As discussed in the November 2023 proposed rule, the flexibility afforded under this proposed amendment to § 460.194(b) would not change our expectation that PACE organizations expeditiously and fully correct any identified deficiencies, and CMS and the SAAs would continue to engage in monitoring efforts that prioritize participant health and safety and program integrity. In addition, as a part

of a PACE organization's oversight compliance program, we require at § 460.63 that PACE organizations adopt and implement effective oversight requirements, which include measures that prevent, detect and correct non-compliance with CMS's program requirements. A PACE organization's oversight compliance program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised. In addition, compliance oversight programs must ensure ongoing compliance with CMS requirements (88 FR 78587).

Since the effect of the proposed change would be to provide CMS and the SAA more flexibility when monitoring the effectiveness of corrective actions without placing new requirements on CMS, the SAAs, or PACE organizations, we believe this change would create no additional burden for PACE organizations. Additionally, we do not expect this change to have economic impact on the Medicare Trust Fund.

We solicited comment on this proposal. A summary of the comments received, and our response follows.

Comment: Most commenters that addressed the proposed change to § 460.194(b) supported the proposal that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. Some of those commenters, while supportive of the proposal, requested clarification regarding how CMS and the SAA will implement the provision. A few of these commenters offered conditional support for the proposed change at § 460.194(b) based on whether CMS and the SAA's increased discretion when monitoring the effectiveness of corrective actions could lead to increases in burden for PACE organizations, particularly during corrective action plan implementation, monitoring, and release following any issues of non-compliance that CMS or the SAA identify during PACE audits as requiring corrective action. Therefore, these commenters suggested that CMS clarify whether the proposed change at § 460.194(b) could increase burden for PACE organizations. One commenter that supported the proposed change at § 460.194(b) requested clarification regarding any thresholds or criteria that would govern CMS's or the SAA's discretion over corrective action monitoring activities. Another commenter in support of the change at § 460.194(b) recommended that CMS and the SAA "liberally" apply their discretion authorities under § 460.194(b) to reduce burden concerns for PACE

organizations related to what the commenter considered unnecessary and prolonged monitoring. In reference to the proposed change at § 460.194(b), one commenter stated that they do not support any proposals that reduce the oversight of corrective actions.

Response: We thank commenters for their general support of the proposed change to § 460.194(b), which specifies that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. In response to the one commenter that expressed they do not support any proposals that reduce the oversight of corrective actions, as initially discussed in the November 2023 proposed rule, we reiterate that the proposed change at § 460.194(b) and subsequent discretion afforded to CMS and the SAA regarding the monitoring of the effectiveness of corrective actions would not reduce meaningful oversight of corrective actions (88 FR 78587). Based on our experience overseeing PACE, it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited PACE organization. The example we provided in the November 2023 proposed rule pertained to unscheduled reassessments due to a change in participant status. Historically, these types of assessments are not conducted frequently; therefore, it may not be worthwhile for CMS or the SAA to expend significant resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor (88 FR 78587). CMS and the SAA will implement the flexibility provided by the change at § 460.194(b) such that we safeguard PACE participant wellbeing and safety and program integrity, and effectively adapt to the growing monitoring demands of the program's rapid expansion. Additionally, regardless of the change to § 460.194(b), PACE organizations must continue to comply with all applicable PACE requirements, and CMS and the SAA will continue to oversee PACE organization compliance through a variety of monitoring and oversight activities that ensure accountability.

In response to commenters that support the change to § 460.194(b), we offer the following clarifications. First, we clarify that we do not expect the implementation of the change at § 460.194(b) to alter the PACE audit corrective action monitoring process in a way that increases PACE organizations' burden. Second, we clarify that, given the complexity and scope of potential corrective actions, we decline to establish specific criteria or thresholds as determinants of whether

CMS or the SAA will monitor the effectiveness of a particular corrective action for the purposes of this final rule. Moreover, it is important for any corrective action monitoring threshold we create as a result of the discretion afforded under § 460.194(b) to be internal to CMS and the SAA in order to ensure we have the flexibility to reassess any thresholds, as needed, based on new information and changing data. However, such discretion, when applied, will safeguard PACE participant wellbeing and safety and program integrity while considering the monitoring resources available to CMS and the SAA, and will be consistently applied across organizations. Whether monitoring a specific corrective action is necessary or worthwhile will depend on CMS and SAA consideration of these objectives.

