Contract Year 2021 and 2022 Proposed Rule and PACE

On February 5, the Centers for Medicare and Medicaid Services (CMS) issued a new proposed rule titled Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE). This rule proposes changes to several aspects of Medicare and Medicaid, including Medicare Advantage. As indicated in the proposal's title, changes to PACE are included in the proposal.

LeadingAge compared the current regulatory language with the new proposed language in a table. This table is meant to assist PACE organizations review the proposed rule and consider potential implications for their operations.

Questions on this table and/or the proposed rule can be directed to Brendan Flinn (bflinn@leadingage.org) of the LeadingAge staff.

Notes on Reading the Table

- The orange section headers indicate which part of the federal PACE regulation the proposed changes are under.
- The left-hand column includes the current text in federal regulation. Yellow highlighted text in the left-hand column summarizes the changes made and whether they appear substantive or technical (e.g., renumbering text but not changing the words).
- The right-hand column includes the text listed in the proposed rule.
- Where applicable, proposed new text is in red highlights and proposed removed text is in red highlights with strikethroughs.
- The blue column indicates where in the proposed rule CMS writes the justification/rationale for each of the proposed changes.
    - Note that the narrative/justification section is not organized by the numerical order of the regulation (e.g., section 460.56 is discussed 20 pages *after* 460.92).

Key Links

- Proposed Rule Landing Page: https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the
- Proposed Rule PDF: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-02085.pdf
- Current PACE Regulation: https://www.law.cornell.edu/cfr/text/42/part-460

Section of Proposed Rule		CMS rationale page #
Current Regulatory Language	**Proposed Language**	
§ 460.6 – Definitions.		
Services includes both items and services.	Service, as used in this part, means all services that could be required under § 460.92, including items and drugs	**488**
§ 460.56 Procedures for imposing sanctions and civil money penalties. (proposed new section)		
Proposed new section.	CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following: (a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b). (b) Section 422.756€(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.	**486**
§ 460.92 Required services.		
The PACE benefit package for all participants, regardless of the source of payment, must include the following: (a) All Medicare-covered ~~items and~~ services. (b) All Medicaid-covered ~~items and~~ services, as specified in the State's approved Medicaid plan. (c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. Part (b) at right is proposed new text. The above current regulation is renumbered as proposed at right but not substantively changed.	(a) The PACE benefit package for all participants, regardless of the source of payment, must include the following: (1) All Medicare-covered services. (2) All Medicaid-covered services, as specified in the State's approved Medicaid plan. (3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. (b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account: (1) The participant's current medical, physical, emotional, and social needs; and	**463**

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Current Regulatory Language	**Proposed Language**	
	(2) Current clinical practice guidelines and professional standards of care applicable to the particular service	
§ 460.96 Excluded services.		
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 nonmedical 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. (e) Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter. (2) As permitted under the State's approved Medicaid plan. Parts (a) and (b) are proposed to be removed per strikethroughs above. Parts (c) through (e) are renumbered as proposed at right but unchanged.	The following services are excluded from coverage under PACE: (a) 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. (b) Experimental medical, surgical, or other health procedures. (c) Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter. (2) As permitted under the State's approved Medicaid plan.	**466**

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§ 460.98 Service delivery.		
(a) ~~Plan~~. 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 a day, every day of the year. CMS proposes to rewrite entire part, as proposed at right.	(a) Access to services. A 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, and must establish and implement a written plan to ensure that care is appropriately furnished.	**474**
(b) Contract requirements. A contract between a PACE organization and a contractor must meet the following requirements: (1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following: (i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements. (ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes. (iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality improvement activities. Part (1) has a sentence proposed to be added as indicated at right. Other items not proposed to be changed but included as reference.	(b) Contract requirements. A contract between a PACE organization and a contractor must meet the following requirements: (1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following. These services must be furnished in accordance with § 460.70(a) (i) unchanged (ii) unchanged (iii) unchanged	**476**