In response to the commenter that supported the change at § 460.194(b) and recommended that CMS and the SAA use their corrective action monitoring discretion "liberally" to reduce burden for PACE organizations, we emphasize that, although the change to § 460.194(b) might reduce burden for audited PACE organizations, we do not anticipate a significant burden reduction for PACE organizations as a result of this provision. Regardless of formal monitoring of corrective actions by CMS or the SAA, as previously mentioned, PACE organizations must correct any issues of noncompliance identified by CMS and the SAA and adopt their own oversight compliance program in accordance with § 460.63 compliance oversight requirements. Additionally, we expect PACE organizations to demonstrate that they have appropriately corrected all noncompliance identified during their previous audit during subsequent audits by CMS and the SAA.

After consideration of the comments we received, we are finalizing the proposed amendments to § 460.194(b) without modification.

L. Service Determination Requests Pending Initial Plan of Care (§ 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. Along with the regulations at § 460.120 related to grievances, and § 460.122 related to appeals, CMS created a process for service determination requests, the first stage of an appeal, at § 460.121.

The PACE regulations define a service determination request as a request to

initiate a service; modify an existing service, including to increase, reduce, eliminate, or otherwise change a service; or to continue coverage of a service that the PACE organization is recommending be discontinued or reduced (see § 460.121(b)(1)(i)-(iii)). In the January 2021 final rule (86 FR 6024), CMS finalized an exception to the definition of service determination request at § 460.121(b)(2), which, as amended, provides that requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. When CMS proposed this exception in the February 2020 proposed rule, we noted that the exception would apply any time before the initial plan was finalized and discussions among the interdisciplinary team (IDT) ceased (85 FR 9125). We explained that we believed this change would benefit both participants and PACE organizations because it would allow the IDT and the participant and/or caregiver “to continue to discuss the comprehensive plan of care taking into account all aspects of the participant’s condition as well as the participant’s wishes” (*Id.*). We also stated that “if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service determination request at that time” (85 FR 9126).

Our intention for this provision was that the IDT would discuss specific requests made by a participant and/or caregiver as part of the care planning process and determine whether these requests needed to be addressed in the plan of care. We stated in the February 2020 proposed rule that if a participant asked for a specific number of home care hours, that the request would not need to be processed as a service determination request because the IDT was actively considering how many home care hours the participant should receive as part of the development of the initial plan of care (85 FR 9125). This rationale is also consistent with our statement in the proposed rule titled “Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE),” which appeared in the August 16, 2016 **Federal Register**, that “CMS expects the plan of care to reflect that the participant was assessed for all services even where a determination is made that certain services were unnecessary at that time” (81 FR 54684).

However, as part of our oversight and monitoring of PACE organizations, we have found that often requests made by participants and/or caregivers prior to

the finalizing of the care plan are not discussed during the care planning process and are therefore not considered by the IDT. These requests are some of the first communications from participants related to the care they will be receiving from the PACE organization and would otherwise be considered service determination requests at any other stage of their enrollment. While we continue to believe that it is not prudent for the PACE organization to process these requests as service determination requests, it is important that the IDT consider these requests and determine whether they are necessary for the participant.

Therefore, we proposed to modify the regulation text at § 460.121(b)(2) to specify that service requests made prior to developing the participant’s initial plan of care must either be approved and incorporated into the participant’s initial plan of care, or the rationale for why it was not approved and incorporated must be documented. Specifically, we proposed to add the following sentence at the end of current § 460.121(b)(2): “For all requests identified in this section, the interdisciplinary team must (i) document the request, and (ii) discuss the request during the care plan meeting, and either: A) approve the requested service and incorporate it into the participant’s initial plan of care, or B) document their rationale for not approving the service in the initial plan of care.” As we stated in the November 2023 proposed rule at 88 FR 78588, we believe this change is consistent with existing plan of care requirements at § 460.104(b) and aligns with our plan of care proposals in the December 2022 proposed rule (87 FR 79452), which we discuss in section IX.F of this final rule.

As the development of the plan of care is a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with documenting the determination of any assessment of a participant and/or caregiver service request during the initial care planning process is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

We solicited comment on this proposal. A summary of the comments received and our responses follow.

Comment: Most commenters supported our proposal to modify the requirements regarding documenting and responding to requests received prior to the finalization of the initial plan of care.

Response: We thank commenters for their support.

Comment: A couple of commenters requested that the regulation language be modified to clarify that the requirement does not pertain to requests for services made by participants prior to the first day of the participant’s enrollment. A commenter opposed the proposed requirement because some States require initial plans of care to be completed prior to enrollment, and the commenter stated it would be inappropriate to process these requests as service determination requests.

Response: We are not persuaded to modify our proposal to clarify that the requirement to document requests for services is only from the time the participant enrolls until the finalization of the initial plan of care. The initial plan of care developed by the IDT is intended to be a comprehensive document that details all necessary services the participant should receive from the PACE organization. As part of that plan of care, the IDT is required to consider the assessments conducted by members of the IDT, but it should also consider the participant’s wishes, and any specific requests for services that the participant makes prior to that initial plan of care being developed. The intention of our proposal was to ensure PACE organizations were appropriately addressing participant service requests during the process of creating the initial plan of care regardless of when the requests are received. We would reiterate that we are not asking that the requests for services received prior to the finalization of the initial plan of care be processed as service determination requests as defined in § 460.121(b)(1). As we stated in the November 2023 proposed rule, we do not believe it is appropriate to process these early requests for services as service determination requests (88 FR 78588). However, we further stated in the November 2023 proposed rule that we have seen through our oversight and monitoring activities instances of participants and/or caregivers making requests during the process of creating the initial care plan, which the IDT did not consider (*Id.*).

While we understand that certain service areas may require PACE organizations to finalize the initial plan of care prior to enrollment, we would expect that any request for service received during the initial care planning process would be documented and that the IDT would discuss the request as part of the normal course of creating the initial plan of care regardless of whether the care planning process occurs prior to or after enrollment. We have seen through our oversight and monitoring activities that these requests for services

are typically made by participants during the initial assessment. Therefore, if a PACE organization chooses (or is required by a State) to conduct initial assessments prior to the date of enrollment, we would expect requests made during that time to be documented and considered by the IDT.

Comment: A commenter expressed concern that the documentation requirement was overly burdensome and does not offer any additional value to the participant as PACE organizations are already required to review the care plan with the participant prior to finalization. The same commenter stated that it was more appropriate to begin documenting requests for services after the participant has an initial plan of care to allow the participant time to become familiar with the PACE organization's services.

Response: We are not persuaded by the argument that the requirement to document requests for services received prior to the finalization of the initial plan of care is overly burdensome or that this proposed requirement holds no inherent value to the participant. While we agree that PACE organizations are already required to develop the care plan in collaboration with the participant and/or caregiver prior to finalization, as we stated in the December 2022 proposed rule in our discussion regarding our proposed changes to the plan of care requirements, we have seen instances "where participants and/or caregivers are unaware of the contents of their plan of care or what services they should be receiving" (87 FR 79660). We have also seen through oversight and monitoring that each PACE organization develops its own approach concerning the participant's involvement in the care planning process. Although § 460.102(d)(2)(ii) requires the IDT to remain alert to pertinent information about participants, including input that comes from the participants themselves, for many PACE organizations, there is no detailed discussion with the participant. Instead, following the IDT meeting, the PACE organization mails the participant the care plan or other information regarding what services have been included in the care plan. This method of informing the participant of the finalized care plan after the fact does not often allow the participant to make a meaningful contribution to the services being incorporated by the IDT into the initial plan of care. When participants are not able to actively participate in the care planning process, participants may not understand why requested services were not included or considered in the initial

plan of care. By documenting the requests for services received during the initial care planning process, the IDT can track the requests to ensure they have addressed all concerns the participant expressed during the initial care planning process and demonstrate to the participant that their concerns were reviewed and considered.

We are also not persuaded by the argument that it is more appropriate to wait until the participant has an initial plan of care to document their requests for services to allow the participant to become more familiar with the services provided by the PACE organization. Per § 460.98(a), PACE organizations are required to provide care that meets participant needs across all care settings, 24 hours a day, every day of the year regardless of whether the participant is familiar with what services are available to them.