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Proposed new section.	(4) 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.	**476**
Proposed new section.	(5) The PACE organization must document, track, and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.	**477**
§ 460.102 Interdisciplinary team.		
(d) Responsibilities of interdisciplinary team. (1) The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery.	(d) Responsibilities of interdisciplinary team. (1) The interdisciplinary team is responsible for the following: (i) The initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery. (ii) 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).	**472**
(2) Each team member is responsible for the following: (i) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant. ~~(ii) Remaining alert to pertinent input from other team members, participants, and caregivers.~~ (iii) Documenting changes of a participant's condition in the participant's medical record consistent with	2) Each team member is responsible for the following: (i) unchanged (ii) Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following: (A) Other team members. (B) Participants. (C) Caregivers.	**472**

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documentation polices established by the medical director. Part (ii) is rewritten as proposed at right. Other items not proposed to be changed but included as reference.	(D) Employees. (E) Contractors. (F) Specialists (iii) unchanged	
§ 460.104 Participant assessment.		
(d) Unscheduled reassessments. In addition to semi-annual reassessments, unscheduled reassessments may be required based on the following: CMS proposes to move the entire current 460.104(d)(2) *Unscheduled reassessments, at the request of the participant or designated representative* to 460.121 below and replace text at 460.104(d)(2) as indicated at right. See 460.121 below for comparison of current 460.104(d)(2) to proposed 460.121.	(d) Unscheduled reassessments. In addition to semi-annual reassessments, unscheduled reassessments may be required based on the following: (2) **In response to a service delivery request.** In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request, and may conduct reassessments as determined necessary for approved services.	**451**
§ 460.112 Specific rights to which a participant is entitled.		
(b) Information disclosure. Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions. Specifically, each participant has the following rights: Part b(4) at right is proposed new text- no revision to current text in this part.	(4) To contact 1-800-MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.	**482**
(c) Choice of providers. Each participant has the right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right to the following:	(c) Unchanged (1) Unchanged (2) Unchanged (3) To have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.	**483**

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(1) To choose his or her primary care physician and specialists from within the PACE network. (2) To request that a qualified specialist for women's health services furnish routine or preventive women's health services. (3) To disenroll from the program at any time and have such disenrollment be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment as set forth in § 460.162(a). Parts (3) through (5) are proposed new sections at right. Other items not proposed to be changed but included as reference. Current part (3) is proposed to be part (5) but not rewritten.	(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community. (5) Current item 3 proposed moved to item 5, otherwise unchanged.	
§ 460.121 Service delivery requests. (*proposed new section*) *Where applicable, this proposed new section is compared to the closest current section of regulation. When a section appears to be new regulation, we indicate as such at left.*		
Proposed new section.	(a) Written procedures. Each PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of this section.	**426**
Proposed new section.	(b) What is a service delivery request-- (1) Requests that constitute a service delivery requests. Except as provided in paragraph (b)(2) of this section, the following requests constitute service delivery requests:	**426**
	(i) A request to initiate a service.	**427**
	(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.	

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	(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.	
Proposed new section.	(2) Requests that do not constitute a service delivery request. Requests to initiate, modify, or continue a service do not constitute a service delivery request if the request is made prior to development of the initial care plan.	**429**
Part of 460.104(d)(2): "If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct a reassessment."	(c) Who can make a service delivery request? Any of the following individuals can make a service delivery request: (1) The participant. (2) The participant's designated representative. (3) The participant's caregiver	**431**
Proposed new section.	(d) Method for making a service delivery request. An individual may make a service delivery request as follows: (1) Either orally or in writing. (2) To any employee or contractor of the PACE organization that provides direct care to a participant.	**432/433**
Part of 460.104(d)(2): (ii) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.	(e) Processing a service delivery request. (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service delivery request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.	**434**
Proposed new section.	(2) If a member of the interdisciplinary team is able to approve the service delivery request in full at the time the request is made, the PACE organization-- (i) Must fulfill all of the following:	**435**

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	(A) Notice of the decision to approve a service delivery request requirements specified in paragraph (j)(1) of this section	**436**
	(B) Effectuation requirements specified in paragraph (k) of this section.	
	(C) Recordkeeping requirements specified in paragraph (m) of this section.	
	(ii) Is not required to process the service delivery request in accordance with paragraphs (f) through (i), (j)(2), and (l) of this section.	
Proposed new section.	(f) Who must review a service delivery request? The full interdisciplinary team must review and discuss each service delivery request and decide to approve, deny, or partially deny the request based on that review.	**438**
Proposed new section.	(g) Interdisciplinary team decision making. The interdisciplinary team must consider all relevant information when evaluating a service delivery request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in § 460.92(b).	**438**
Part of 460.104(d)(2): (2) At the request of the participant or designated representative. If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct a reassessment. The interdisciplinary team member(s) may conduct the reassessment via remote technology when the interdisciplinary team	(h) Reassessments in response to a service delivery request. (1) If the interdisciplinary team expects to deny or partially deny a service delivery request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.	**440**