Additionally, in the early part of a participant's enrollment into PACE, prior to an initial plan of care being finalized, participants are actively engaged in communicating the services they hope to receive from the PACE organization. Those requests that indicate the participant's wishes for treatment should be considered and addressed as part of the development of the initial plan of care. It is the IDT's responsibility to document, assess, and determine whether a requested service is necessary to meet the needs of the participant based on the requirements in § 460.92(b). Due to the PACE benefit including any service that is determined necessary by the IDT, the participant's understanding of the benefit should not hinder their ability to advocate for services they believe are necessary for their medical, physical, social, or emotional needs.

Comment: A commenter supported the proposed changes but requested that we require PACE organizations to inform participants of the formal grievance process for any declined requests. The same commenter requested that we add a requirement for data collection and reporting related to declined requests to identify inequities and systemic issues to hold PACE organizations accountable.

Response: We are not persuaded by the suggestion to modify our proposal to require PACE organizations to discuss the grievance process for any declined requests received prior to the finalization of the initial plan of care. If the IDT reviews a request for a service and decides not to include the request in the initial plan of care, nothing in our proposal would prevent the IDT from explaining the grievance process and providing the participant the right to

submit a grievance. However, to the extent that a participant still wants a service that was not included in the initial plan of care, we would expect the PACE organization to process that request as a service determination request and, if the service determination request were denied, to provide appeal rights as detailed in § 460.121(j)(2) and § 460.122. The grievance process would not be the appropriate process if a participant still wanted to advocate for the inclusion of a particular service. The suggestion to require data collection and reporting of declined service requests is beyond the scope of our proposal.

After reviewing and considering the public comments received, we are finalizing the regulation as proposed.

X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a "collection of information," as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our December 27, 2022 (CMS–4201–P; RIN 0938–AU96; 87 FR 79452) and November 15, 2023 (CMS–4205–P; RIN 0938–AV24; 88 FR 78476) proposed rules we solicited public comment on each of the aforementioned issues for the following information collection requirements. The following ICRs received PRA-related comment: #2 (Standards for Electronic Prescribing), #7 (Mid-Year Notice of Unused Supplemental Benefits), #9 (Agent Broker Compensation), and #14 (Part D Medication Therapy Management Program Eligibility Criteria). A summary of the comments and our response can be found below under the applicable ICR section.

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

* * * * *

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) For contract years through contract year 2024, Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, Part D sponsors are limited to the compensation amounts outlined in this section.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, Part D sponsors may pay compensation at or below FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, Part D sponsors may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in a renewal year, MA organizations may pay compensation at 50 percent of FMV.

* * * * *

(e) * * *

(1) For contract years through contract year 2024, payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in

the calculation of enrollment-based compensation.

(g) * * *

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into a Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the information and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 80. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 80a. Section 460.12 is amended by revising paragraph (a) to read as follows:

§ 460.12 Application requirements.

(a) *Submission of application.* (1) An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area or add a PACE center site must submit to CMS a complete application in the form and manner, including timeframes for submission, specified by CMS, that describes how the entity or PACE organization meets all requirements in this part.

(2) An individual authorized to act for an entity that seeks to become a PACE organization must submit an application to qualify as a Part D sponsor in the form and manner required by CMS in accordance with 42 CFR part 423, subpart K.

■ 81. Section 460.18 is amended by adding paragraphs (c) and (d) to read as follows:

§ 460.18 CMS evaluation of applications.

* * * * *

(c) *Use of information from a current or prior PACE program agreement.* (1) If, during the 12 months preceding the deadline established by CMS for the submission of an application or submission of a response to a CMS request for additional information, a PACE organization fails to comply with the requirements of the PACE program under any current or prior PACE program agreement or fails to complete a corrective action plan during the

applicable 12-month period, CMS may deny an application based on the applicant's failure to comply with the requirements of the PACE program under any current or prior PACE program agreement even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with the requirements of the PACE program under a PACE program agreement for purposes of an application denial under paragraph (c)(1) of this section if any of the following conditions apply with respect to the applicant during the applicable 12-month review period:

(A) Was subject to the imposition of an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40.

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 460.80(a) after the end of the trial period.

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Met or exceeded 13 points for compliance actions for any one PACE program agreement.

(i) CMS determines the number of points accumulated during the performance period for compliance actions based on the following point values:

(i) Each corrective action plan issued under § 460.19(c)(3) during the performance period counts for 6 points. Corrective action requests issued under § 460.194 are not included in the point calculations.

(ii) Each warning letter issued under § 460.19(c)(2) during the performance period counts for 3 points.

(iii) Each notice of non-compliance issued under § 460.19(c)(1) during the performance period counts for 1 point.

(2) CMS adds all the point values for each PACE organization's program agreement to determine if the 13-point threshold described in paragraph (c)(1)(i)(D) of this section has been reached.

(ii) CMS may deny an application submitted by an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (c)(1)(i) of this section. This paragraph does not apply to a parent organization that completed the acquisition of a subsidiary that meets the criteria for denial within the 24 months preceding the application submission deadline.

(d) If CMS has terminated a PACE program agreement under § 460.50, or

did not renew a PACE program agreement, and that termination or non-renewal took effect within the 38 months preceding the submission of an initial or expansion PACE application from the same organization, CMS may deny the application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant currently meets all of the requirements of this part.

* * * * *

■ 81. Section 460.19 is added to read as follows:

§ 460.19 Issuance of compliance actions for failure to comply with the terms of the PACE program agreement.

(a) CMS may take compliance actions as described in paragraph (c)(1) of this section if CMS determines that the PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and a State administering agency.

(1) CMS may determine that a PACE organization is out of compliance with requirements when the organization fails to meet performance standards articulated in sections 1894 and 1934 of the Act and regulations in this chapter.

(2) If CMS has not already articulated a measure for determining non-compliance, CMS may determine that a PACE organization is out of compliance when its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

(b) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the non-compliance, including all of the following:

(1) The nature of the conduct.

(2) The degree of culpability of the PACE organization.

(3) The actual or potential adverse effect on beneficiaries which resulted or could have resulted from the conduct of the PACE organization.

(4) The history of prior offenses by the PACE organization or its related entities.

(5) Whether the non-compliance was self-reported.

(6) Other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

(c) CMS may take one of three types of compliance actions based on the nature of the non-compliance.

(1) *Notice of non-compliance.* A notice of non-compliance may be issued for any failure to comply with the

requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section.

(2) *Warning letter.* A warning letter may be issued for serious and/or continued non-compliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(3) *Corrective action plan.* (i) Corrective action plans are issued for particularly serious or continued non-compliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(ii) CMS issues a corrective action plan if CMS determines that the PACE organization has repeated or not corrected non-compliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its non-compliance, or must implement a detailed plan to correct the underlying causes of the non-compliance.

■ 82. Section 460.20 is amended by revising paragraph (c) to read as follows:

§ 460.20 Notice of CMS determination.

(c) *Incomplete application due to the lack of required State assurances documentation.* An application that, upon submission, is determined to be incomplete under § 460.12(b)(3) is withdrawn by CMS and the applicant is notified accordingly. The applicant is not entitled to a fair hearing when CMS withdraws an incomplete application on this basis.

■ 83. Section 460.64 is amended by revising paragraph (a)(5) and adding paragraph (a)(6) to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) * * *

(5) Be medically cleared for communicable diseases before engaging in direct participant contact.

(i) Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice, unless—

(A) The PACE organization conducts an individual risk assessment that meets

the conditions specified in paragraph (a)(5)(iii) of this section; and

(B) The results of the risk assessment indicate the individual does not require a physical examination for medical clearance.

(ii) As part of the initial physical examination, staff must be determined to be free of active Tuberculosis disease.

(iii) If the PACE organization conducts a risk assessment on an individual under paragraphs (a)(5)(i)(A) and (B) of this section—

(A) Policies and procedures for conducting a risk assessment on each individual with direct participant contact must be based on accepted professional standards of care;

(B) The PACE organization's risk assessment must identify when a physical examination is required based on the results of the assessment; and

(C) The results of the risk assessment must be reviewed by a registered nurse, physician, nurse practitioner, or physician assistant.

(D) At a minimum, the risk assessment must do both of the following:

(1) Assess whether staff have been exposed to or have any symptoms of the following diseases:

- (i) COVID-19.
- (ii) Diphtheria.
- (iii) Influenza.
- (iv) Measles.
- (v) Meningitis.
- (vi) Meningococcal Disease.
- (vii) Mumps.
- (viii) Pertussis.
- (ix) Pneumococcal Disease.
- (x) Rubella.
- (xi) Streptococcal Infection.
- (xii) Varicella Zoster Virus.
- (xiii) Any other infectious diseases

noted as a potential threat to public health by the CDC.