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determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology. (i) An in-person reassessment must be conducted: (A) When participant or his or her designated representative declines the use of remote technology. (B) Before a PACE organization can deny a service request	(2) The interdisciplinary team may conduct a reassessment prior to approving a service delivery request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary	**440**
Part of 460.104(d)(2): (iii) Except as provided in paragraph (d)(2)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than ~~72 hours after the date~~ the interdisciplinary team receives the request for reassessment.	(i) Notification timeframe. Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service delivery request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.	**443**
Part of 460.104(d)(2): (iv) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:	(1) Extensions. The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:	
Part of 460.104(d)(2): (A) The participant or designated representative requests the extension.	(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.	

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Part of 460.104(d)(2): (B) The team documents its need for additional information and how the delay is in the interest of the participant.	(ii) The extension is in the participant's interest because the interdisciplinary team 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. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.	**444**
Proposed new section.	(2) Notice of extension. When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.	**445**
Proposed new section.	(j) Notification requirements— (1) Notice of decisions to approve a service delivery request. If the interdisciplinary team makes a determination to approve a service delivery request, it must provide the participant or the designated representative either oral or written notice of the determination. Notice of any decision to approve a service delivery request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.	**445, 446**

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Part of 460.104(d)(2): (v) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:	(2) Notice of decisions to deny a service delivery request. If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—	
	(i) 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.	**447**
Part of 460.104(d)(2): (A) Informing the participant or designated representative of his or her right to appeal the decision as specified in § 460.122.	(ii) Inform the participant or designated representative of his or her right to appeal the decision under § 460.122.	
Part of 460.104(d)(2): (B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.	(iii) 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 as specified in § 460.122.	**448**
Part of 460.104(d)(2): (C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in § 460.122(e). Note: proposed new text is specific to Medicaid participants.	(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):	
	(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.	

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	(B) The conditions for continuing to receive disputed services.	
Proposed new section.	(k) Effectuation requirements. If the interdisciplinary team approves a service delivery request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section	**448**
Part of 460.104(d)(2): (vi) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.	(l) Effect of failure to meet the processing timeframes. If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with §460.122.	**449**
Proposed new section.	(m) Recordkeeping. The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.	**450**

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§ 460.122 - PACE organization's appeals process.		
For purposes of this section, an appeal 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.	For purposes of this section, an appeal 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. A request to initiate, modify or continue a service must first be processed as a service delivery request under § 460.121 before the PACE organization can process an appeal under this section.	**451**
(b) Notification of participants. Upon enrollment, at least annual thereafter, and whenever the interdisciplinary team ~~denies a request for services or payment~~, the PACE organization must give a participant written information on the appeals process.	(b) Notification of participants. Upon enrollment, at least annual thereafter, and whenever the interdisciplinary team denies a service delivery request or other request for services or payment, the PACE organization must give a participant written information on the appeals process.	**452**
(c) Minimum requirements. At a minimum, the PACE organization's appeals process must include written procedures for the following:	(c) Unchanged	
(1) Timely preparation and processing of a written denial of coverage or payment as provided in ~~§ 460.104(d)(2)(iv).~~	(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.121(g).	**457**
(2) How a participant files an appeal.	(2) How a participant or their designated representative files an appeal, including procedures for accepting oral and written appeal requests.	**460**
(3) Documentation of a participant's appeal.	Unchanged	**n/a**
~~(4) Appointment of an appropriately credentialed and impartial third-party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal.~~	(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:	**454**