(2) Determine if staff are free of active Tuberculosis during the initial risk assessment.

(6) Have all immunizations up to date before engaging in direct participant contact.

* * * * *

■ 84. Section 460.71 is amended by—

■ a. Revising paragraph (b)(4);

■ b. Redesignating paragraph (b)(5) and (6) as paragraphs (b)(6) and (7), respectively; and

■ c. Adding new paragraph (b)(5).

The revision and addition read as follows:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) * * *

(4) Be medically cleared for communicable diseases before engaging

in direct participant contact as required under § 460.64(a)(5).

(5) Have all immunizations up to date before engaging in direct participant contact.

* * * * *

■ 85. Section 460.98 is amended by:

- a. Removing paragraph (b)(4);
- b. Redesignating paragraphs (b)(5) and (c) through (e) as paragraphs (b)(4) and (d) through (f), respectively; and
- c. Adding new paragraph (c).

The addition reads as follows:

§ 460.98 Service delivery.

* * * * *

(c) *Timeframes for arranging and providing services*—(1) *Medications*. The PACE organization must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication.

(2) *All other services*. The PACE organization must arrange or schedule the delivery of interdisciplinary team approved services, other than medications, as identified in paragraph (c)(2)(i) of this section, as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the interdisciplinary team or member of the interdisciplinary team first approves the service, except as identified in paragraph (c)(3) of this section.

(i) Interdisciplinary team approved services include:

- (A) Services approved by the full interdisciplinary team.
- (B) Services approved by a member of the interdisciplinary team.
- (C) Services ordered by a member of the interdisciplinary team.
- (D) Care planned services.

(ii) [Reserved]

(3) *Routine or preventative services*. Routine or preventive services are excluded from the requirement in paragraph (c)(2) of this section when all of the following requirements are met:

(i) The PACE organization documents that they were unable to schedule the appointment due to circumstances beyond the control of the PACE organization.

(ii) The participant does not have a change in status that requires the service to be provided more quickly.

(iii) The PACE organization provides the service as expeditiously as the participant's condition requires.

(4) *Providing approved services*. Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs.

■ 87. Section 460.102 is amended by revising paragraph (d)(1) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following for each participant:

(i) *Assessments and plan of care*. The initial assessment, periodic reassessments, and plan of care.

(ii) *Coordination of care*. Coordination and implementation of 24-hour care delivery that meets participant needs across all care settings, including but not limited to the following:

(A) Ordering, approving, or authorizing all necessary care.

(B) Communicating all necessary care and relevant instructions for care.

(C) Ensuring care is implemented as it was ordered, approved, or authorized by the IDT.

(D) Monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.

(E) Promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

(iii) *Documenting recommended services*. Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(iv) *Consideration of recommended services*. The interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists. Specifically, the interdisciplinary team must ensure the following requirements are met:

(A) The appropriate member(s) of the interdisciplinary team must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

(B) The appropriate member(s) of the interdisciplinary team must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as

expeditiously as the participant's health condition requires, but no later than 7 calendar days from the date the recommendation was made.

(C) If recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c).

■ 88. Section 460.104 is amended by revising paragraph (e) to read as follows:

§ 460.104 Participant assessments.

* * * * *

(e) *Changes to plan of care*. When the interdisciplinary team conducts semiannual or unscheduled reassessments, the interdisciplinary team must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments.

■ 87. Section 460.106 is revised to read as follows:

§ 460.106 Plan of care.

(a) *Definition and basic requirements*—(1) *Definition*. For purposes of this section, a “change in participant's status” means a major decline or improvement in a participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status and requires interdisciplinary team review or revision of the care plan, or both.

(2) *Basic requirements*. (i) The interdisciplinary team members specified in § 460.102(b) must develop, evaluate, and if necessary, revise a comprehensive person-centered plan of care for each participant.

(ii) Each plan of care must do all of the following:

(A) Take into consideration the most current assessment findings.

(B) Identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being.

(b) *Timeframes for developing, evaluating, and revising plan of care*. (1) *Initial plan of care*. The interdisciplinary team must complete the initial plan of care within 30 calendar days of the participant's date of enrollment.

(2) *Semi-annual plan of care evaluation*. At least once every 180 calendar days from the date the latest plan of care was finalized the interdisciplinary team must complete a reevaluation of, and if necessary,

revisions to each participant's plan of care.

(3) *Change in participant's status.* (i) Except as specified in paragraph (b)(3)(ii) of this section, the interdisciplinary team must complete a re-evaluation of, and if necessary, revisions to a participant's plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status, or more expeditiously if the participant's condition requires.

(ii) If a participant is hospitalized within 14 calendar days of the change in participant status, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital.

(c) *Content of plan of care.* At a minimum, each plan of care must meet the following requirements:

(1) Identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. At a minimum, the care plan must address the following factors:

- (i) Vision.
- (ii) Hearing.
- (iii) Dentition.
- (iv) Skin integrity.
- (v) Mobility.
- (vi) Physical functioning, including activities of daily living.
- (vii) Pain management.
- (viii) Nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs.
- (ix) The participant's ability to live safely in the community, including the safety of their home environment.
- (x) Home care.
- (xi) Center attendance.
- (xii) Transportation.
- (xiii) Communication, including any identified language barriers.

(2)(i) Identify each intervention (the care and services) needed to meet each medical, physical, emotional, and social needs.

(ii) It does not have to identify the medications needed to meet the participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record.

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify how each intervention will be implemented, including a timeframe for implementation.

(5) Identify a measurable goal for each intervention.

(6) Identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

(7) The participant's preferences and goals of care.

(d) *Implementation of the plan of care.* The team must continuously do all of the following:

(1) Implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors, across all care settings.

(2) Evaluate and monitor the participant's medical, physical, emotional, and social needs as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other employees or contractors.

(e) *Participant and caregiver involvement in plan of care.* (1) The interdisciplinary team must develop, evaluate, and revise each plan of care in collaboration with the participant, the participant's caregiver, or both.

(2) The interdisciplinary team must review and discuss each plan of care with the participant or the participant's caregiver or both before the plan of care is completed to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must do all of the following:

(1) Establish and implement a process to document and maintain records related to all requirements for plans of care, in the participant's medical record.

(2) Ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

■ 88. Section 460.112 is amended by—

- a. Removing paragraph (d);
- b. Redesignating paragraphs (a) through (c) as paragraphs (b) through (d);
- c. Adding new paragraph (a);
- d. Adding paragraph (b)(8);
- e. Revising newly redesignated paragraph (c) introductory text;
- f. Adding paragraph (c)(5);
- g. Revising paragraph (e)(1);
- h. Redesignating paragraphs (e)(2) through (6) as (e)(3) through (7);
- i. Adding new paragraph (e)(2);

- j. Revising the paragraph heading for paragraphs (g) introductory text and revise paragraph (g)(2); and
- k. Adding paragraph (g)(3).

The additions and revisions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Right to treatment.* Each participant has the right to appropriate and timely treatment for their health conditions, including the right to all of the following:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(b) * * *

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(c) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health decisions. A participant has the right to have all information in this section shared with their designated representative. Specifically, each participant has the following rights:

* * * * *

(5) To be fully informed of the following, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services:

(i) A description of the PACE organization's palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving.

(ii) Whether palliative care, comfort care, or end-of-life care services (as applicable) is provided in addition to or in lieu of the care the participant is currently receiving.

(iii) Identify all services that are impacted and provide a detailed explanation of how the services will be impacted if the participant or designated representative elects to initiate palliative care, comfort care, or end-of-life care, including but not limited to the following types of services.

(A) Physician services, including specialist services.

(B) Hospital services.

(C) Long-term care services.

(D) Nursing services.

(E) Social services.

(F) Dietary services.

- (G) Transportation.
- (H) Home care.
- (I) Therapy, including physical, occupation, and speech therapy.
- (J) Behavioral health.
- (K) Diagnostic testing, including imaging and laboratory services.
- (L) Medications.
- (M) Preventative healthcare services.
- (N) PACE center attendance.
- (ii) The right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing.

* * * * *

(e) * * *

(1) To make health care decisions, including the right to all of the following:

(i) Have all treatment options fully explained.

(ii) Refuse any and all care and services.