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This part is rewritten as proposed at right but does not substantively change the regulation.	(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal. (ii) An impartial third party who meets both of the following: A) Was not involved in the original action. B) Does not have a stake in the outcome of the appeal.	
Proposed new section	(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following: (i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98. (ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made. (iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.	**455**
(5) Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal. (6) Maintenance of confidentiality of appeals.	Unchanged in proposal, but proposed renumbering to section 6 and 7, respectively.	**n/a**
~~(d) Notification. A PACE organization must give all parties involved in the appeal the following:~~ ~~(1) Appropriate written notification.~~	(d) Opportunity to submit evidence. A PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.	**456**

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~~(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing~~. The proposal would divide sections (d) 1 and 2 of the current section such that part 2 (evidence) is covered by proposed (d) and part 1 is covered by part (g) below.		
~~(d) Notification. A PACE organization must give all parties involved in the appeal the following:~~ ~~(1) Appropriate written notification.~~	(g) Notification. A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal,	**457**
Proposed new section	(1) Notice of a favorable decision. Notice of any favorable decision must explain the conditions of the approval in understandable language.	
Proposed new section	(2) Notice of adverse decisions. (i) If an appeal decision is partially or fully adverse to a participant, the PACE organization must provide the participant with written notification of the decision. Notice of any denial must— (A) State the specific reason(s) for the denial; (B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status; (C) Inform the participant of his or her right to appeal the decision; and (D) Describe the external appeal rights under § 460.124.	

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(h) Determination adverse to participant. For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following: (1) CMS. (2) The State administering agency. (3) The participant. This part is moved to (g) (2) (ii) at right but not substantively changed.	(ii) If an appeal decision is partially or fully adverse to a participant, at the same time the decision is made, the PACE organization must notify the following: (A) CMS. (B) The State administering agency. (C) The participant.	
(g) Determination in favor of participant. A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal. This part is rewritten as proposed at right but does not substantively change the regulation. Also moved from part g to proposed part h.	(h) Actions following a favorable decision. A PACE organization must furnish the dispute service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.	**456**
§ 460.124 Additional appeal rights under Medicare or Medicaid.		
A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.	A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.	**458**
Proposed new sections.	(a) Appeal rights under Medicare. Medicare participants have the right to a reconsideration by an independent review entity.	
	(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under §460.122.	

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	(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.	
	(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.	
	(b) Appeal rights under Medicaid. Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.	**460**
	(c) Appeal rights for dual eligible participants. Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section	
§ 460.200 Maintenance of records and reporting of data.		
(b) Access to data and records. A PACE organization must allow CMS and the State administering agency access to data and records including, but not limited to, the following: (1) Participant health outcomes data. (2) Financial books and records. (3) Medical records. (4) Personnel records. This part is renumbered as proposed at right but the wording is not changed.	(b) Access to data and records. (1) A PACE organization must allow CMS and the State administering agency access to data and records including, but not limited to, the following: (i) Participant health outcomes data. (ii) Financial books and records. (iii) Medical records. (iv) Personnel records.	**461**
Proposed new section	(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may	

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	include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.	
(d) Safeguarding data and records. A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. Section (d) is renumbered as proposed at right at (d) and (d)(1). Proposed (d)(2) is new text.	(d) Safeguarding data and records. PACE organization must do all of the following: (1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration (2) Maintain all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6).	**461**
§ 460.210 Medical records.		
(b) Content of medical records. At a minimum, the medical record must contain the following: (1) Appropriate identifying information. (2) Documentation of all services furnished, including the following: (i) A summary of emergency care and other inpatient or long-term care services. (ii) Services furnished by employees of the PACE center. (iii) Services furnished by contractors and their reports. (3) Interdisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment. (4) Laboratory, radiological and other test reports.	Inserted: (4) All recommendations for services made by employees or contractors of the PACE organization, including specialists. (5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service. (6) Original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following: (i) Communications from the participant, his or her designated	**478**

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(5) Medication records. (6) Hospital discharge summaries, if applicable. (7) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin). (8) Enrollment Agreement. (9) Physician orders. (10) Discharge summary and disenrollment justification, if applicable. (11) Advance directives, if applicable. (12) A signed release permitting disclosure of personal information. Section (d) is renumbered as proposed at right such that current (b)(4) through (b)(12) would become (b)(7) through (b)(15) and otherwise unchanged. Proposed (b)(4) through b(6) at right is new text.	representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both. (ii) Communications from an advocacy or governmental agency such as Adult Protective Services	