(iii) Be informed of the consequences their decisions may have on their health and/or psychosocial status.

(2) To fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Specifically, the PACE organization must do all of the following before palliative care, comfort care, or end-of-life care services can be initiated:

(i) Fully explain the applicable treatment options.

(ii) Provide the participant with written information about their treatment options, in accordance with paragraph (c)(5) of this section.

(iii) Obtain written consent from the participant or designated representative prior to initiating palliative care, comfort care, or end-of-life care.

* * * * *

(g) *Complaints, requests, and appeals.*

* * * * *

(2) To request services from the PACE organizations, its employees, or contractors through the process described in § 460.121.

(3) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122.

■ 89. Section 460.119 is added to read as follows:

§ 460.119 Resolution of complaints in the complaints tracking module.

The PACE organization must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the PACE organization within the required timeframes.

References to the MA organization or MA plan in those regulations must be read as references to the PACE organization. Nothing in this section should be construed to affect the PACE organization's obligation to resolve grievances as described in § 460.120, service determinations as described in § 460.121, or appeals as described in § 460.122.

■ 90. Section 460.120 is revised to read as follows:

§ 460.120 Grievance process.

(a) *Written procedures.* A PACE organization must have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the requirements in this part.

(b) *Definition of grievance.* For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.

(c) *Grievance process notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process in understandable language, including all of the following:

(1) A participant or other individual specified in paragraph (d) of this section has the right to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal.

(2) A Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

(3) The requirements under paragraphs (b) and (d) through (j) of this section.

(d) *Who can submit a grievance.* Any of the following individuals can submit a grievance:

- (1) The participant.
- (2) The participant's family member.
- (3) The participant's designated representative.
- (4) The participant's caregiver.

(e) *Methods for submitting a grievance.* (1) Any individual as permitted under paragraph (d) of this section may file a grievance with the PACE organization either orally or in writing.

(2) The PACE organization may not require a written grievance to be submitted on a specific form.

(3) A grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

(f) *Conducting an investigation.* The PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known.

(g) *Grievance resolution and notification timeframes.* The PACE organization must do all of the following:

(1) Take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance.

(2) Notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with paragraph (g)(1) of this section.

(h) *Grievance resolution notification.* The PACE organization must inform the individual who submitted the grievance of the resolution as follows:

(1) Either orally or in writing, based on the individual's preference for notification, except for grievances identified in paragraph (h)(3) of this section.

(2) At a minimum, oral or written notification of grievance resolutions must include the following, if applicable:

(i) A summary statement of the participant's grievance including all distinct issues.

(ii) A summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation.

(iii) For a grievance that requires corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur.

(3) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing.

(i) The response must describe the right of a Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services.

(ii) For any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint.

(4) The PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. The PACE organization is still responsible for paragraphs (h)(1) through (3) of this section.

(i) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(j) *Maintaining confidentiality of grievances.* The PACE organization must develop and implement procedures to maintain the confidentiality of a grievance, including protecting the identity of all individuals involved in the grievance from other employees and contractors when appropriate.

(k) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of paragraph (j) of this section, must be

available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

(l) *Analyzing grievance information.* The PACE organization must aggregate and analyze the information collected under paragraph (k) of this section for purposes of its internal quality improvement program.

■ 91. Section 460.121 is amended by revising paragraph (b)(2) to read as follows:

§ 460.121 Service determination process.

* * * *

(b) * * *

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. For all requests identified in this section, the interdisciplinary team must—

(i) Document the request; and

(ii) Discuss the request during the care planning meeting, and either:

(A) Approve the requested service and incorporate it into the participant's initial plan of care, or

(B) Document their rationale for not approving the service in the initial plan of care.

* * * *

■ 92. Section 460.194 is amended by revising paragraph (b) to read as follows:

§ 460.194 Corrective action.

* * * *

(b) At their discretion, CMS or the State administering agency may monitor the effectiveness of corrective actions.

* * * *

■ 93. Section 460.198 is added to read as follows:

§ 460.198 Disclosure of compliance deficiencies.

CMS may require a PACE organization to disclose to its PACE participants or potential PACE participants the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS.

* * * *

§ 460.202 [Amended]

■ 94. Section 460.202(b) is amended by removing the last sentence.

Xavier Becerra,
Secretary, Department of Health and Human Services.

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